

**INFORMAL SECTION ROUGH DRAFT – APRIL 2005**

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

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**PART 13. MAMMOGRAPHY INSTALLATIONS**

Reorganize Rule order to match FDA order:

- (A)** Purpose, Scope, Authorization
- (B)** Personnel requirements (physicians, techs, physicists)
- (C)** Equipment
- (D)** Medical Records and Reports
- (E)** QA – General
- (F)** Quality Control Testing
- (G)** Etc.

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**GENERAL PROVISIONS**

**R325.5601. Purpose and scope.**

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**Rule 601. (1)** This part establishes requirements governing the use of x-radiation for mammography and apply to all persons who use x-radiation for mammography for the intentional exposure of humans. A person shall not use a radiation machine to perform mammography unless the radiation machine is registered with the department pursuant to the provisions of R325.5181 to R325.5196 and is specifically authorized to perform mammography pursuant to the provisions of the act.

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**(2)** In addition to the requirements of this part, all persons are subject to the provisions of R325.5001 to R325.5511.

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**(3)** A facility shall not misrepresent to its employees, to the public, or to the department its status with respect to accreditation of the mammography equipment by the American college of radiology, department authorization to perform mammography, or compliance with department rules.

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**R325.5602. Definitions A to B.**

**Rule 602. (1)** As used in this part:

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**(a)** "Accreditation body" means an entity that has been approved by FDA to accredit mammography facilities.

**(a)(b)** "Act" means sections 13501 to 13536 of Act No. 368 of the Public Acts of 1978, as amended, being "333.13501 to 333.13536 of the Michigan Compiled Laws.

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**(c)** "Action limits" means the minimum and maximum values of a quality assurance measurement that

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111 can be interpreted as representing acceptable performance with respect to the parameter being tested.  
112 Values less than the minimum or greater than the maximum action limit or level indicate that corrective  
113 action must be taken by the facility. Action limits or levels are also sometimes called control limits or levels.

114 (d) "Action levels" (See "action limits").

115 (e) "Adverse event" means an undesirable experience associated with mammography activities that  
116 include but are not limited to:

117 (i) Poor image quality

118 (ii) Failure to send mammography reports within thirty days to the referring physician or in a  
119 timely manner to the self-referred patient

120 (iii) Use of personnel that do not meet the applicable requirements of these rules.

121 (f) "Air kerma" means kerma in a given mass of air. The unit used to measure the quantity of air kerma is  
122 the gray (Gy). For X-rays with energies less than 300 kiloelectronvolts (keV), 1 Gy = 100 rad. In air, 1 Gy of  
123 absorbed dose is delivered by 114 roentgens (R) of exposure.

124 (g) "Annual" means a period of time that is not more than 365 days.

125 (e)(h) "Asymptomatic" means without signs or symptoms of breast disease.

126 (f)(i) "Automatic exposure control" means a device that automatically controls 1 or more technique  
127 factors to obtain a required quantity of radiation at a preselected location or locations.

128 (j) "Body" (See "accreditation body")

129 (k) "Breast implant" means a prosthetic device implanted in the breast.

130  
131 **R325.XXX1. Definitions C to D.**

132  
133 **Rule XXX1. (1) As used in this part:**

134 (a) "Calendar quarter" see "quarter".

135 (b) "Category I" means medical education activities that have been designated as category I by the  
136 accreditation council for continuing medical education (ACCME), the American osteopathic association  
137 (AOA), a state medical society, or an equivalent organization.

138 (c) "Certificate" means the certificate described in this part.

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139 (d) "Certification" means the process of approval of a facility by the FDA or FDA approved certifying  
140 agency to provide mammography services.

141 (e) "Clinical image" means a mammogram.

142 ~~(F)~~(f) "Compression device" means a rigid apparatus that compresses the breast to immobilize the  
143 breast and provide uniform thickness during mammography.

144 (g) "Consumer" means an individual who chooses to comment or complain in reference to a  
145 mammography examination, including the patient or representative of the patient (e.g., family member or  
146 referring physician).

147 (h) "Contact hour" means an hour of training received through direct instruction.

148 (i) "Continuing education credit" (See "continuing education unit").

149 (j) "Continuing education unit" means one contact hour of training.

150 (k) "Control limits" (See "action limits").

151 (l) "Control levels" (See "action limits").

152 ~~(H)~~(m) "Cranio-caudal" means a mammographic projection where the image receptor is placed  
153 inferior to the breast and the x-ray beam is directed superior to inferior through the breast.

154 ~~(m)~~(n) "Diagnostic mammography" means the mammographic examination of symptomatic  
155 individuals.

156 ~~(n) "Diagnostic physics" means the branch of medical physics that deals with the diagnostic applications of~~  
157 ~~ionizing radiation and the equipment associated with its production and use.~~

158 (o) "Direct instruction" means

159 (i) Face-to-face interaction between instructor(s) and student(s), as when the instructor provides  
160 a lecture, conducts demonstrations, or reviews student performance; or

161 (ii) The administration and correction of student examinations by an instructor(s) with subsequent  
162 feedback to the student(s).

163 (p) "Direct supervision" means that:

164 (i) During joint interpretation of mammograms, the supervising interpreting physician reviews,  
165 discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report  
166 before it is entered into the patient's records; or

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167        (ii) During the performance of a mammography examination or survey of the facility's equipment  
168        and quality assurance program, the supervisor is present to observe and correct, as needed, the  
169        performance of the individual being supervised who is performing the examination or conducting the  
170        survey.

171  
172 **R325.XXX2. Definitions E to L.**

173  
174 **Rule XXX2. (1) As used in this part:**

175        (a) "Established operating level" means the value of a particular quality assurance parameter that has  
176        been established as an acceptable normal level by the facility's quality assurance program.

177        (b) "Facility" means, with reference to mammography, a hospital, outpatient department, clinic, radiology  
178        practice, mobile unit, office of a physician, or other facility that conducts mammography activities, including  
179        the following: Operation of equipment to produce a mammogram, processing of the mammogram, initial  
180        interpretation of the mammogram, and maintaining viewing conditions for that interpretation.

181        (c) "FDA" means the Food and Drug Administration.

182        (d) "First allowable time" means the earliest time a resident physician is eligible to take the diagnostic  
183        radiology boards from an FDA-designated certifying body. The "first allowable time" may vary with the  
184        certifying body.

185        (a)(e) "Focal spot" means the primary source of x rays produced at the location where the anode of  
186        an x-ray tube intercepts the electron beam.

187        (b)(f) "Grid" means a device which is used to control scattered radiation and which is composed of  
188        alternating strips of high-x ray-absorption material and low-x ray-absorption spacer material encased in a  
189        protective cover.

190        (g) "Image receptor support device" means, for mammography x-ray systems, that part of the system  
191        designed to support the image receptor during a mammographic examination and to provide a primary  
192        protective barrier.

193        (h) "Interim regulations" means the regulations entitled "Requirements for Accrediting Bodies of  
194        Mammography Facilities (58 FR 67558-67565) and "Quality Standards and Certification Requirements for

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195 Mammography Facilities" (58 FR 67565-67572), published by FDA on December 21, 1993, and amended on  
196 September 30, 1994 (59FR 49808-49813). These regulations established the standards that had to be met  
197 by mammography facilities in order to lawfully operate between October 1, 1994, and April 28, 1999.

198 (i) "Interpreting physician" means a licensed physician who interprets mammograms and who meets the  
199 requirements set forth in this part.

200 (j) "Kerma" means the sum of the initial energies of all charged particles liberated by uncharged ionizing  
201 particles in a material of given mass.

202 (k) "Laterality" means the designation of either the right or left breast.

203 (l) "Lead interpreting physician" means the interpreting physician assigned the general responsibility for  
204 ensuring that a facility's quality assurance program meets all of the requirements of this part. The  
205 administrative title and other supervisory responsibilities of the individual, if any, are left to the discretion of  
206 the facility.

207  
208 **R325.XXX3. Definitions M to O.**

209  
210 **Rule XXX3. (1)** As used in this part:

211 (a) "Mammogram" means a radiographic image of the breast produced through mammography.

212 (b) "Mammographic Modality" means a technology for radiography of the breast. Examples are digital,  
213 and screen-film mammography.

214 ~~(a)~~(c) "Mammography" means radiography of the breast for the purpose of enabling a physician to  
215 determine the presence, size, location, and extent of cancerous or potentially cancerous tissue in the breast.  
216 Mammography does not include radiography of the breast performed during invasive interventions for  
217 localization or biopsy procedures.

218 (d) "Mammography equipment evaluation" means an onsite assessment of mammography unit or image  
219 processor performance by a medical physicist for the purpose of making a preliminary determination as to  
220 whether the equipment meets all of the applicable standards in this part.

221 (e) "Mammography medical outcomes audit" means a systematic collection of mammography results and  
222 the comparison of those results with outcomes data.

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223 (d)(f) "Mammography phantom" means a device that is designed to attenuate the x-ray beam in a  
224 similar way as a typical compressed breast and to simulate breast tissue pathology. A mammography  
225 phantom contains test objects that simulate microcalcifications, fibers, and tumor masses and is used both in  
226 the determination of typical patient radiation exposures and to evaluate imaging performance. X-ray images  
227 of the phantom are evaluated in terms of the number of the test objects of each type that are visualized  
228 under standard viewing conditions.

229 ~~(e) "Mammography supervisor" means the individual who is responsible for, and in control of, quality~~  
230 ~~control, radiation safety, and the technical aspects of all x-ray examinations and procedures for a~~  
231 ~~mammography machine and a mammography facility.~~

232 (g) "Mammography unit(s)" means an assemblage of components for the production of x-rays for use  
233 during mammography, including, at a minimum: an x-ray generator, an x-ray control, a tube housing  
234 assembly, a beam limiting device, and the supporting structures for these components.

235 (h) "Mean optical density" means the average of the optical densities measured using phantom  
236 thicknesses of 2, 4, and 6 centimeters with values of kilovolt peak (kVp) clinically appropriate for those  
237 thicknesses.

238 (i) "Medical physicist" means a person trained in evaluating performance of mammography equipment  
239 and facility quality assurance programs and who meets the qualifications for a medical physicist set forth in  
240 this part.

241 (j) "MQSA" means the Mammography Quality Standards Act of 1992.

242 (k) "MQSRA" means the Mammography Quality Standards Reauthorization Act of 1998.

243 (l) "Multi-reading" means two or more physicians, at least one of whom is an interpreting physician,  
244 interpreting the same mammogram.

### 246 R325.XXX4. Definitions P to R.

#### 247 Rule XXX4. (1) As used in this part:

249 (a) "Patient" means any individual who undergoes a mammography evaluation in a facility, regardless of  
250 whether the person is referred by a physician or is self-referred.

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251 (b) "Phantom" means a test object used to simulate radiographic characteristics of compressed breast  
252 tissue and containing components that radiographically model aspects of breast disease and cancer.

253 (c) "Phantom image" means a radiographic image of a phantom.

254 (d) "Physical science" means physics, chemistry, radiation science (including medical physics and health  
255 physics), and engineering.

256 (e) "Positive mammogram" means a mammogram that has an overall assessment of findings that are  
257 either "suspicious" or "highly suggestive of malignancy."

258 (f) "Provisional certificate" means the provisional certificate described in this part.

259 (g) "Qualified instructor" means an individual whose training and experience adequately prepared him or  
260 her to carry out specified training assignments. Interpreting physicians, radiologic technologists, or medical  
261 physicists who meet the requirements of this part would be considered qualified instructors in their  
262 respective areas of mammography. Other examples of individuals who may be qualified instructors for the  
263 purpose of providing training to meet the regulations of this part include, but are not limited to, instructors in  
264 a post-high school training institution and manufacturer's representatives.

265 (h) "Quality control technologist" means an individual meeting the requirements of this part who is  
266 responsible for those quality assurance responsibilities not assigned to the lead interpreting physician or to  
267 the medical physicist.

268 (i) "Quarter" means any one of the following time periods during a given year: January 1 through March  
269 31, April 1 through June 30, July 1 through September 30, or October 1 through December 31.

270 (j) "Radiologic technologist" means an individual specifically trained in the use of radiographic equipment  
271 and the positioning of patients for radiographic examinations and when performing mammography without  
272 direct supervision, also meets the requirements set forth in this part.

273 ~~(a) "Radiological physics" means the branch of medical physics that includes diagnostic physics,~~  
274 ~~therapeutic physics, and medical nuclear physics.~~

275  
276 **R325.XXX5. Definitions S to Z.**

277  
278 **Rule XXX5. (1) As used in this part:**

279 **(a) "Screen-film mammography" means mammography in which the image is recorded on x-ray film that**

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280 is used in conjunction with an intensifying screen or screens.

281 **(b)** "Screening mammography" means the periodic mammographic examination of asymptomatic women  
282 to detect unsuspected breast cancer in its earliest stage.

283 **(c)** "Serious adverse event" means an adverse event that may significantly compromise clinical  
284 outcomes, or an adverse event for which a facility fails to take appropriate corrective action in a timely  
285 manner.

286 **(d)** "Serious complaint" means a report of a serious adverse event.

287 **(e)** "Standard breast" means a 4.2 centimeter (cm) thick compressed breast consisting of 50 percent  
288 glandular and 50 percent adipose tissue.

289 **(e)(f)** "Survey" means an onsite physics consultation and evaluation of a facility quality assurance  
290 program performed by a medical physicist.

291 **(g)** "Time cycle" means the film development time.

292 **(h)** "Traceable to a national standard" means an instrument is calibrated at either the National Institute of  
293 Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program  
294 with NIST at least once every two years and the results of the proficiency test conducted within 24 months of  
295 calibration show agreement within + 3 percent of the national standard in the mammography energy range.

296 ~~**(d)** "Xeromammography" means mammography in which the image is recorded on an electrostatically~~  
297 ~~charged photoconductive plate that is held in a lightproof cassette.~~

298  
299 **(2)** The terms defined in the act shall have the same meanings when used in these rules.

300

301 **R325.5603. Department inspections.**

302

303 **Rule 603. (1)** The department shall inspect a mammography machine and system not later than ~~60~~90 days  
304 after initial mammography authorization is issued. After that initial inspection, the department shall annually  
305 inspect the mammography machine and system and may inspect more frequently

Pending change in Part 135A of the public health code.
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**Rule 605.** The department shall issue a 3-year mammography authorization if the mammography facility is in compliance with all of the following standards:

**(a)** The radiation machine is in compliance with either of the following requirements:

**(i)** The machine meets the criteria for the American college of radiology mammography accreditation program dated ~~October, 1991, and January, 1992~~(most recent date?), and the facility submits an evaluation report issued by the American college of radiology as evidence that the mammography machine meets the criteria. A stereotactic breast biopsy or needle localization machine shall meet the criteria of the ACR stereotactic breast biopsy accreditation program dated 10/17/2004. The criteria are adopted by reference in these rules for the purpose of applying this paragraph only. Copies of the criteria are available at no cost from the ~~Division of Radiological Health, Michigan Department of Public Health, 3423 North Logan/Martin L. King Jr. Boulevard, P.O. Box 30195, Lansing, Michigan 48909~~ Radiation Safety Section, Michigan Department of Community Health, P.O. Box 30664, Lansing, Michigan 48909.

**(ii)** The machine is used in a facility that has successfully completed the department's evaluation of the machine for the items described in R325.5610.

**(b)** The radiation machine, the film, or other image receptor that is used with the machine and the facility where the machine is used are in compliance with the requirements of this part and **R325.5001 to R325.5511(or appropriate numbering after update).**

**(c)** The radiation machine is specifically designed to perform mammography.

**(d)** The radiation machine is used exclusively to perform mammography.

**(e)** The radiation machine is used in a facility that, at least annually, has a qualified ~~radiation~~radiation-medical physicist provide on-site consultation to the facility as described in these rules. Records and findings of on-site consultations shall be maintained for not less than 7 years.

**(f)** The radiation machine is used according to department rules on patient exposure and radiation dose levels, being R325.5661662(5)(g) of this part.

**(g)** The radiation machine is operated only by an individual who can demonstrate to the department that he or she meets the standards described in this part or by an individual who is a physician or an osteopathic

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363 physician.

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365 ~~[Note: As a result of Executive Orders 1996-1 and 1996-2, the authority, powers, duties, functions, and~~  
366 ~~responsibilities of the radiation machine registration, licensing, and compliance program were transferred to~~  
367 ~~the Michigan Department of Consumer & Industry Services. With respect to machine sources of ionizing~~  
368 ~~radiation, any correspondence to the Michigan Department of Public Health should now be addressed to the~~  
369 ~~Michigan Department of Consumer & Industry Services, BHS, Radiation Safety Section, P.O. Box 30664,~~  
370 ~~Lansing, Michigan 48909.]~~  
371

372 **R325.5606. Temporary mammography authorization.**

373

374 **Rule 606. (1)** The department may issue a nonrenewable temporary mammography authorization. A  
375 temporary authorization may only be issued if additional time is needed to allow the submission of evidence  
376 that is satisfactory to the department to demonstrate compliance with the provisions of R325.5605.

377

378 **(2)** The department may withdraw a temporary authorization before its expiration if the radiation machine  
379 does not meet 1 or more of the criteria specified in R325.5605.

380

381 **R325.5607. Application.**

382

383 **Rule 607. (1)** Each person who has a machine that is authorized for use for mammography on the effective  
384 date of this part shall be required to complete a mammography authorization application form if requested by  
385 the department. This application form shall be returned to the department within 45 days of the department's  
386 request.

387

388 **(2)** An applicant who seeks mammography authorization shall apply to the department using an  
389 application form that is supplied by the department. If mammography is performed at more than 1 location or  
390 address, a separate application shall be used for each location or address. An applicant shall accurately  
391 provide all information that is requested on the form. The information submitted as part of the application shall  
392 be sufficient, as determined by the department, to address all of the standards for authorization. Applications  
393 that do not provide sufficient information shall be returned to the applicant for completion and resubmission.

394 Applications shall include all of the following information:

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395       **(a)** Information about the facility, including all of the following:

396           **(i)**       Name, address, and telephone number.

397           **(ii)**       Type of practice.

398           **(iii)**       The name to be used or which is currently used on the certificate of registration.

399       **(b)** Personnel information, including the education, training, experience, and certification of the  
400 | ~~mammography supervisor~~ lead interpreting physician, any qualified radiation physicist who provides on-site  
401 | consultation and evaluation of the mammography system, and any individual who actually performs  
402 | mammography.

403       **(c)** Mammography machine technical information, including all of the following:

404           **(i)**       Manufacturer.

405           **(ii)**       Model.

406           **(iii)**       Year of manufacture.

407           **(iv)**       The imaging system in use.

408           **(v)**       Target material.

409           **(vi)**       Filter material.

410           **(vii)**       Phototiming capability.

411           **(viii)**       The nominal focal spot size.

412           **(ix)**       The source-to-image distance.

413           **(x)**        The half-value layer.

414           **(xi)**       The type of compression device used.

415           **(xii)**       The capability of magnification studies.

416           **(xiii)**       The grid availability and type.

417           **(xiv)**       The grid ratio.

418           **(xv)**       Grid lines per inch or per centimeter.

419           **(xvi)**       Film size and grid size capability.

420           **(xvii)**       The make and model of film and screens.

421       **(d)** Image processor information, including all of the following:

422           **(i)**        The manufacturer.

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- 423        **(ii)**        Model.
- 424        **(iii)**        Whether the processor is dedicated to mammography image processing.
- 425        **(iv)**        Chemistry type.
- 426        **(v)**        Temperature.
- 427        **(vi)**        Development time.
- 428        **(e)** Mammography techniques, including all of the following:
- 429        **(i)**        Number of views per breast.
- 430        **(ii)**        Typical views employed.
- 431        **(iii)**        Machine settings for routine mammograms.
- 432        **(iv)**        Grid use.
- 433        **(f)** A copy of the facility's mammography quality assurance plan which includes a description of all of the
- 434 following:
- 435        **(i)**        Quality control tests performed.
- 436        **(ii)**        The frequency of tests.
- 437        **(iii)**        By whom the tests are performed.
- 438        **(iv)**        The limits of acceptability of those tests.
- 439        **(v)**        The protocol for making corrections when a test does not fall within the limits of acceptability.
- 440        **(g)** The type of patient medical history information collected by the facility, including whether a history is
- 441 taken as part of the mammographic procedure and, if taken, the items that are included in the history.
- 442        **(h)** The type of patient physical examination information collected by the facility, including all of the
- 443 following:
- 444        **(i)**        Whether a physical examination is conducted and, if so, by whom.
- 445        **(ii)**        The training the individual has specific to breast physical examination.
- 446        **(iii)**        Whether the patient is instructed in breast self-examination during the physical examination or
- 447 at any time by staff of the facility.
- 448        **(i)** Mammography interpretation reporting mechanisms, including all of the following:
- 449        **(i)**        A description of whether the report includes both mammographic and clinical findings.
- 450        **(ii)**        A description of the mechanism in place to follow-up on positive or equivocal results to assure

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451 that a patient's physician has received the report and understands any recommendations.

452 (iii) An indication of whether patients who have equivocal results are contacted for a follow-up  
453 examination at a prescribed time.

454 (iv) A description of procedures for handling self-referred patients in terms of sending a report.

455 (v) A description of the follow-up mechanisms in place to determine factors such as the results of  
456 biopsies, the number of cancers with negative and positive mammograms, the number of localizations  
457 with positive results, and the proportion of cases for which additional views are done.

458 (j) Image retention policy.

459

460 (3) The department shall respond to an application within 30 days after the date of receipt of the  
461 application.

462

463 **R325.5608. Application fee schedule; waiver.**

464

465 **Rule 608. (1)** An application form for mammography authorization shall be accompanied by a  
466 nonrefundable payment, in full, by the applicant, for department evaluation of compliance with the provisions of  
467 R325.5605(a). The fee schedule is specified in the act.

468

469 (2) If an applicant for mammography authorization submits an evaluation report which is issued by the  
470 American college of radiology and which evidences compliance with the provisions of R325.5605(a), then the  
471 fee for department evaluation of compliance with the provisions of R325.5605(a) shall be waived.

472

473 **R325.5609 Application expiration.**

474

475 **Rule 609.** An application for mammography authorization submitted to the department shall expire 6  
476 months from the date of the department's receipt of the completed application unless the time limit is extended  
477 by the department.

478

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479 **R325.5610. Supplemental machine information; effect of failure to submit information.**

480

481 **Rule 610. (1)** Upon notice from the department that an application for mammography authorization  
482 has been determined to be complete and to be in compliance with the requirements of these rules and at the  
483 specific request of the department, the applicant shall, within 45 days of the department's request, provide all  
484 of the following information for each machine for which mammography authorization is being sought:

485 **(a)** Confirmation that a mammography phantom that is approved by the department is on-site when  
486 mammography is performed and is used in the facility's ongoing quality control program. The confirmation  
487 shall include the make, model, and serial number of the phantom and the serial number of the wax insert  
488 that contains imaging test objects.

489 **(b)** For each machine, processor quality control data and corrective actions, if any, taken as a result of  
490 that data for a 30-day period beginning after the date the application was sent to the department.

491 **(c)** For each machine, an x-ray image of a mammography phantom which is approved by the department  
492 and which is taken during the 30-day period for which processor quality control data is required pursuant to  
493 the provisions of subdivision (b) of this subrule. The phantom image shall be taken using routine machine  
494 settings being used by the facility for that mammography machine for a cranio-caudal view of a  
495 4.5-centimeter compressed breast composed of 50% glandular and 50% adipose tissue. The phantom  
496 image shall be accompanied by documentation of the date that the image was taken and the machine  
497 settings that were used.

498 **(d)** For each machine, determinations of the half-value layer, radiation exposure at skin entrance, and  
499 mean glandular dose that are made with the use of a department-approved thermoluminescent dosimetry  
500 device that is placed on top of an approved mammography phantom during the same exposure of the  
501 phantom that is used to produce an x-ray image to be submitted pursuant to the provisions of subdivision (c)  
502 of this subrule or that are made by other methods as specified or approved by the department.

503 **(e)** For each machine, a set of clinical patient mammography images without pathology which is produced  
504 by that machine for each of 2 representative patients, 1 with dense breasts and 1 with fatty breasts. Each  
505 set of clinical images shall consist of not less than 2 standard views of each breast, totaling not less than 4  
506 films for each type of breast. The images shall contain clear documentation of all of the following:

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- 507           **(i)**       The name of the facility.
- 508           **(ii)**       The date of the mammography examination.
- 509           **(iii)**       Mammography machine operator identification information.
- 510           **(iv)**       Cassette-screen or xeroradiographic cassette-plate identification information.

511       The date of the mammography examination shall be on or after the date that the application was sent to the  
512       department, and the x-ray images shall be accompanied by clear documentation of the mammography  
513       machine used, including the department-assigned machine registration number, and the name of the  
514       individual or individuals who operated the machine.

515

516       **(2)**     The department may waive the requirements of subrule (1) of this rule if the mammography machine  
517       is accredited, or is in the process of becoming accredited, by the American college of radiology. To have the  
518       requirements of subrule (1) of this rule waived, an applicant shall provide, to the department, within 45 days of  
519       the department's request, copies of the applicant's current accreditation application, current accreditation-  
520       related correspondence to and from the American college of radiology, or current accreditation certificate that  
521       is issued by the American college of radiology.

522

523       **(3)**     Failure of an applicant to submit the information required by the provisions of either subrule (1) or (2)  
524       of this rule within 45 days of the department's request may be considered a basis for withdrawal or denial of  
525       the mammography authorization, unless the time limit is extended by the department for cause.

526

527       **R325.5611.     Contracts for technical evaluation.**

528

529       **Rule 611.     (1)**     In evaluating clinical image quality and acceptability for mammography authorization,  
530       upon receipt of the information required in R325.5610(1)(e), the department may enter into any necessary  
531       contracts with mammography experts, submit the images to those experts for technical evaluation, and rely  
532       upon their expert evaluation in arriving at a department conclusion regarding image quality and acceptability in  
533       terms of granting or not granting mammography authorization.

534

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535       **(2)** Technical parameters that are used in evaluating clinical image quality and acceptability pursuant to  
536 the provisions of subrule (1) of this rule shall include judgments of all of the following:

- 537       **(a)** Positioning.
- 538       **(b)** Compression.
- 539       **(c)** Radiation exposure and dose level.
- 540       **(d)** Sharpness.
- 541       **(e)** Contrast.
- 542       **(f)** Noise.
- 543       **(g)** Exam identification.
- 544       **(h)** Artifacts.
- 545       **(i)** Processing.

546

547 **R325.5612. Notice of change in application information; authorization not transferable.**

548

549       **Rule 612. (1)** A facility that is authorized to perform mammography shall notify the department, in  
550 writing, of any change in the information contained in the application or supporting material upon which  
551 authorization was granted or any change that affects the accuracy of information which is provided or obtained  
552 during the application and evaluation process for authorization. Changes that shall be reported include  
553 changes in any of the following:

- 554       **(a)** Facility ownership.
- 555       **(b)** Facility location.
- 556       **(c)** Mammography machine.
- 557       **(d)** Image processor.
- 558       **(e)** Brand or model of imaging materials in use.
- 559       **(f)** Personnel providing mammography supervision.
- 560       **(g)** Personnel providing interpretation of mammograms.
- 561       **(h)** Personnel providing qualified radiation physicist services.
- 562       **(i)** Personnel actually performing mammography.

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563           (j) American college of radiology accreditation status.

564

565           (2) Upon receipt of a notice of change, the department shall advise the facility if reapplication for  
566 mammography authorization, resubmittal of phantom or clinical images, or other actions are deemed by the  
567 department to be necessary to establish that the facility, machine, system, and personnel remain in  
568 compliance with the requirements of these rules. Upon department request, a facility shall provide any  
569 requested information or materials within 45 days after the request is made.

570

571           (3) If changes in information are deemed to require reapplication for mammography authorization, the  
572 application shall be filed and processed in the same manner as set forth in R325.5607 and R325.5608.

573

574           (4) Mammography authorization that is issued by the department is not transferable between machines or  
575 between persons who own or lease a radiation machine.

576

577   **R325.5613.     Authorization withdrawal; reinstatement.**

578

579           **Rule 613. (1)** Three-year mammography authorization is subject to continued compliance with this part and  
580 the provisions of **R325.5001 to R325.5511(or appropriate numbering after update)**. Authorization may be  
581 withdrawn based on evidence of noncompliance with this part and the provisions of **R325.5001 to R325.5511**  
582 **(or appropriate numbering after update)** in accordance with the provisions of **Act No. 306 of the Public**  
583 **Acts of 1969, as amended, being '24.201 et seq. (?)** of the Michigan Compiled Laws.

584

585           (2) If the department withdraws the mammography authorization of a machine, the machine shall not be  
586 used for mammography. An application for reinstatement of a mammography authorization shall be filed and  
587 processed in the same manner as an application for mammography authorization pursuant to the provisions of  
588 R325.5607 and R325.5608.

589

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590       **(3)** The department shall not issue a reinstated mammography authorization until the department receives  
591 the reinspection fee, inspects the machine, and determines that the facility meets the standards set forth in  
592 R325.5605.

**MAMMOGRAPHY SUPERVISOR LEAD INTERPRETING PHYSICIAN**

Terminology change in order to be consistent with FDA MQSA final regulations. <b>COMBINE THIS SECTION WITH RULE 660?</b>
--

596  
597 **R325.5617. Designation; identification; agreement between ~~supervisor~~ lead interpreting physician**  
598 **and facility; availability; continuing education.**

599  
600       **Rule 617. (1)** Each mammography facility shall designate a ~~mammography supervisor~~ lead interpreting  
601 physician in order to be authorized to perform mammography.

602  
603       **(2)** An applicant who seeks mammography authorization shall identify the ~~mammography supervisor~~ lead  
604 interpreting physician on the application form for mammography authorization.

605  
606       **(3)** If the ~~mammography supervisor~~ lead interpreting physician is not the employer of the mammography  
607 machine operators at the facility, a written agreement shall be executed between the ~~mammography~~  
608 ~~supervisor~~ lead interpreting physician and the facility. The written agreement shall include at least both of the  
609 following:

610       **(a)** A statement that the ~~mammography supervisor~~ lead interpreting physician is responsible for assuring  
611 compliance with this part and the provisions of **R325.5001 to R325.5511** **(or appropriate numbering after**  
612 **update).**

613       **(b)** A statement that the ~~mammography supervisor~~ lead interpreting physician has been given the  
614 authority to make changes in the mammography program that are necessary to achieve compliance as  
615 specified in subdivision (a) of this subrule or a statement that the facility will make the changes requested by  
616 the ~~mammography supervisor~~ lead interpreting physician to achieve compliance.

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617

618 | **(4)** A mammography supervisor ~~lead interpreting physician~~ shall be readily available telephonically or in  
619 | person for consultation with any radiation machine operator who performs mammography.

620

621 | **(5)** A mammography supervisor ~~lead interpreting physician~~ lead interpreting physician shall obtain  
622 | ~~not less than 15 hours of continuing education every 3 years in the technical aspects or clinical aspects, or~~  
623 | ~~both, of mammography and related subjects that is accredited by the American medical association or the~~  
624 | ~~American society of radiologic technologists or any other organizations acceptable to the department.~~ meet all  
625 | interpreting physician requirements of the public health code and the rules in this part.

Modified to simplify. This requirement is already listed for all interpreting physicians in Part 135a of the Public Health Code.

626

627 | **R325.5618. — Responsibilities.**

628

629 | **Rule 618.** — A mammography supervisor ~~LEAD INTERPRETING PHYSICIAN~~ shall be responsible for  
630 | each of the following:

631 | **(a)** ~~Establishment and maintenance of a quality control program.~~

632

This is the physicist's responsibility under FDA MQSA regulations.

633

634 | **(b)** ~~Annual review and updating of the procedures manual.~~

635 | **(c)** ~~Evaluation of each mammography machine operator's performance at least semiannually as~~  
636 | ~~described in R325.5619.~~

Operator initial training, initial experience, continuing education, and continuing experience requirements along with daily oversight and review of images created by the operators is sufficient.

637

638 | **(d)** ~~Assurance that each mammography machine operator other than a physician has successfully~~  
639 | ~~completed special mammography training as specified in R325.5621 and R325.5623 or possesses the~~  
640 | ~~American registry of radiologic technologists certificate of advanced qualifications in mammography as~~  
641 | ~~identified in R325.5622. Documents that verify training shall be maintained at the facility and copies shall be~~  
642 | ~~submitted to the department together with the facility application for mammography machine authorization.~~

643 | **(e)** ~~Assurance that the mean glandular dose for 1 contact cranio-caudal view of a 4.5-centimeter~~  
644 | ~~compressed breast that is composed of 50% glandular and 50% adipose tissue is not more than the limits~~  
645 | ~~prescribed by R325.5661662(5)(g).~~

646 | **(f)** ~~Assurance that mammography is performed only on dedicated equipment that is designed specifically~~  
647 | ~~for use for mammography and that has been authorized by the department for use for mammography.~~

648 | **(g)** ~~Assuring that all patients who undergo mammography screening procedures designate a physician or~~  
649 | ~~other licensed health care provider responsible for primary care, to whom the written results of the~~  
650 | ~~mammography examination will be reported.~~

651 | **(h)** ~~Assuring the review of records of mammography system quality assurance evaluations conducted by~~

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652 a qualified radiation physicist and, when necessary, assuring the correction of deficiencies and violations.  
653 ~~(i) Compliance with quality assurance and radiation protection criteria prescribed by these rules.~~

This section is covered by the FDA regs inserted as rules 659 thru 661.

654  
655 **R325.5619. — Machine operator performance evaluation.**  
656

657 **Rule 619. — (1)** — A mammography supervisor shall evaluate the performance of each individual, other  
658 than a physician, who operates a mammography machine at least semiannually. The evaluation shall be  
659 based on both the mammography supervisor's direct observation of the operator during a standard  
660 mammography procedure being performed by the operator on at least 1 patient and on the mammography  
661 supervisor's review of clinical images.

662  
663 **(2)** — The performance evaluation shall evaluate all of the following:

664 **(a)** Proper and compassionate patient handling skills.

665 **(b)** Proper breast positioning for the cranio-caudal projection of the breast, including all of the following  
666 steps, unless other procedures are deemed appropriate and acceptable by the department:

667 **(i)** — Determining the proper image receptor size.

668 **(ii)** — Moving the photocell to the appropriate position.

669 **(iii)** — Standing on the medial side of the breast to be imaged.

670 **(iv)** — Elevating the inframammary fold to its maximum height, adjusting the height of the bucky  
671 accordingly.

672 **(v)** — Using 1 hand, gently scooping the breast onto the image receptor tray.

673 **(vi)** — Centering the breast over the photocell, with the nipple in profile, if possible.

674 **(vii)** — Anchoring the breast with 1 hand and not removing the hand until the compression process  
675 begins.

676 **(viii)** — With the other hand, draping the opposite breast over the corner of the bucky.

677 **(ix)** — Slightly rotating the patient's head away from the side being imaged.

678 **(x)** — Leaning the patient toward the machine with the head forward and around the tube.

679 **(xi)** — Placing an arm against the patient's back with a hand on the shoulder of the side being  
680 imaged, making sure the shoulder is relaxed.

681 **(xii)** — With a hand on the shoulder, sliding the skin up over the clavicle.

682 **(xiii)** — With the hand that is anchoring the breast pulling lateral tissue onto the image receptor tray,  
683 without losing medial tissue, while applying compression.

684 **(xiv)** — On the side being imaged, checking that the patient's arm is relaxed by her side with the  
685 shoulder externally rotated.

686 **(c)** Proper breast positioning for the medio-lateral oblique projection of the breast, including all of the  
687 following steps, unless other procedures are deemed appropriate and acceptable by the department:

688 **(i)** — Determining the proper image receptor size.

689 **(ii)** — Moving the photocell to the appropriate position.

690 **(iii)** — Determining the degree of obliquity parallel to the pectoral muscle.

691 **(iv)** — Rotating the C-arm so that the long edge of the bucky is parallel to the pectoral muscle.

692 **(v)** — Adjusting the height of the film tray so that the top is level with the axilla.

693 **(vi)** — Lifting the arm on the side to be imaged up and over the corner of the bucky.

694 **(vii)** — Placing the corner of the bucky in axilla, that is, anterior to the latissimus dorsi.

695 **(viii)** — Placing the patient's hand that is on the side being imaged on the C-arm, with the elbow  
696 flexed and the shoulder relaxed.

697 **(ix)** — Pulling the breast and muscle anteriorly and medially with the flat front surface of the hand.

698 **(x)** — Scooping the breast tissue up with the hand, grasping the lateral border of the breast with the  
699 fingers and the medial border of the breast with the thumb.

700 **(xi)** — Turning the patient toward the bucky making sure that the patient's feet are facing the  
701 machine.

702 **(xii)** — Centering the breast with the nipple in profile, if possible.

703 **(xiii)** — Holding the breast up and out by rotating the hand so that the base of the thumb supports the  
704 breast and so that the fingers are pointing away from the breast and continuing to hold the breast up and

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705 out throughout compression.

706 ~~(xiv) Applying compression with the corner of the paddle below the clavicle.~~

707 ~~(xv) Pulling down on the abdominal tissue to open the inframammary fold.~~

708 ~~(d) The use of appropriate compression.~~

709 ~~(e) Proper technique factor selection for the patient being x-rayed, including selecting the proper kVp-~~  
710 ~~target filter combination for the image receptor being used.~~

711 ~~(f) Proper maintenance of records, including examination identification information.~~

712 ~~(g) Familiarity with image processor quality assurance procedures and mammography machine quality~~  
713 ~~assurance procedures that are applicable to the machine operator, including the use of a mammography~~  
714 ~~phantom as a means of evaluating machine performance.~~

715 ~~(h) Knowledge of each of the following:~~

716 ~~(i) The American college of radiology accreditation status of the machine.~~

717 ~~(ii) The most recent department inspection of the machine and regulatory inspection frequency.~~

718 ~~(iii) The most recent consulting physicist evaluation of the mammography system and the~~  
719 ~~frequency of those evaluations.~~

720 ~~(iv) The radiation dose for an average patient.~~

721 ~~(v) The recent phantom image results for the machine being used.~~

722 ~~(i) The ability to produce acceptable clinical mammography images. Clinical images shall be~~  
723 ~~evaluated on the basis of all of the following criteria:~~

724 ~~(i) Positioning.~~

725 ~~(ii) Compression.~~

726 ~~(iii) Optical density.~~

727 ~~(iv) Sharpness.~~

728 ~~(v) Contrast.~~

729 ~~(vi) Noise.~~

730 ~~(vii) Exam identification.~~

731 ~~(viii) Artifacts.~~

732  
733 ~~(3) A machine operator performance evaluation shall be recorded on an evaluation form which includes~~  
734 ~~all of the items described in subrule (2) of this rule and which contains all of the following information:~~

735 ~~(a) The names and signatures of the mammography supervisor and machine operator.~~

736 ~~(b) The date of the mammography examination for which the operator was evaluated.~~

737 ~~(c) Examination and x ray image identification information.~~

738 ~~(d) The date the evaluation results were discussed with the operator.~~

739 ~~The form shall also document that the operator has received a copy of the evaluation.~~

740  
741 ~~(4) A mammography supervisor shall formally discuss the evaluation results with the operator within 10~~  
742 ~~days of observation. A copy of the evaluation form shall be given to the operator at the time the evaluation~~  
743 ~~results are discussed.~~

744  
745 ~~(5) If an individual fails to receive a satisfactory evaluation for any item specified in subrule (2) of this rule,~~  
746 ~~the individual shall receive additional training pertaining to the deficient item and shall be reevaluated within 60~~  
747 ~~days of the original evaluation.~~

748  
749 ~~(6) A facility shall maintain each evaluation form on permanent, available file for a period of not less than~~  
750 ~~7 years. Copies of the evaluation forms shall be forwarded to the department for review upon a written~~  
751 ~~request by the department.~~

752  
753 ~~(7) Upon termination of employment, an operator may request that a facility provide copies of the~~  
754 ~~operator's evaluation reports to the operator or to another designated individual. Upon written request, a~~  
755 ~~facility shall provide evaluation reports to an employee or former employee for the 7-year period prior to the~~  
756 ~~date of the request.~~

Operator performance testing is covered by the other operator training, education, and experience requirements.
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757

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Following are the quality standards for mammography, taken from the MQSA final regulations, Sec. 900.12 Quality standards. In cases where these standards and Michigan standards address the same area, any additional existing Michigan standards that are more stringent, but still needed, will be added and noted.

**MAMMOGRAPHY PERSONNEL**

**R325.5621. Applicability.**

**Rule 621.** Rules **622 through 624** apply to all personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities. Rule 622 does not apply to mammography performed using stereotactic breast biopsy or needle localization machines.

**R325.5622. Interpreting physicians.**

**Rule 622.** All physicians interpreting mammograms shall meet the following qualifications:

**(a) Initial qualifications.** Unless the exemption in paragraph **(c)** of this rule applies, before beginning to interpret mammograms independently, the interpreting physician shall:

**(i)** Be licensed to practice medicine in Michigan.

**(ii)** (1) Be certified in an appropriate specialty area by a body determined by the department to have procedures and requirements adequate to ensure that physicians certified by the body are competent to interpret radiological procedures, including mammography; **or** (2) have had at least 3 months of documented formal training in the interpretation of mammograms and in topics related to mammography. The training shall include instruction in radiation physics, including radiation physics specific to mammography, radiation effects, and radiation protection. The mammographic interpretation component shall be under the direct supervision of a physician who meets the requirements of **rule 622.**

**(iii)** 3 years (***pending legislation change from 2 years***) after becoming eligible for board certification, all interpreting physicians must meet rule 622(a)(ii)(1).

**(iv)** Have a minimum of 60 hours of documented medical education in mammography, which shall include: Instruction in the interpretation of mammograms and education in basic breast anatomy,

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785 pathology, physiology, technical aspects of mammography, and quality assurance and quality control in  
786 mammography. All 60 of these hours shall be category I and at least 15 of the category I hours shall have  
787 been acquired within the 3 years immediately prior to the date that the physician qualifies as an  
788 interpreting physician. Hours spent in residency specifically devoted to mammography will be considered  
789 as equivalent to Category I continuing medical education credits and will be accepted if documented in  
790 writing by the appropriate representative of the training institution.

791 (v) Unless the exemption in **Rule 622 (c)(ii)** applies, have interpreted or multi-read at least 240  
792 mammographic examinations within the 6-month period immediately prior to the date that the physician  
793 qualifies as an interpreting physician. This interpretation or multi-reading shall be under the direct  
794 supervision of an interpreting physician.

795 **(b) Continuing experience and education.** All interpreting physicians shall maintain their qualifications  
796 by meeting the following requirements:

797 (i) Following the second anniversary date of the end of the calendar quarter in which the  
798 requirements of **Rule 622(a)** were completed, the interpreting physician shall have interpreted or multi-  
799 read at least 960 mammographic examinations during the 24 months immediately preceding the date of  
800 the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date  
801 in-between the two. The facility will choose one of these dates to determine the 24-month period.

802 (ii) Following the third anniversary date of the end of the calendar quarter in which the  
803 requirements of **Rule 622(a)** were completed, the interpreting physician shall have taught or completed at  
804 least 15 category I continuing medical education units in mammography during the 36 months immediately  
805 preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the  
806 inspection or any date in between the two. The facility will choose one of these dates to determine the 36-  
807 month period. This training shall include at least six category I continuing medical education credits in  
808 each mammographic modality used by the interpreting physician in his or her practice; and

809 (iii) Before an interpreting physician may begin independently interpreting mammograms  
810 produced by a new mammographic modality, that is, a mammographic modality in which the physician has  
811 not previously been trained, the interpreting physician shall have at least 8 hours of training in the new  
812 mammographic modality.

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813 (iv) Units earned through teaching a specific course can be counted only once towards the 15  
814 required by Rule 622(b)(ii), even if the course is taught multiple times during the previous 36 months.

815 **(c) Exemptions.**

816 (i) Those physicians who qualified as interpreting physicians prior to the effective date of  
817 these rules, are considered to have met the initial requirements of paragraph (a) of this rule. They may  
818 continue to interpret mammograms provided they continue to meet the licensure requirement of  
819 paragraph (a)(i) of this rule and the continuing experience and education requirements of paragraph  
820 (b) of this rule.

821 (ii) Physicians who have interpreted or multi-read at least 240 mammographic examinations  
822 under the direct supervision of an interpreting physician in any 6-month period during the last 2 years  
823 of a diagnostic radiology residency and who become appropriately board certified at the first allowable  
824 time, as defined by an eligible certifying body, are otherwise exempt from paragraph (a)(v) of this rule.

825 **(d) Reestablishing qualifications.** Interpreting physicians who fail to maintain the required continuing  
826 experience or continuing education requirements shall reestablish their qualifications before resuming the  
827 independent interpretation of mammograms, as follows:

828 (i) Interpreting physicians who fail to meet the continuing experience requirements of paragraph  
829 (b)(i) of this rule shall:

830 (A) Interpret or multi-read at least 240 mammographic examinations under the direct supervision  
831 of an interpreting physician, or

832 (B) Interpret or multi-read a sufficient number of mammographic examinations, under the direct  
833 supervision of an interpreting physician, to bring the physician's total up to 960 examinations for the prior  
834 24 months, whichever is less.

835 (C) The interpretations required under paragraph (d)(i)(A) or (d)(i)(B) of this rule shall be done  
836 within the 6 months immediately prior to resuming independent interpretation.

837 (ii) Interpreting physicians who fail to meet the continuing education requirements of paragraph  
838 (b)(ii) of this rule shall obtain a sufficient number of additional category I continuing medical education  
839 credits in mammography to bring their total up to the required 15 credits in the previous 36 months before  
840 resuming independent interpretation.

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**OPERATORS OF MAMMOGRAPHY EQUIPMENT**

There is a question if old Rules 621 through 624 following are still needed or if we can remove them and use FDA wording.

**R325.5621. — Qualifications.**

**Rule 621.** — An individual, other than a physician, who operates a mammography machine shall meet all of the following qualifications:

(a) An individual who operates a mammography machine shall have successfully completed a radiography program that meets the standards for accrediting radiography programs adopted by the committee on allied health education and accreditation, or its successor, of the American medical association in cooperation with the joint review committee on education in radiologic technology, entitled "Essentials and Guidelines," (1990). These standards are adopted by reference in these rules. These standards are available from the Division of Radiological Health, Michigan Department of Public Health, 3423 North Logan/Martin L. King Jr. Boulevard, P.O. Box 30195, Lansing, Michigan 48909, and from the American Medical Association, 515 North State Street, Chicago, Illinois 60610, at no charge at the time of adoption of this part. Accreditation of a radiography program by the committee on allied health education and accreditation of the American medical association in cooperation with the joint review committee on education in radiologic technology shall be prima facie evidence that the radiography program is in compliance with the standards adopted by reference in this subdivision.

(b) An individual who operates a mammography machine shall meet the standards for issuance of a registration certificate as a registered technologist from the American registry of radiologic technologists or meet the standards for issuance of a registration certificate as a radiography technologist from the American registry of clinical radiography technologists. These standards, entitled "Rules and Regulations," as revised in February, 1990, and "By Laws," as revised in September, 1989, of the American registry of radiologic technologists and "Overview of the A.R.C.R.T. Organization," as revised in August, 1991, and "Application for Registration Radiography Technologist," (1991), of the American registry of clinical radiography technologists, are adopted by reference in this rule. These standards are available from the Division of Radiological Health, Michigan Department of Public Health, 3423 North Logan/Martin L. King Jr. Boulevard, P.O. Box 30195, Lansing, Michigan 48909, at no charge at the time of adoption of this part. The respective standards are also available from the American Registry of Radiologic Technologists, 1255 Northland Drive, Mendota Heights, Minnesota 55120, and from the American Registry of Clinical Radiography Technologists, 710 Higgins Road, Park Ridge, Illinois 60068, at no charge at the time of adoption of this part. A determination by the American registry of radiologic technologists or the American registry of clinical radiography technologists that an individual meets its respective standards for issuance of a registration certificate shall be prima facie evidence that the individual complies with the standards that are adopted by reference in this subdivision.

(c) Two years after the effective date of this part, shall have successfully completed a formal program of mammography instruction as prescribed by R325.5625.

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

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### 888 **R325.5622. — Technologist exemptions.**

889  
890 **Rule 622. — (1)** — ~~An individual who meets the standards of the American registry of radiologic~~  
891 ~~technologists for its certificate of advanced qualification in mammography shall be exempt from the provisions~~  
892 ~~of R325.5621(c). The standards, entitled "Handbook For Advanced Level Examinations," (November, 1991),~~  
893 ~~are adopted by reference in this rule. These standards are available from the Division of Radiological Health,~~  
894 ~~Michigan Department of Public Health, 3423 North Logan/Martin L. King Jr. Boulevard, P.O. Box 30195,~~  
895 ~~Lansing, Michigan 48909, and from the American Registry of Radiologic Technologists, 1255 Northland Drive,~~  
896 ~~Mendota Heights, Minnesota 55120, at no charge at the time of adoption of this part. A determination by the~~  
897 ~~American registry of radiologic technologists that an individual meets the standards for issuance of a certificate~~  
898 ~~of advanced qualification in mammography shall be prima facie evidence that an individual meets the~~  
899 ~~standards adopted by reference in this subrule. However, the technologist shall be required to obtain~~  
900 ~~continued education as prescribed by R325.5623 and meet performance requirements prescribed by~~  
901 ~~R325.5619(2).~~

902  
903 **(2)** — ~~Students in a radiography program that is in compliance with the requirements of R325.5621(a) shall~~  
904 ~~be exempt from the provisions of R325.5621 while performing mammography within the context of the~~  
905 ~~radiography program and under the direct supervision of a qualified mammography equipment operator.~~  
906 ~~Registry eligible graduates of an accredited radiography program that is in compliance with the requirements~~  
907 ~~of R325.5621(a) shall be exempt from the provisions of R325.5621(b) and (c) for 2 years after graduation.~~

908  
909 *[Note: — As a result of Executive Orders 1996-1 and 1996-2, the authority, powers, duties, functions, and*  
910 *responsibilities of the radiation machine registration, licensing, and compliance program were transferred to*  
911 *the Michigan Department of Consumer & Industry Services. With respect to machine sources of ionizing*  
912 *radiation, any correspondence to the Michigan Department of Public Health should now be addressed to the*  
913 *Michigan Department of Consumer & Industry Services, BHS, Radiation Safety Section, P.O. Box 30664,*  
914 *Lansing, Michigan 48909.]*

### 915 916 **R 325.5623. — Continuing education.**

917  
918 **Rule 623.** — ~~An individual, other than a physician, who operates a mammography machine shall, every 3~~  
919 ~~years, obtain not less than 15 hours of continuing education in the technical aspects or clinical aspects, or~~  
920 ~~both, of mammography and related subjects that is accredited by the American medical association or the~~  
921 ~~American society of radiologic technologists or any other organizations acceptable to the department.~~

### 922 923 **R325.5624. — Operator prohibitions.**

924  
925 **Rule 624.** — ~~An individual, other than a physician, who operates a mammography machine shall not do any~~  
926 ~~of the following:~~

- 927 ~~(a) Perform mammography without the supervision of the mammography supervisor.~~  
928 ~~(b) Use a mammography machine without following standing orders and repeat film policies.~~  
929 ~~(c) Make a diagnosis based on any radiograph or image.~~  
930 ~~(d) Operate a mammography machine without having been trained to operate the mammography~~  
931 ~~machine safely and effectively.~~  
932 ~~(e) Report any diagnosis to a patient, except as ordered by a licensed physician.~~

Moved to the technologist section.

### 933 934 **R325.5625. — Program of mammography instruction; topics.**

935  
936 **Rule 625.** — ~~A formal program of mammography instruction for operators of mammography equipment~~  
937 ~~shall include all of the following topics:~~

- 938 ~~(a) — Anatomy and physiology of the female breast, including all of the following:~~  
939 ~~(i) — Mammary glands.~~  
940 ~~(ii) — External anatomy.~~  
941 ~~(iii) — Subdivision for localization.~~  
942 ~~(iv) — Retromammary space.~~

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- 943 ~~(v) — Central portion.~~
- 944 ~~(vi) — Cooper's or suspensory ligament.~~
- 945 ~~(vii) — Vessels, nerves, and lymphatics.~~
- 946 ~~(viii) Breast tissue.~~
- 947 ~~(b) Classification of breast tissue, including all of the following types of tissue:~~
- 948 ~~(i) — Fibro-glandular.~~
- 949 ~~(ii) — Fibro-fatty.~~
- 950 ~~(iii) — Fatty.~~
- 951 ~~(iv) — Lactating.~~
- 952 ~~(c) — Epidemiology of breast cancer, breast cancer detection methods, and information sources.~~
- 953 ~~(d) Influence of technical factors.~~
- 954 ~~(e) — Positioning of the breast, including all of the following:~~
- 955 ~~(i) — Cranio-caudal.~~
- 956 ~~(ii) — Medio-lateral oblique.~~
- 957 ~~(iii) — Axillary.~~
- 958 ~~(iv) — Magnification.~~
- 959 ~~(v) — Errors in positioning.~~
- 960 ~~(vi) — Special techniques for mammography for the postoperative breast and the augmented breast.~~
- 961 ~~(vii) — Special radiographic techniques for breast localization and specimen radiography.~~
- 962 ~~(viii) — Special techniques for additional mammography projections.~~
- 963 ~~(f) Film or image evaluation and critique, including all of the following:~~
- 964 ~~(i) — Optimum mammographic images, including all of the following:~~
- 965 ~~(A) — Radiographic density.~~
- 966 ~~(B) — Radiographic contrast.~~
- 967 ~~(C) — Definition.~~
- 968 ~~(D) — Distortion.~~
- 969 ~~(E) — Positioning.~~
- 970 ~~(ii) — Detection of pathology.~~
- 971 ~~(iii) — Benign and malignant lesions.~~
- 972 ~~(iv) — Mass lesion borders as smooth, irregular, or with calcification.~~
- 973 ~~(g) — Radiation biology and radiation protection.~~
- 974 ~~(h) — Quality assurance.~~

**R325.5623. Radiologic technologists.**

**Rule 623** All mammographic examinations shall be performed by radiologic technologists who meet the following general requirements, mammography requirements, and continuing education and experience requirements:

**(a) General requirements.** Have general certification from the American Registry of Radiologic Technologists or one of the bodies determined by the department to have procedures and requirements adequate to ensure that radiologic technologists certified by the body are competent to perform radiologic examinations.

**(b) Mammography requirements.** Have, prior to the effective date of these rules, qualified as a radiologic technologist under **Part 14 of the previous rules**, or completed at least 40 contact hours of

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986 documented training specific to mammography under the supervision of a qualified instructor. The hours  
987 of documented training shall include, but not necessarily be limited to:

988 (i) Training in breast anatomy and physiology, positioning and compression, quality  
989 assurance/quality control techniques, imaging of patients with breast implants.

990 (ii) The performance of a minimum of 25 examinations under the direct supervision of an  
991 individual qualified under **Rule 623**.

992 (iii) At least 8 hours of training in each mammography modality to be used by the technologist  
993 in performing mammography exams.

994  
995 **(c) Continuing education requirements.**

996 (i) Following the third anniversary date of the end of the calendar quarter in which the  
997 requirements of paragraphs (a) and (b) of this rule were completed, the radiologic technologist shall  
998 have taught or completed at least 15 continuing education units in mammography during the 36  
999 months immediately preceding the date of the facility's annual inspection or the last day of the  
1000 calendar quarter preceding the inspection or any date in between the two. The facility will choose one  
1001 of these dates to determine the 36-month period.

1002 (ii) Units earned through teaching a specific course can be counted only once towards the 15  
1003 required in paragraph (d)(i) of this rule, even if the course is taught multiple times during the previous  
1004 36 months.

1005 (iii) At least six of the continuing education units required in paragraph (d)(i) of this rule shall  
1006 be related to each mammographic modality used by the technologist.

1007 (iv) **Requalification.** Radiologic technologists who fail to meet the continuing education  
1008 requirements of paragraph (d)(i) of this rule shall obtain a sufficient number of continuing education  
1009 units in mammography to bring their total up to at least 15 in the previous 3 years, at least 6 of which  
1010 shall be related to each modality used by the technologist in mammography. The technologist may not  
1011 resume performing unsupervised mammography examinations until the continuing education  
1012 requirements are completed.



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1042 **Rule 631.** ~~(1) A radiation physicist shall be certified in diagnostic or radiological physics by the~~  
1043 ~~American board of radiology or by the American board of medical physics or shall meet equivalent~~  
1044 ~~requirements, as determined by the department, to be qualified to provide on-site consultation and evaluation~~  
1045 ~~of mammography systems to mammography facilities.~~

1046  
1047 ~~(2) "Equivalent requirements," as used in subrule (1) of this rule, means that all of the following factors~~  
1048 ~~have been satisfied:~~

1049 ~~(a) The radiation physicist possesses either of the following:~~

1050 ~~(i) A bachelor's degree in physics or applied physics or in a physical science with the equivalent~~  
1051 ~~of a physics minor and, in addition, 11 years of work experience in diagnostic radiological physics.~~

1052 ~~(ii) A masters or doctoral degree in medical physics or physics or in a physical science with the~~  
1053 ~~equivalent of a physics minor and, in addition, 3 years of work experience in diagnostic radiological~~  
1054 ~~physics.~~

1055 ~~(b) Work experience in diagnostic radiological physics shall have been performed under the supervision~~  
1056 ~~of a certified diagnostic or radiological physicist or a radiologist who is certified by the American board of~~  
1057 ~~radiology or the American osteopathic board of radiology.~~

1058 ~~(c) References have been provided listing the names of a physician certified in radiology and a physicist~~  
1059 ~~who is certified in diagnostic or radiological physics, 1 of whom has directed the individual's training~~  
1060 ~~specified in subdivision (b) of this subrule.~~

1061  
1062 ~~(3) To be qualified to provide on site consultation and evaluation of mammography systems to~~  
1063 ~~mammography facilities, a radiation physicist shall meet all of the following requirements on a continuing basis~~  
1064 ~~in addition to the requirements specified in subrule (1) or (2) of this rule:~~

1065 ~~(a) Submit evidence, acceptable to the department, of formal training or experience in medical physics~~  
1066 ~~and in the evaluation of mammography systems.~~

1067 ~~(b) Demonstrate competence in performing, recording, and interpreting the results of required quality~~  
1068 ~~control checks.~~

1069 ~~(c) Submit a sample of a mammography evaluation report, or the contents of a report, to the department~~  
1070 ~~for approval.~~

1071 ~~(d) Have appropriate testing equipment available to perform the medical physics quality control checks~~  
1072 ~~required by R325.5632(3).~~

1073  
1074 ~~(4) In evaluating the qualifications pursuant to this rule, the department shall establish an advisory~~  
1075 ~~committee of qualified mammography physicists to evaluate the submitted credentials. The department may~~  
1076 ~~rely on their expert evaluation in arriving at a department decision regarding the acceptability of the individual's~~  
1077 ~~qualifications.~~

### 1078 **R325.5632. Mammography system evaluation.**

1079  
1080  
1081 **Rule 632.** ~~(1) At least annually, each mammography facility shall have a qualified radiation physicist~~  
1082 ~~provide an on-site consultation to the facility, including a complete evaluation of the entire mammography~~  
1083 ~~system to ensure compliance with the provisions of the act and the rules promulgated under the act. This~~  
1084 ~~evaluation of the mammography system shall be in addition to the annual regulatory inspection that is~~  
1085 ~~conducted by the department as prescribed by R325.5603.~~

1086  
1087 ~~(2) The mammography facility shall make and document appropriate corrections to any item found during~~  
1088 ~~the annual mammography system evaluation by a radiation physicist that does not meet the requirements of~~  
1089 ~~these rules.~~

1090  
1091 ~~(3) The items to be inspected and evaluated during on-site consultations shall include all of the following:~~

1092 ~~(a) Mammography machine performance to determine compliance with the provisions of R325.5637 to~~  
1093 ~~R325.5652.~~

1094 ~~(b) Measurement of skin exposure for a cranio-caudal view for a 4.5 centimeter compressed breast that is~~  
1095 ~~composed of 50% glandular and 50% adipose tissue. For equipment that has an automatic exposure~~  
1096 ~~control, the measurement shall be made with a mammography phantom which has a serial numbered wax~~

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1097 insert and which is used in the American college of radiology accreditation program or a phantom that is  
1098 deemed to be equivalent by the department in the x-ray beam.

1099 ~~(c) Calculation of the average or mean glandular dose per cranio-caudal view of a 4.5-centimeter~~  
1100 ~~compressed breast that is composed of 50% glandular and 50% adipose tissue. The mean glandular dose~~  
1101 ~~shall not be more than any of the values specified in R325.5661.~~

1102 ~~(d) Evaluation of an image of a mammography phantom which has a serial numbered wax insert and~~  
1103 ~~which is used in the American college of radiology accreditation program, or an alternate phantom that is~~  
1104 ~~approved by the department, using exposure techniques for a cranio-caudal view of a 4.5-centimeter~~  
1105 ~~compressed breast that is composed of 50% glandular and 50% adipose tissue. The image of the~~  
1106 ~~mammography phantom shall be in compliance with the criteria prescribed by R325.5660.~~

1107 ~~(e) Measurement of the equivalent focal spot resolution, both parallel and perpendicular to the anode-~~  
1108 ~~cathode axis with a focal spot test device.~~

1109 ~~(f) Evaluation of the performance of the automatic exposure control system with regard to all of the~~  
1110 ~~following:~~

1111 ~~(i) Reproducibility.~~

1112 ~~(ii) Performance capability, including kilovoltage and thickness compensation.~~

1113 ~~(iii) Density control function.~~

1114 ~~(g) Evaluation of the darkroom for integrity and safelight conditions.~~

1115 ~~(h) Review of the film processing quality control records, including all of the following:~~

1116 ~~(i) Medium density.~~

1117 ~~(ii) Density difference.~~

1118 ~~(iii) Base plus fog.~~

1119 ~~(iv) Developer temperature.~~

1120 ~~(i) For screen film mammography, evaluation of the uniformity of the radiographic speed of each~~  
1121 ~~cassette screen that is normally used for mammography. For each cassette screen of a given class of~~  
1122 ~~screen speed, the ratio of the optical density of a test image to the average optical density of the test images~~  
1123 ~~shall fall within the range of 0.9 to 1.1.~~

1124

1125 **~~R325.5633. Records of on-site evaluations and consultations.~~**

1126

1127 **~~Rule 633.~~** ~~Records of on-site evaluations and consultations shall be provided and maintained in~~  
1128 ~~accordance with both of the following provisions:~~

1129 ~~(a) Records of evaluations and consultations performed pursuant to the provisions of~~  
1130 ~~R325.5605(e) shall be provided to the mammography facility. The records shall be provided within 30 days~~  
1131 ~~after completion of the evaluation and consultation. The records shall clearly indicate all of the following~~  
1132 ~~information:~~

1133 ~~(i) The tests, evaluations, and consultations performed and the date these occurred.~~

1134 ~~(ii) The name of the person or persons who performed the tests, evaluations, and consultations.~~

1135 ~~(iii) The results of the tests, evaluations, and consultations.~~

1136 ~~(iv) The testing equipment used, including the date of the last calibration of radiation detection~~  
1137 ~~equipment or cross calibration to a calibrated instrument.~~

1138 ~~The records shall be in a format that is approved by the department. These records shall be maintained~~  
1139 ~~by the mammography facility for not less than 7 years.~~

1140 ~~(b) Copies of records that are provided to mammography facilities shall also be maintained by the person~~  
1141 ~~who performed the tests, evaluations, and consultations. These records shall be maintained for not less~~  
1142 ~~than 7 years. Copies of the records shall be made available for examination by the department and, if~~  
1143 ~~requested in writing by the department, copies shall be forwarded to the department within 30 days of the~~  
1144 ~~written request.~~

Above physicist requirements are now covered by the modified MQSA final regulations as noted below.

1145

1146 **R325.5624. Medical physicists.**

1147

1148 **Rule 624.** All medical physicists conducting surveys of mammography facilities and providing oversight

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1149 of the facility quality assurance program under ~~paragraph (e) of this section~~ **Rules 660(c), 662(9), and 662(10)**

1150 shall meet the following:

1151 **(a) Initial qualifications.**

1152 **(i)** Certification. Have been approved by the department prior to [the effective date of the rules]  
1153 or have certification in an appropriate specialty area by one of the bodies determined by the department to  
1154 have procedures and requirements to ensure that medical physicists certified by the body are competent  
1155 to perform physics survey.

1156 **(ii)** Education and experience.

1157 **(A)** Have a masters degree or higher in a physical science from an accredited institution, with no  
1158 less than 20 semester hours or equivalent (e.g., 30 quarter hours) of college undergraduate or graduate  
1159 level physics.

1160 **(B)** Have 20 contact hours of documented specialized training in conducting surveys of  
1161 mammography facilities.

1162 **(C)** Have the experience of conducting surveys of at least 1 mammography facility and a total of  
1163 at least 10 mammography units. No more than one survey of a specific unit within a period of 60 days  
1164 can be counted towards the total mammography unit survey requirement. After the effective date of  
1165 these rules, experience conducting surveys must be acquired under the direct supervision of a medical  
1166 physicist who meets all the requirements of paragraphs **(a)** and **(c)** of this rule.

1167

Alternative initial qualifications were not adopted from the MQSA regulations..
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1168

1169 **(b) Continuing qualifications.**

1170 **(i)** Continuing education. Following the third anniversary date of the end of the calendar quarter  
1171 in which the requirements of paragraph **(a)** or **(b)** of this rule were completed, the medical physicist shall  
1172 have taught or completed at least 15 continuing education units in mammography during the 36 months  
1173 immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter  
1174 preceding the inspection or any date in between the two. The facility shall choose one of these dates to  
1175 determine the 36-month period. This continuing education shall include hours of training appropriate to

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1176 each mammographic modality evaluated by the medical physicist during his or her surveys or oversight of  
1177 quality assurance programs. Units earned through teaching a specific course can be counted only once  
1178 towards the required 15 units in a 36-month period, even if the course is taught multiple times during the  
1179 36 months.

1180 **(ii)** Continuing experience. Following the second anniversary date of the end of the calendar  
1181 quarter in which the requirements of paragraph (a) or (b) of this rule were completed or of the effective  
1182 date of these rules, whichever is later, the medical physicist shall have surveyed at least two  
1183 mammography facilities and a total of at least six mammography units during the 24 months immediately  
1184 preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the  
1185 inspection or any date in-between the two. The facility shall choose one of these dates to determine the  
1186 24-month period. No more than one survey of a specific facility within a 10-month period or a specific unit  
1187 within a period of 60 days can be counted towards this requirement.

1188 **(iii)** Before a medical physicist may begin independently performing mammographic surveys of a  
1189 new mammographic modality, that is, a mammographic modality other than one for which the physicist  
1190 received training to qualify under paragraph (a) or (b) of this rule, the physicist must receive at least 8  
1191 hours of training in surveying units of the new mammographic modality.

1192 **(c) Reestablishing qualifications.** Medical physicists who fail to maintain the required continuing  
1193 qualifications of paragraph (c) of this rule may not perform the surveys without the supervision of a qualified  
1194 medical physicist. Before independently surveying another facility, medical physicists must reestablish their  
1195 qualifications, as follows:

1196 **(i)** Medical physicists who fail to meet the continuing educational requirements of paragraph  
1197 **(c)(i)** of this rule shall obtain a sufficient number of continuing education units to bring their total units up to  
1198 the required 15 in the previous 3 years.

1199 **(ii)** Medical physicists who fail to meet the continuing experience requirement of paragraph **(c)(ii)**  
1200 of this section shall complete a sufficient number of surveys under the direct supervision of a medical  
1201 physicist who meets the qualifications of paragraphs (a) and (c) of this section to bring their total surveys  
1202 up to the required two facilities and six units in the previous 24 months. No more than one survey of a

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1203 specific unit within a period of 60 days can be counted towards the total mammography unit survey  
1204 requirement.

1205 ~~(e)(d)~~ **State Approval.** To be qualified to provide on-site consultation and evaluation of  
1206 mammography systems to mammography facilities, a radiation physicist shall meet all of the following  
1207 requirements on a continuing basis in addition to the requirements specified in **subrule (a) through (d)**  
1208 of this rule:

1209 ~~(i)~~ **Submit evidence, acceptable to the department, of formal training or experience in medical**  
1210 ~~physics and in the evaluation of mammography systems. Meet the initial qualification requirements of rule~~  
1211 ~~624.~~

1212 ~~(ii) Demonstrate competence in performing, recording, and interpreting the results of required quality~~  
1213 ~~control checks.~~

1214 ~~(iii)(ii)~~ **Submit a sample of a mammography evaluation report, or the contents of a report, to the**  
1215 **department for approval.**

1216 ~~(iv)(iii)~~ **Have appropriate testing equipment available to perform the medical physics quality control**  
1217 **checks required by Rule 662(9&10)**

1218  
1219 ~~(d)(e)~~ **Credential Advisory Committee.** In evaluating the qualifications pursuant to this rule, the  
1220 department shall establish an advisory committee of qualified mammography physicists to evaluate the  
1221 submitted credentials. The department may rely on their expert evaluation in arriving at a department  
1222 decision regarding the acceptability of the individual's qualifications.

(d) and (e) are kept from the old rules.

1223  
1224 **R325.5625. Retention of personnel records.**

1225  
1226 **Rule 625.** Facilities shall maintain records to document the qualifications of all personnel who  
1227 worked at the facility as interpreting physicians, radiologic technologists, or medical physicists. These  
1228 records must be available for review by the inspectors. Records of personnel no longer employed by the  
1229 facility should not be discarded until the next annual inspection has been completed and the department  
1230 has determined that the facility is in compliance with the personnel requirements.

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1231 | **X-RAY EQUIPMENT**

1232

**Most of the equipment requirements from the old rules are now covered under the MQSA equipment and annual equipment QC requirements to follow. Rules that are kept from this section are noted accordingly.**

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**R325.5637. — Compliance with provisions of R325.5325; machine design.**

1236

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**Rule 637.** ~~(1) The mammographic x-ray equipment shall be in compliance with the requirements of R325.5325(1) and (17) to (23).~~

1238

1239

~~(2) — The machine that is used for mammography shall be a radiation machine that is specifically designed to perform mammography.~~

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1243

**R325.5638. — Machine output.**

1244

1245

~~**Rule 638.** (1) Mammography machines shall generate a high-frequency, constant potential, 3-phase, or equivalent output.~~

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1248

~~(2) — Mammography machines shall be capable of an output at 28 kilovolts of not less than 500 milliroentgens per second at breast entrance for a 4.5-centimeter compressed breast with the compression plate in the beam for any mammographic technique that is used other than for magnification techniques.~~

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**R 325.5639. — Accuracy of technique factors.**

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1253

~~**Rule 639.** (1) The deviation of peak tube potential from indicated values shall not be more than 5% in the useful mammographic range. The coefficient of variation for peak tube potential reproducibility shall not be more than 5%, and a determination of compliance shall be based on not less than 4 consecutive measurements.~~

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~~(2) — For machines with timer controls, the deviation of exposure time from indicated values shall not be more than 5% for exposures that are more than 100 milliseconds and shall not deviate more than 10 milliseconds for shorter exposure times. The coefficient of variation for exposure timer reproducibility shall not be more than 5% and a determination of compliance shall be based on not less than 4 consecutive measurements.~~

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**R325.5640. — Permissible degree of coefficient of variation of radiation exposure for combination of selected technique factors.**

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1266

~~**Rule 640.** — For any specific combination of selected technique factors, the coefficient of variation of radiation exposures shall be not greater than 5%. A determination of compliance shall be based on not less than 4 consecutive measurements.~~

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**R325.5641. — Permissible difference in average ratios of exposure to indicated milliampere-seconds product obtained at 2 consecutive settings.**

1271

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1273

~~**Rule 641.** — The average ratios of exposure to the indicated milliampere-seconds product, or mR/mAs, obtained at any 2 consecutive mA or mAs settings shall not differ by more than 0.10 times their sum. That is:  $X_1 - X_2 \leq 0.10 (X_1 + X_2)$ ; where  $X_1$  and  $X_2$  are the average mR/mAs values that are obtained at each of 2 consecutive mA or mAs settings.~~

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Rule 641 inserted into annual equipment QC requirements below.

1278

1279

**R325.5642. — Target and filter material.**

1280

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1281 **Rule 642. (1)** For screen-film mammography, the target material of the x-ray tube shall be molybdenum with  
1282 molybdenum filtration and a beryllium window. Exceptions may be granted for other combinations if beam  
1283 quality, imaging capabilities, and patient dose are consistent with the requirements of this part.  
1284

1285 **(2)** For xeromammography, the target material of the x-ray tube shall be tungsten with aluminum filtration.  
1286 Exceptions may be granted for other combinations if beam quality, imaging capabilities, and patient dose are  
1287 consistent with the requirements of this part.  
1288

1289 **R325.5643. Nominal focal spot size.**

1291 **Rule 643. (1)** The nominal focal spot size of any available focal spot shall not be more than any of  
1292 the following values:

- 1293 (a) 0.6 at a source-image-receptor distance of 80 centimeters or more.
- 1294 (b) 0.5 at a source-image-receptor distance of 65 to 79 centimeters.
- 1295 (c) 0.4 at a source-image-receptor distance of 50 to 64 centimeters.

1296  
1297 **(2)** The focal spot dimensions, both parallel and perpendicular to the anode-cathode axis, shall be in  
1298 compliance with vendor-provided specifications and national electrical manufacturers association  
1299 specifications.  
1300

1301 **R325.5644. Half-value layer.**

1303 **Rule 644. (1)** The half-value layer for a screen-film system at a measured tube potential of 30 kilovolts shall  
1304 not be less than 0.30 millimeter of aluminum and shall not be more than 0.42 millimeter of aluminum. It is  
1305 recommended that the half-value layer be not more than 0.40 millimeter of aluminum at a measured tube  
1306 potential of 30 kilovolts. The half-value layer shall be measured with the compression device in the x-ray  
1307 beam.  
1308

1309 **(2)** The half-value layer for xeromammography shall not be less than 1.0 millimeter of aluminum and shall  
1310 not be more than 2.0 millimeters of aluminum at the clinically employed peak tube potential.  
1311

1312 **(3)** Positive means shall be provided to insure that the minimum filtration that is needed to achieve the  
1313 beam quality requirements set forth in this rule is in the useful beam during each exposure.  
1314

1315 **R325.5645. Focal spot to image receptor distance.**

1317 **Rule 645.** The focal spot to image receptor distance shall not be less than 50 centimeters.  
1318

1319 **R325.5646. Machine design; x-ray beam geometry.**

1321 **Rule 646.** A mammography machine shall be designed so that the plane of the useful beam that is  
1322 adjacent to the chest wall is parallel to the chest wall and is perpendicular to the plane of the image receptor  
1323 for all cassette sizes.  
1324

1325 **R325.5647. Reciprocating grid capability; grid ratio; exception; grid lines.**

1327 **Rule 647.(1)** Each mammography machine that is used for screen-film mammography shall be capable of  
1328 using a reciprocating grid for each available film size. The grid ratio shall be less than or equal to 5:1.  
1329 Exceptions may be granted for ratios higher than 5:1 if imaging capabilities and patient dose are consistent  
1330 with these rules.  
1331

1332 **(2)** Grid lines shall not be apparent on clinical or mammography phantom images.

Added to annual QC requirements below.
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1334 **R325.5648.——Image receptor capability.**

1335  
1336 **Rule 648.**—— Each location or address where screen film mammography is performed shall have the  
1337 capability of using both an 18 by 24 centimeter image receptor and a 24 by 30 centimeter image receptor.  
1338

1339 **R325.5649.——Beam limiting device.**

1340  
1341 **Rule 649.**—— Each mammography machine shall have a means to limit the useful beam so that the x ray  
1342 field at the plane of the image receptor does not extend beyond any edge of the image receptor at any  
1343 designated source image receptor distance (SID) other than the edge of the image receptor that is designed to  
1344 be adjacent to the chest wall. The x ray field shall not extend beyond the edge of the image receptor that is  
1345 designed to be adjacent to the chest wall by more than 2% of the SID. Each fixed aperture, beam limiting  
1346 device shall have clear and permanent markings to indicate the image receptor size and SID for which it is  
1347 designed. For systems that are equipped with a light localizer, the light field shall be aligned with the x ray  
1348 field to within 2% of the SID.  
1349

1350 **R325.5650.——Compression device.**

1351  
1352 **Rule 650.**—— Each mammography machine shall have a compression device. For screen film  
1353 mammography, the compression device shall be of the flat plate type. For xeromammography, a contoured  
1354 compression paddle may be used and balloons shall not be used for compression.  
1355

1356 **R325.5651.——Primary beam transmission through the image receptor support.**

1357  
1358 **Rule 651.**—— The transmission of the primary beam through any image receptor support provided with the  
1359 system shall be limited so that the exposure 5 centimeters from any accessible surface of the supporting  
1360 device beyond the plane of the image receptor is not more than 0.1 milliroentgen for each activation of the  
1361 tube. Exposure shall be measured with the system operated at the minimum source image receptor distance  
1362 for which it is designed. Compliance shall be determined at the maximum peak tube potential clinically  
1363 employed for the system and extrapolated to the maximum rated product of the tube current and exposure  
1364 time for that peak tube potential.

Moved to equipment requirements below.

1365  
1366 **R325.5652.——Automatic exposure control system.**

1367  
1368 **Rule 652. (1)** Each screen film mammography machine shall be provided with an automatic exposure  
1369 control system.

1370  
1371 **(2)**—— The automatic exposure control system for screen film mammography shall provide a coefficient of  
1372 variation that is not more than 5% for exposure or image optical density. A determination of compliance shall  
1373 be based on not less than 4 consecutive measurements with 4 centimeters of acrylic or BR-12 attenuator in  
1374 the beam.  
1375

1376 **(3)**—— One year after the effective date of this part, the automatic exposure control system for screen film  
1377 mammography shall maintain image optical density to within plus or minus 0.30 of the average as the  
1378 kilovoltage is varied within the clinically employed range and as attenuator thickness is varied from 2  
1379 centimeters to 6 centimeters for each clinically employed kilovoltage. Two years after the effective date of this  
1380 part, the automatic exposure control system shall maintain image optical density to within plus or minus 0.20 of  
1381 the average as the kilovoltage is varied within the clinically employed range and as attenuator thickness is  
1382 varied from 2 centimeters to 6 centimeters for each clinically employed kilovoltage. Compliance with this  
1383 subrule is not required for specific attenuator thickness/kilovoltage combinations if, during the test with those  
1384 attenuator thickness/kilovoltage combinations, the maximum automatically controlled exposure limit is  
1385 reached, causing the test films to have an optical density lower than the standard. The attenuator that is used  
1386 for determining compliance shall be either acrylic or BR-12 material.  
1387

1388 **(4)**—— The automatic exposure control system for screen film mammography shall limit the maximum

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1389 | ~~automatically controlled exposure to 750 milliamperere seconds.~~

Moved to draft rule 642(4).

1390

1391 | ~~(5) — One year after the effective date of this part, each mammography machine shall indicate, or~~  
1392 | ~~provide the means of determining, the milliamperere seconds resulting from each exposure made with the~~  
1393 | ~~automatic exposure control.~~

1394

1395 | **R325.5655. — Enclosure requirements.**

1396

1397 | ~~**Rule 655. (1)** An x ray equipment enclosure shall be in compliance with the requirements of R325.5334.~~

1398

1399 | ~~**(2)** — For mammography, the operator's barrier shall provide radiation protection that is equivalent to not~~  
1400 | ~~less than 0.5 millimeter of lead when the maximum potential is limited electrically or mechanically to less than~~  
1401 | ~~or equal to 35 kilovolts and 0.8 millimeter of lead when the maximum potential is more than 35 kilovolts.~~

Enclosure requirements moved to Rule 648.

1402

1403 | **R325.5656. — Operation requirements.**

1404

1405 | ~~**Rule 656. (1)** The operation of each mammography x ray machine shall be in compliance with the~~  
1406 | ~~requirements of R325.5333.~~

1407

1408 | ~~**(2)** — Mammograms shall be retained for not less than 7 years or shall be given to another person for~~  
1409 | ~~placement in the patient's medical record as directed by the patient or the primary care provider.~~

1410

1411

1412 | **X-RAY EQUIPMENT**

1413

1414 | **R325.5630. Compliance with provisions of R325.5325; machine design.**

1415

1416 | **Rule 630.** The mammographic x-ray equipment shall be in compliance with the requirements of  
1417 | **R325.5325(1) and (17) to (23) (or appropriate numbering after update – general equipment**  
1418 | **requirements).**

1419

MQSA final regulations equipment standards and quality assurance standards are inserted below.

Additions or changes based on current state regulations that are not addressed by MQSA are noted.

1420

1421 | **R325.5631. Prohibited equipment.**

1422

1423 | **Rule 631. (1)** Radiographic equipment designed for general purpose or special nonmammography

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1424 procedures shall not be used for mammography. This prohibition includes systems that have been  
1425 modified or equipped with special attachments for mammography. This requirement supersedes the  
1426 implied acceptance of such systems in ~~(Sec. 1020.31(f)(3) of this chapter??)~~.

1427

1428 **(2)** General. All radiographic equipment used for mammography shall be specifically designed for  
1429 mammography.

1430

1431 **R325.5632. Primary beam transmission through the image receptor support.**

1432

1433 **Rule 632.** The transmission of the primary beam through any image receptor support provided with the  
1434 system shall be limited so that the exposure 5 centimeters from any accessible surface of the supporting  
1435 device beyond the plane of the image receptor is not more than 0.1 milliroentgen for each activation of the  
1436 tube. Exposure shall be measured with the system operated at the minimum source-image receptor distance  
1437 for which it is designed. Compliance shall be determined at the maximum peak tube potential clinically  
1438 employed for the system and extrapolated to the maximum rated product of the tube current and exposure  
1439 time for that peak tube potential.

Moved from old rules.

1440

1441 **R325.5633. Motion of tube-image receptor assembly.**

1442 **Rule 633 (1)** The assembly shall be capable of being fixed in any position where it is designed to  
1443 operate. Once fixed in any such position, it shall not undergo unintended motion.

1444

1445 **(2)** The mechanism ensuring compliance with ~~paragraph (b)(3)(i) Rule 635(1) of this section~~ shall not  
1446 fail in the event of power interruption.

1447

1448 **R325.5634. Image receptor sizes.**

1449

1450 **Rule 634 (1)** Systems using screen-film image receptors shall provide, at a minimum, for operation with  
1451 image receptors of 18 x 24 centimeters (cm) and 24 x 30 cm.

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2) Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.

(3) Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.

(4) Stereotactic breast biopsy and needle localization machines are exempt from this rule.

**R325.5635. Light fields.**

Rule 635. For any mammography system with a light beam that passes through the x-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux (15 foot candles) at 100 cm or the maximum source-image receptor distance (SID), whichever is less.

**R325.5636. Magnification.**

Rule 636. (1) Systems used to perform noninterventional problem solving procedures shall have radiographic magnification capability available for use by the operator.

(2) Systems used for magnification procedures shall provide, at a minimum, at least one magnification value within the range of 1.4 to 2.0.

(3) Stereotactic breast biopsy and needle localization machines are exempt from this rule.

**R325.5637. Focal spot selection.**

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1479 Rule 637. (1) When more than one focal spot is provided, the system shall indicate, prior to exposure,  
1480 which focal spot is selected.

1481  
1482 (2) When more than one target material is provided, the system shall indicate, prior to exposure, the  
1483 preselected target material.

1484  
1485 (3) When the target material and/or focal spot is selected by a system algorithm that is based on the  
1486 exposure or on a test exposure, the system shall display, after the exposure, the target material and/or  
1487 focal spot actually used during the exposure.

1488  
1489 **R325.5638. Compression.**

1490  
1491 Rule 638. (1) All mammography systems shall incorporate a compression device.

1492  
1493 (2) Application of compression. Each system shall provide:

1494 (a) An initial power-driven compression activated by hands-free controls operable from both sides of  
1495 the patient.

1496 (b) Fine adjustment compression controls operable from both sides of the patient.

1497  
1498 (3) Systems shall be equipped with different sized compression paddles that match the sizes of all  
1499 full-field image receptors provided for the system. Compression paddles for special purposes, including  
1500 those smaller than the full size of the image receptor (for "spot compression") may be provided. Such  
1501 compression paddles for special purposes are not subject to the requirements of paragraphs  
1502 ~~((b)(8)(ii)(D)??) Rules 640(5&6) and ((b)(8)(ii)(E)??) of this section.~~

1503  
1504 (4) Except as provided in paragraph ~~((b)(8)(ii)(C)??) of this section~~ **Rule 640(4)**, the compression  
1505 paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than  
1506 1.0 cm at any point on the surface of the compression paddle when compression is applied.

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(5) Equipment intended by the manufacturer's design to not be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.

(6) The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.

(7) The chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.

**R325.5639. Technique factor selection and display.**

Rule 639 (1) Manual selection of milliampere seconds (mAs) or at least one of its component parts (milliampere (mA) and/or time) shall be available.

(2) The technique factors (peak tube potential in kilovolt (kV) and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs) to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls (AEC) are used, in which case the technique factors that are set prior to the exposure shall be indicated.

(3) Following AEC mode use, the system shall indicate the actual kilovoltage peak (kVp) and mAs used during the exposure. The mAs may be displayed as mA and time.

**R325.5640. Automatic exposure control.**

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1533 **Rule 640. (1)** Each screen-film system shall provide an AEC mode that is operable in all combinations  
1534 of equipment configuration provided, e.g., grid, nongrid; magnification, nonmagnification; and various  
1535 target-filter combinations.

1536  
1537 **(2)** The positioning or selection of the detector shall permit flexibility in the placement of the detector  
1538 under the target tissue.

1539 **(a)** The size and available positions of the detector shall be clearly indicated at the X-ray input surface  
1540 of the breast compression paddle.

1541 **(b)** The selected position of the detector shall be clearly indicated.

1542  
1543 **(3)** The system shall provide means for the operator to vary the selected optical density from the  
1544 normal (zero) setting.

1545  
1546 **(4)** The automatic exposure control system for screen-film mammography shall limit the maximum  
1547 automatically controlled exposure to 750 milliamperere-seconds.

Old Rule 652(4) moved here.
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1548

1549  
1550 **R325.5641. X-ray film.**

1551  
1552 **Rule 641.** The facility shall use X-ray film for mammography that has been designated by the film  
1553 manufacturer as appropriate for mammography.

1554  
1555 **R325.5642. Intensifying screens.**

1556  
1557 **Rule 642.** The facility shall use intensifying screens for mammography that have been designated by  
1558 the screen manufacturer as appropriate for mammography and shall use film that is matched to the  
1559 screen's spectral output as specified by the manufacturer.

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**R325.5643. Film processing solutions.**

**Rule 643.** For processing mammography films, the facility shall use chemical solutions that are capable of developing the films used by the facility in a manner equivalent to the minimum requirements specified by the film manufacturer.

**R325.5644. Lighting.**

**Rule 644.** The facility shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the view box, available to the interpreting physicians.

**R325.5645. Film masking devices.**

**Rule 645.** Facilities shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.

**R325.565546. Enclosure requirements.**

**Rule 65546. (1)** An x-ray equipment enclosure shall be in compliance with the requirements of **R325.5331. (or appropriate numbering after update)**

**(2)** For mammography, the operator's barrier shall provide radiation protection that is equivalent to not less than 0.5 millimeter of lead when the maximum potential is limited electrically or mechanically to less than or equal to 35 kilovolts and 0.8 millimeter of lead when the maximum potential is more than 35 kilovolts.

Enclosure requirements moved and re-numbered here from old rules.
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1587 | **R325.565647. Operation requirements.**

1588

1589 | **Rule 65647 (1)** The operation of each mammography x-ray machine shall be in compliance with the  
1590 requirements of **R325.5333(or appropriate numbering after update).**

Operation requirements inserted here from old rules.

1591

The following section on records and reports has been added from the MQSA requirements.

1592

1593 | **MEDICAL RECORDS AND MAMMOGRAPHY REPORTS**

1594

1595 | **R325.5652. Contents and terminology.**

1596

1597 | **Rule 652.** Each facility shall prepare a written report of the results of each mammography  
1598 examination performed under its authorization. The mammography report shall include the following  
1599 information:

1600 | **(a)** The name of the patient and an additional patient identifier.

1601 | **(b)** Date of examination.

1602 | **(c)** The name of the interpreting physician who interpreted the mammogram.

1603 | **(d)** Overall final assessment of findings, classified in one of the following categories:

1604 | **(i)** “Negative:” Nothing to comment upon (if the interpreting physician is aware of clinical  
1605 findings or symptoms, despite the negative assessment, these shall be explained);

1606 | **(ii)** “Benign:” Also a negative assessment;

1607 | **(iii)** “Probably Benign:” Finding(s) has a high probability of being benign;

1608 | **(iv)** “Suspicious:” Finding(s) without all the characteristic morphology of breast cancer but  
1609 indicating a definite probability of being malignant;

1610 | **(v)** “Highly suggestive of malignancy:” Finding(s) has a high probability of being malignant;

1611 | **(e)** In cases where no final assessment category can be assigned due to incomplete work-up,

1612 | “Incomplete: Need additional imaging evaluation” shall be assigned as an assessment and reasons

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1613 why no assessment can be made shall be stated by the interpreting physician; and

1614 (f) Recommendations made to the health care provider about what additional actions, if any, should  
1615 be taken. All clinical questions raised by the referring health care provider shall be addressed in the  
1616 report to the extent possible, even if the assessment is negative or benign.

1617  
1618 **R325.5653. Communication of mammography results to the patients.**

1619  
1620 **Rule 653.** Each facility shall send each patient a summary of the mammography report written in lay  
1621 terms within 30 days of the mammographic examination. If assessments are “Suspicious” or “Highly  
1622 suggestive of malignancy,” the facility shall make reasonable attempts to ensure that the results are  
1623 communicated to the patient as soon as possible.

1624 (a) Patients who do not name a health care provider to receive the mammography report shall be  
1625 sent the report described in Rule 652 within 30 days, in addition to the written notification of results in  
1626 lay terms.

1627 (b) Each facility that accepts patients who do not have a health care provider shall maintain a system  
1628 for referring such patients to a health care provider when clinically indicated.

1629  
1630 **R325.5654. Communication of mammography results to health care providers.**

1631  
1632 **Rule 654.** When the patient has a referring health care provider or the patient has named a health  
1633 care provider, the facility shall:

1634 (a) Provide a written report of the mammography examination, including the items listed in ~~paragraph~~  
1635 ~~(c)(1) of this section~~ Rule 652, to that health care provider as soon as possible, but no later than 30  
1636 days from the date of the mammography examination; and

1637 (b) If the assessment is “Suspicious” or “Highly suggestive of malignancy,” make reasonable  
1638 attempts to communicate with the health care provider as soon as possible, or if the health care provider  
1639 is unavailable, to a responsible designee of the health care provider.

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1641 **R325.5655. Recordkeeping.**

1642

1643 **Rule 655.** Each facility that performs mammograms:

1644 **(a)** Shall (except as provided in ~~paragraph (c)(4)(ii) of this section~~ Rule 655(b)) maintain  
1645 mammography films and reports in a permanent medical record of the patient for a period of not less  
1646 than 5 years, or not less than 10 years if no additional mammograms of the patient are performed at the  
1647 facility; and

1648 **(b)** Shall upon request by, or on behalf of, the patient, permanently or temporarily transfer the original  
1649 mammograms and copies of the patient's reports to a medical institution, or to a physician or health care  
1650 provider of the patient, or to the patient directly;

1651 **(c)** Any fee charged to the patients for providing the services in ~~paragraph (c)(4)(ii) of this section~~  
1652 Rule 655(b) shall not exceed the documented costs associated with this service.

1653

1654 **R325.5656. Mammographic image identification.**

1655

1656 **Rule 656.** Each mammographic image shall have the following information indicated on it in a  
1657 permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

1658 **(a)** Name of patient and an additional patient identifier.

1659 **(b)** Date of examination.

1660 **(c)** View and laterality. This information shall be placed on the image in a position near the axilla.

1661 Standardized codes specified by the accreditation body shall be used to identify view and laterality.

1662 **(d)** Facility name and location. At a minimum, the location shall include the city, State, and zip code of  
1663 the facility.

1664 **(e)** Technologist identification.

1665 **(f)** Cassette/screen identification.

1666 **(g)** Mammography unit identification, if there is more than one unit in the facility.

1667

1668 **R325.5657. Stereotactic breast biopsy and needle localization exemptions.**

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**Rule 657.** Stereotactic breast biopsy and needle localization procedures are exempt from Rules 652 through 655.

The following quality control section is deleted and replaced by FDA MQSA quality assurance requirements with the exception of the dose limit as noted below.

**QUALITY CONTROL**

~~**R325.5659.**— Quality control responsibilities of supervisor; establishment of quality assurance manual; provision of mammography phantom; submission of phantom images.~~

~~**Rule 659.**— (1) A mammography supervisor shall be responsible for maintaining a quality control program and for insuring the standardization of quality control methodology. This responsibility may be delegated to a quality control technologist, although the mammography supervisor shall be ultimately responsible.~~

~~(2) A mammography facility shall establish a written quality assurance manual, which shall include all of the following:~~

- ~~(a) The quality control tests to be performed.~~
- ~~(b) The frequency of each quality control test.~~
- ~~(c) The forms to be used to record the results of the quality control tests.~~
- ~~(d) The limits of acceptability of each quality control test.~~
- ~~(e) A protocol for making corrections when a quality control test does not fall within the limits of acceptability.~~

~~The quality assurance manual shall be available at the facility for examination by the department.~~

~~(3) The owner or person who is in control of mammography x-ray equipment shall provide a mammography phantom at each location or address where mammography is performed. The phantom shall be a mammography phantom which has a serial numbered wax insert and which is used in the American college of radiology accreditation program or any other phantom that is deemed appropriate and acceptable by the department.~~

~~(4) Upon written request by the department, a mammography facility shall, for each of its mammography x-ray machines, submit to the department an x-ray image of a mammography phantom which has a serial numbered wax insert and which is used in the American college of radiology accreditation program or other department approved phantom taken at routine machine settings used for a 4.5 centimeter compressed breast that is composed of 50% glandular and 50% adipose tissue. For each phantom image that is submitted to the department, the facility shall specify all of the following information:~~

- ~~(a) The serial number of the phantom.~~
- ~~(b) The registration number of the x-ray machine.~~
- ~~(c) The machine settings used, such as kilovoltage, milliamperage, time, and density setting.~~
- ~~(d) The type of x-ray film and intensifying screens used.~~

~~**R325.5660.**— Phantom image quality.~~

~~**Rule 660.**— The quality of an image of a mammography phantom which has a serial numbered wax insert~~

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1715 and which is used in the American college of radiology accreditation program, or other department approved  
1716 phantom, taken at clinically employed machine settings for a 4.5 centimeter compressed breast that is  
1717 composed of 50% glandular and 50% adipose tissue, shall be in compliance with all of the following criteria as  
1718 determined by the department:

- 1719 (a) Each fibril down to and including the 0.75 millimeter fibril shall be visualized.
- 1720 (b) Each mass down to and including the 0.75 millimeter thick mass shall be visualized.
- 1721 (c) All specks in each group down to and including the 0.32 millimeter speck group shall be visualized.

### 1722 **R325.5661. — Radiation dose limits.**

1725 **Rule 661.**— The mean glandular dose for a cranio-caudal view of a 4.5 centimeter compressed breast that  
1726 is composed of 50% glandular and 50% adipose tissue shall not be more than any of the following values:

- 1727 (a) Screen film without grid: 100 millirads per view.
- 1728 (b) Screen film with grid: 200 millirads per view.
- 1729 (c) Xeromammography: 400 millirads per view.

### 1731 **R325.5662. — Screen film processor adjustment.**

1733 **Rule 662.**— A processor for screen film mammography shall be adjusted to optimize image quality.

### 1735 **R325.5663. — Mammography phantom imaging required; corrective action; phantom imaging for 1736 mobile units; repeat analysis; compression check.**

1738 **Rule 663. (1)** A mammography phantom which has a serial numbered wax insert and which is used in the  
1739 American college of radiology accreditation program, or other department approved phantom, shall be imaged  
1740 at least monthly at machine settings that are normally used for an average patient with 4.5 centimeter  
1741 compressed breasts that are composed of 50% glandular and 50% adipose tissue. The facility shall maintain  
1742 an available file of such images for inspection by the department and for comparison with earlier images to  
1743 note changes in image quality. If the phantom image does not meet the criteria prescribed by R325.5660,  
1744 corrective action shall be taken. After corrective action and before the machine is used on a patient, an  
1745 additional phantom image shall be obtained to demonstrate compliance with R325.5660. Each operator of  
1746 mammography equipment shall also be familiar with phantom imaging procedures and the use of the phantom  
1747 as a method of evaluating machine performance.

1749 **(2)**— After each relocation of a mobile unit or transportable van, and before the machine is used on a  
1750 patient, a mammography phantom image, at machine settings that are normally used for an average patient  
1751 with 4.5 centimeter compressed breasts that are composed of 50% glandular and 50% adipose tissue, shall  
1752 be made for comparison with earlier images to assure the proper functioning of the mammography system.  
1753 The resultant milliamperere seconds shall be recorded and compared with the mean milliamperere seconds  
1754 determined from the most recent exposure reproducibility test of the automatic exposure control system. The  
1755 facility shall maintain an available file of the images for inspection by the department and for comparison with  
1756 earlier data to note changes in mammography system performance. Mammograms and phantom images shall  
1757 be processed within 24 hours of being obtained. If the phantom images do not meet the criteria prescribed by  
1758 R325.5660 or if the resultant milliamperere seconds is not within plus or minus 15% of the mean milliamperere  
1759 seconds determined from the most recent exposure reproducibility test of the automatic exposure control  
1760 system, corrective action shall be taken.

1762 **(3)**— A repeat analysis shall be performed at least quarterly, or, for low volume practices, after 250 patients,  
1763 by comparing the number of rejected or repeated films to the total number of films that were used during the  
1764 test period.

1766 **(4)**— Compression in the manual and powered modes shall be checked at least semiannually. The  
1767 maximum compression force shall be not less than 25 pounds nor more than 40 pounds in the power drive  
1768 mode.

### 1770 **R325.5664. — Screen film mammography quality control.**

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1771 **Rule 664.**— All of the following quality control procedures for screen film mammography shall be  
1772 performed at the indicated intervals and when components are initially placed into service, when problems are  
1773 suspected, or after service or preventive maintenance:

1774 (a) The darkroom that is used for mammography shall be cleaned each operational day before processing  
1775 or handling any films.

1776 (b) A facility shall have a sensitometer, densitometer, non-mercury thermometer, and control charts or  
1777 computerized control charts readily available to perform and record the required processor quality control  
1778 tests. The control film shall be of the same type that is used in mammography.

1779 (c) A facility shall conduct processor quality control tests at the beginning of each operational day before  
1780 processing any patient films. The tests shall include measuring and plotting all of the following data points:

1781 (i) Medium density, which is the optical density of a particular step on the sensitometric step  
1782 wedge, which is determined during the establishment of processor quality control operating levels, and  
1783 which has an average density closest to 1.20.

1784 (ii) Density difference, which is the difference in optical density between 2 consistently chosen  
1785 sensitometric steps. These steps, which are determined during the establishment of processor quality  
1786 control operating levels, shall be the step that has a density closest to 2.20 and the step that has a density  
1787 closest to, but not less than, 0.45.

1788 (iii) Base plus fog, which is the optical density from the unexposed area of the sensitometric film.

1789 (iv) Developer temperature.

1790 (d) Processor quality control operating levels for medium density, density difference, and base plus fog  
1791 shall be determined over not less than 5 consecutive days after the processor is cleaned. Developer  
1792 temperature shall be set at the temperature that is specified in the film manufacturer's written literature.

1793 (e) The medium density and density difference shall be within plus or minus 0.10 of their respective  
1794 operating levels, and the base plus fog shall be within plus or minus 0.03 of its operating level. If the  
1795 medium density or density difference falls outside of the plus or minus 0.10 control limits, but is within plus or  
1796 minus 0.15, the test shall be repeated immediately. If the same result is obtained, it shall be acceptable to  
1797 process clinical films, but the processor shall be monitored closely. If the medium density or density  
1798 difference exceeds the control limits of plus or minus 0.15, the source of the problem shall be determined  
1799 and corrected before clinical mammograms are processed in that processor. If the base plus fog exceeds  
1800 the control limit of plus or minus 0.03, immediate corrective action shall be taken before clinical  
1801 mammograms are processed.

1802 (f) The processor crossover rollers shall be cleaned each operational day.

1803 (g) Mammography intensifying screens shall be cleaned at least weekly using the manufacturer's  
1804 recommended materials and procedures. The outside of film cassettes shall be checked or cleaned at least  
1805 monthly.

1806 (h) Mammography darkroom fog shall be checked semiannually, when safelight filters or bulbs are  
1807 changed, or when fog is suspected. Film that is exposed to visible light with a sensitometer and then  
1808 exposed for 2 minutes in the darkroom shall not produce more than a 0.05 density increase in the mid-  
1809 density of 1.30 to 1.40 optical density portion of the sensitometric strip.

1810 (i) Mammography screen film contact shall be checked semiannually.

1811 (i) (Mammography clinical images shall be interpreted in subdued ambient lighting conditions on a view  
1812 box that is masked to reduce glare. View box surfaces shall be cleaned weekly.

1813 **R325.5665. — Xeromammography; plate management system.**

1814 **Rule 665. (1)** Each facility that utilizes xeromammography shall maintain a plate management system to  
1815 track suspected plate artifacts. If an artifact is observed on an image, the facility shall record the serial number  
1816 of the suspect plate, the type of artifact, and the date of observance of the artifact. The suspect plate shall be  
1817 cycled through the system for reevaluation or removed from service. If on reevaluation the artifact is  
1818 determined to be reproducible and to be significant enough to affect diagnostic quality, that plate shall be  
1819 removed from service.

1820 (2) Dark dusting of each newly installed plate shall be performed before the plate is put into service to  
1821 evaluate the plate for artifacts. Dark dusting means processing a charged plate without exposing the plate. If  
1822 artifacts that would affect diagnostic quality are noted, the plate that has the noted artifacts shall not be put into  
1823 service.

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1827 | service-

1828

1829 | ~~(3) If artifacts are observed that are not plate related, the source of the problem shall be determined and~~

1830 | ~~corrected.~~

1831

FDA MQSA quality assurance requirements:

1832

1833 | **QUALITY ASSURANCE**

1834

1835 | **R325.5659. Quality assurance--general.**

1836

1837 | **Rule 659. (1)** Each facility shall establish and maintain a quality assurance program to ensure the

1838 | safety, reliability, clarity, and accuracy of mammography services performed at the facility.

1839 | **(2)** A mammography facility shall establish a written quality assurance manual, which shall include all of

1840 | the following:

1841 | **(a)** The quality control tests to be performed.

1842 | **(b)** The frequency of each quality control test.

1843 | **(c)** The forms to be used to record the results of the quality control tests.

1844 | **(d)** The limits of acceptability of each quality control test.

1845 | **(e)** A protocol for making corrections when a quality control test does not fall within the limits of

1846 | acceptability.

1847 | The quality assurance manual shall be available at the facility for examination by the department.

Old Rule 659(2) inserted here.

1848

1849 | **R325.5660. Responsible individuals.**

1850

1851 | **Rule 660.** Responsibility for the quality assurance program and for each of its elements shall be

1852 | assigned to individuals who are qualified for their assignments and who shall be allowed adequate time to

1853 | perform these duties.

1854 | **(a)** Lead interpreting physician. The facility shall identify a lead interpreting physician who shall have

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1855 the general responsibility of ensuring that the quality assurance program meets all requirements of  
1856 paragraphs (d) through (f) of this section **Rules 659 through 663**. No other individual shall be assigned  
1857 or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has  
1858 determined that the individual's qualifications for, and performance of, the assignment are adequate.

1859 (b) Interpreting physicians. All interpreting physicians interpreting mammograms for the facility shall:

1860 (i) Follow the facility procedures for corrective action when the images they are asked to  
1861 interpret are of poor quality, and

1862 (ii) Participate in the facility's medical outcomes audit program.

1863 (c) Medical physicist. Each facility shall have the services of a medical physicist available to survey  
1864 mammography equipment and oversee the equipment-related quality assurance practices of the facility.  
1865 At a minimum, the medical physicist(s) shall be responsible for performing the surveys and  
1866 mammography equipment evaluations and providing the facility with the reports described in ~~paragraphs~~  
1867 ~~(e)(9) and (e)(10) of this section~~ **Rules 662(9&10)**.

1868 (d) Quality control technologist. Responsibility for all individual tasks within the quality assurance  
1869 program not assigned to the lead interpreting physician or the medical physicist shall be assigned to a  
1870 quality control technologist(s). The tasks are to be performed by the quality control technologist or by  
1871 other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the  
1872 quality control technologist shall ensure that the tasks are completed in such a way as to meet the  
1873 requirements of ~~paragraph (e) of this section~~ Rule 662.

1874  
1875 **R325.5661. Quality assurance records.**

1876  
1877 **Rule 661.** The lead interpreting physician, quality control technologist, and medical physicist shall  
1878 ensure that records concerning mammography technique and procedures, quality control (including  
1879 monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of  
1880 the corrective actions), safety, protection and employee qualifications to meet assigned quality assurance  
1881 tasks are properly maintained and updated. These quality control records shall be kept for each test  
1882 specified in ~~paragraphs (e) and (f) of this section~~ **Rules 662 and 663** until the next annual inspection has

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1883 been completed and the department has determined that the facility is in compliance with the quality  
1884 assurance requirements or until the test has been performed two additional times at the required  
1885 frequency, whichever is longer.

1886

1887 **R325.5662. Quality assurance—equipment.**

1888

1889 **Rule 662. (1) Daily quality control tests.**

1890 **(a) Film processors used to develop mammograms shall be adjusted and maintained to meet the**  
1891 **technical development specifications for the mammography film in use. As part of this, the crossover**  
1892 **rollers shall be cleaned on each day that clinical films are processed. A processor performance test**  
1893 **shall be performed on each day that clinical films are processed before any clinical films are processed**  
1894 **that day. The test shall include an assessment of base plus fog density, mid-density, density difference,**  
1895 **and developer temperature using the mammography film used clinically at the facility.**

1896 **(i). The base plus fog density shall be within + 0.03 of the established operating level.**

1897 **(ii). The mid-density shall be within  $\pm 0.15$  of the established operating level.**

1898 **(iii). The density difference shall be within  $\pm 0.15$  of the established operating level.**

1899 **(b) Machines used for localization procedures shall perform a needle localization accuracy test each**  
1900 **day of use.**

1901

1902 **(2) Weekly quality control tests. Facilities with screen-film systems shall perform an image quality**  
1903 **evaluation test, using a department-accepted phantom, at least weekly.**

1904 **(a) The optical density of the film at the center of an image of a standard department-accepted**  
1905 **phantom shall be at least 1.20 when exposed under a typical clinical condition.**

1906 **(b) The optical density of the film at the center of the phantom image shall not change by more than  $\pm$**   
1907 **0.20 from the established operating level.**

1908 **(c) The phantom image shall achieve at least the minimum score established by the accreditation**  
1909 **body.**

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1910 (d) The density difference between the background of the phantom and an added test object, used to  
1911 assess image contrast, shall be measured and shall not vary by more than  $\pm 0.05$  from the established  
1912 operating level.

1913

1914 (3) Quarterly quality control tests. Facilities with screen-film systems shall perform the following  
1915 quality control tests at least quarterly:

1916 (a) Fixer retention in film. The residual fixer shall be no more than 5 micrograms per square cm.

1917 (b) Repeat analysis. If the total repeat or reject rate changes from the previously determined rate by  
1918 more than 2.0 percent of the total films included in the analysis, the reason(s) for the change shall be  
1919 determined. Any corrective actions shall be recorded and the results of these corrective actions shall be  
1920 assessed. For stereotactic breast biopsy and needle localization machines, the repeat analysis test  
1921 shall be performed at least semiannually.

1922

1923 (4) Semiannual quality control tests. Facilities with screen-film systems shall perform the following  
1924 quality control tests at least semiannually:

1925 (a) Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a  
1926 mammography film of the type used in the facility, which has a mid-density of no less than 1.2 OD, is  
1927 exposed to typical darkroom conditions for 2 minutes while such film is placed on the counter top  
1928 emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this  
1929 test.

1930 (b) Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper  
1931 screen. All cassettes used in the facility for mammography shall be tested.

1932 (c) Compression device performance.

1933 (i) A compression force of at least 111 newtons (25 pounds) shall be provided.

1934 (ii) ~~Effective October 28, 2002,~~ The maximum compression force for the initial power drive  
1935 shall be between 111 newtons (25 pounds) and 200 newtons (45 pounds).

1936

1937 (5) Annual quality control tests. Facilities with screen-film systems shall perform the following quality

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1938 control tests at least annually:

1939 (a) Automatic exposure control performance.

1940 (i) ~~After October 28, 2002,~~ The AEC shall be capable of maintaining film optical density (OD)  
1941 within <plus-minus> 0.15 of the mean optical density when thickness of a homogeneous material is  
1942 varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp  
1943 range used clinically in the facility.

1944 (ii) The optical density of the film in the center of the phantom image shall not be less than  
1945 1.20.

1946 (b) Kilovoltage peak (kVp) accuracy and reproducibility.

1947 (i) The kVp shall be accurate within <plus-minus> 5 percent of the indicated or selected kVp  
1948 at:

1949 (A) The lowest clinical kVp that can be measured by a kVp test device;

1950 (B) The most commonly used clinical kVp;

1951 (C) The highest available clinical kVp, and

1952 (ii) At the most commonly used clinical settings of kVp, the coefficient of variation of  
1953 reproducibility of the kVp shall be equal to or less than 0.02.

1954 (c) Focal spot condition. ~~Until October 28, 2002, focal spot condition shall be evaluated either by~~  
1955 ~~determining system resolution or by measuring focal spot dimensions. After October 28, 2002, Facilities~~  
1956 shall evaluate focal spot condition ~~only~~ by determining the system resolution.

1957 (i) System Resolution.

1958 (A) Each X-ray system used for mammography, in combination with the mammography  
1959 screen-film combination used in the facility, shall provide a minimum resolution of 11  
1960 Cycles/millimeter (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented  
1961 with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-  
1962 pairs/mm when the bars are parallel to that axis.

1963 (B) The bar pattern shall be placed 4.5 cm above the breast support surface, centered with  
1964 respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 cm of  
1965 the chest wall edge of the image receptor.

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1966 (C) When more than one target material is provided, the measurement in ~~paragraph~~  
 1967 ~~(e)(5)(iii)(A) of this section~~ **Rule 662(5)(c)(i)** shall be made using the appropriate focal spot for each  
 1968 target material.

1969 (D) When more than one SID is provided, the test shall be performed at SID most commonly  
 1970 used clinically.

1971 (E) Test kVp shall be set at the value used clinically by the facility for a standard breast and  
 1972 shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in  
 1973 the beam to increase exposure times. The screen-film cassette combination used by the facility shall  
 1974 be used to test for this requirement and shall be placed in the normal location used for clinical  
 1975 procedures.

1976 (II) Focal spot dimensions. Measured values of the focal spot length (dimension parallel to  
 1977 the anode cathode axis) and width (dimension perpendicular to the anode cathode axis) shall be  
 1978 within the tolerance limits specified in Table 1.

Table 1

<u>Focal Spot Tolerance Limit</u>		
<u>Nominal Focal Spot Size (mm)</u>	<u>Maximum Measured Dimensions</u>	
	<u>Width(mm)</u>	<u>Length(mm)</u>
<u>0.10</u>	<u>0.15</u>	<u>0.15</u>
<u>0.15</u>	<u>0.23</u>	<u>0.23</u>
<u>0.20</u>	<u>0.30</u>	<u>0.30</u>
<u>0.30</u>	<u>0.45</u>	<u>0.65</u>
<u>0.40</u>	<u>0.60</u>	<u>0.85</u>
<u>0.60</u>	<u>0.90</u>	<u>1.30</u>

1982

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1983 (d) Beam quality and half-value layer (HVL). The HVL shall meet the specifications shown in Table 2.  
1984 Values not shown in Table 2 may be determined by linear interpolation or extrapolation. The HVL shall  
1985 be measured with the compression device in the x-ray beam.

1987 Table 2  
1988

<u>X-ray Tube Voltage (kilovolt peak) and Minimum HVL</u>		
<u>Designed Operating Range</u> <u>(kV)</u>	<u>Measured Operating Voltage</u> <u>(kV)</u>	<u>Minimum HVL (millimeters of</u> <u>aluminum)</u>
<u>Below 50</u>	<u>20</u>	<u>0.20</u>
	<u>25</u>	<u>0.25</u>
	<u>30</u>	<u>0.30</u>

1989  
1990 (e) Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma  
1991 and mAs shall not exceed 0.05.

1992 (f) Dosimetry. The average glandular dose delivered during a single cranio-caudal view of a  
1993 department-accepted phantom simulating a standard breast shall not exceed 3.0 milligray (mGy) (0.3  
1994 rad) per exposure. The dose shall be determined with technique factors and conditions used clinically for  
1995 a standard breast.

Some new technologies require doses above the current 0.2 rad limit for optimal imaging. We do not wish to limit optimal imaging, and yet do not want to allow excessive exposure that could be reduced by optimizing film processing and/or quality assurance. It appears that the ACR/FDA limit of 0.3 rad may be set higher than necessary, but we wish to be consistent with established national standards. Therefore a 0.25 rad standard of care advisory limit should be used in conjunction with this rule to encourage minimizing dose while maintaining optimal film quality.

1996  
1997 (g) X-ray/light field/image receptor/compression paddle alignment.

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1998        (i) X-ray field alignment. All systems shall have beam-limiting devices that allow the entire  
1999        chest wall edge of the x-ray field to extend to the chest wall edge of the image receptor and provide  
2000        means to assure that the x-ray field does not extend beyond any edge of the image receptor by more  
2001        than 2 percent of the SID.

2002        (ii) Light-field alignment. If a light field that passes through the X-ray beam limitation device  
2003        is provided, it shall be aligned with the X-ray field so that the total of any misalignment of the edges of  
2004        the light field and the X-ray field along either the length or the width of the visually defined field at the  
2005        plane of the breast support surface shall not exceed 2 percent of the SID.

2006        (iii) Compression paddle alignment. The chest wall edge of the compression paddle shall not  
2007        extend beyond the chest wall edge of the image receptor by more than one percent of the SID when  
2008        tested with the compression paddle placed above the breast support surface at a distance equivalent  
2009        to standard breast thickness. The shadow of the vertical edge of the compression paddle shall not be  
2010        visible on the image.

2011        (h) Uniformity of screen speed. Uniformity of screen speed of all the cassettes in the facility shall be  
2012        tested and the difference between the maximum and minimum optical densities shall not exceed 0.30.  
2013        Screen artifacts shall also be evaluated during this test.

2014        (i) System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of  
2015        homogeneous material large enough to cover the mammography cassette and shall be performed for all  
2016        cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts  
2017        shall also be evaluated for all available focal spot sizes and target filter combinations used clinically. Grid  
2018        lines shall not be apparent on clinical or mammography phantom images.

Last sentence added from old rules.
-------------------------------------

2019

2020        (j) Radiation output. ~~The system shall be capable of producing a minimum output of 4.5 mGy air~~  
2021        ~~kerma per second (513 milli-Roentgen (mR) per second) when operating at 28 kVp in the standard~~  
2022        ~~mammography (moly/moly) mode at any SID where the system is designed to operate and when~~  
2023        ~~measured by a detector with its center located 4.5 cm above the breast support surface with the~~  
2024        ~~compression paddle in place between the source and the detector.~~ After October 28, 2002, The system;

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2025 under the same measuring conditions shall be capable of producing a minimum output of 7.0 mGy air  
2026 kerma per second (800 mR per second) when operating at 28 kVp in the standard (moly/moly)  
2027 mammography mode at any SID where the system is designed to operate. The system shall be capable  
2028 of maintaining the required minimum radiation output averaged over a 3.0 second period.

2029 (k) Decompression. If the system is equipped with a provision for automatic decompression after  
2030 completion of an exposure or interruption of power to the system, the system shall be tested to confirm  
2031 that it provides:

2032 (i) An override capability to allow maintenance of compression;

2033 (ii) A continuous display of the override status; and

2034 (iii) A manual emergency compression release that can be activated in the event of power or  
2035 automatic release failure.

2036  
2037 (6) Quality control tests--other modalities. For systems with image receptor modalities other than  
2038 screen-film, the quality assurance program shall be substantially the same as the quality assurance  
2039 program recommended by the image receptor manufacturer, except that the maximum allowable dose  
2040 shall not exceed the maximum allowable dose for screen-film systems in ~~paragraph (e)(5)(vi) of this~~  
2041 **section Rule 662(5)(g).**

2042  
2043 (7) Mobile Units. The facility shall verify that mammography units used to produce mammograms at  
2044 more than one location meet the requirements in ~~paragraphs (e)(1) through (e)(6) of this section Rules~~  
2045 **662(1) through 662(7).** In addition, at each examination location, before any examinations are conducted,  
2046 the facility shall verify satisfactory performance of such units using a test method that establishes the  
2047 adequacy of the image quality produced by the unit.

2048  
2049 (8) Use of test results.

2050 (a) After completion of the tests specified in rules 662(1-7) of this section, the facility shall compare  
2051 the test results to the corresponding specified action limits; or, for nonscreen-film modalities, to the

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2052 manufacturer's recommended action limits; or, for post-move, preexamination testing of mobile units, to  
2053 the limits established in the test method used by the facility.

2054 (b) If the test results fall outside of the action limits, the source of the problem shall be identified and  
2055 corrective actions shall be taken:

2056 (i) Before any further examinations are performed or any films are processed using a  
2057 component of the mammography system that failed any of the tests described in ~~paragraphs (e)(1),~~  
2058 ~~(e)(2), (e)(4)(i), (e)(4)(ii), (e)(4)(iii), (e)(5)(vi), (e)(6), or (e)(7) of this section; Rules 662(1), (2), (4),~~  
2059 ~~(5)(d), (6), and (7).~~

2060 (ii) Within 30 days of the test date for all other tests described in ~~paragraph (e) of this section~~  
2061 ~~Rule 662.~~

2062  
2063 **(9) Surveys.**

2064 (a) At least once a year, each facility shall undergo a survey by a medical physicist or by an individual  
2065 under the direct supervision of a medical physicist. At a minimum, this survey shall include the  
2066 performance of tests to ensure that the facility meets the quality assurance requirements of the annual  
2067 tests described in ~~paragraphs (e)(5) and (e)(6) of this section~~ **Rules 662 (5 and 6)** and the weekly  
2068 phantom image quality test described in ~~paragraph (e)(2) of this section~~ **Rule 662(2).**

2069 (b) The results of all tests conducted by the facility in accordance with ~~paragraphs (e)(1) through~~  
2070 ~~(e)(7) of this section~~ **Rules 662 (1-7)**, as well as written documentation of any corrective actions taken  
2071 and their results, shall be evaluated for adequacy by the medical physicist performing the survey.

2072 (c) The medical physicist shall prepare a survey report that includes a summary of this review and  
2073 recommendations for necessary improvements.

2074 (D) The survey report shall be sent to the facility within 30 days of the date of the survey.

2075 (E) The survey report shall be dated and signed by the medical physicist performing or supervising  
2076 the survey. If the survey was performed entirely or in part by another individual under the direct  
2077 supervision of the medical physicist, that individual and the part of the survey that individual performed  
2078 shall also be identified in the survey report.

2079 (F) The survey report shall include the testing equipment used, including the date of the last

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2080 calibration of radiation detection equipment or cross-calibration to a calibrated instrument.

2081

2082 **(10)** Mammography equipment evaluations. Additional evaluations of mammography units or image  
2083 processors shall be conducted whenever a new unit or processor is installed, a unit or processor is  
2084 disassembled and reassembled at the same or a new location, or major components of a mammography  
2085 unit or processor equipment are changed or repaired. These evaluations shall be used to determine  
2086 whether the new or changed equipment meets the requirements of applicable standards in paragraphs (b)  
2087 and (c) of this section **Rules 630 through 647 and Rule 662.** All problems shall be corrected before the  
2088 new or changed equipment is put into service for examinations or film processing. The mammography  
2089 equipment evaluation shall be performed by a medical physicist or by an individual under the direct  
2090 supervision of a medical physicist.

2091

2092 **(11)** Facility cleanliness.

2093 **(a)** The facility shall establish and implement adequate protocols for maintaining darkroom, screen,  
2094 and view box cleanliness.

2095 **(b)** The facility shall document that all cleaning procedures are performed at the frequencies specified  
2096 in the protocols.

2097

2098 **(12)** Calibration of air kerma measuring instruments. Instruments used by medical physicists in their  
2099 annual survey to measure the air kerma or air kerma rate from a mammography unit shall be calibrated at  
2100 least once every 2 years and each time the instrument is repaired. The instrument calibration must be  
2101 traceable to a national standard and calibrated with an accuracy of  $\pm 6$  percent (95 percent confidence  
2102 level) in the mammography energy range.

2103

2104 **(13)** Infection control. Facilities shall establish and comply with a system specifying procedures to be  
2105 followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or  
2106 other potentially infectious materials. This system shall specify the methods for documenting facility  
2107 compliance with the infection control procedures established and shall:

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- 2108        (a) Comply with all applicable Federal, State, and local regulations pertaining to infection control; and  
2109        (b) Comply with the manufacturer's recommended procedures for the cleaning and disinfection of the  
2110        mammography equipment used in the facility; or  
2111        (c) If adequate manufacturer's recommendations are not available, comply with generally accepted  
2112        guidance on infection control, until such recommendations become available.

2113

2114        **R325.5663.     Quality assurance-mammography medical outcomes audit.**

2115

2116        **Rule 663. (1) Each facility shall establish and maintain a mammography medical outcomes audit**  
2117        program to followup positive mammographic assessments and to correlate pathology results with the  
2118        interpreting physician's findings. This program shall be designed to ensure the reliability, clarity, and  
2119        accuracy of the interpretation of mammograms.

2120

2121        **(2) General requirements. Each facility shall establish a system to collect and review outcome data**  
2122        for all mammograms performed, including followup on the disposition of all positive mammograms and  
2123        correlation of pathology results with the interpreting physician's mammography report. Analysis of these  
2124        outcome data shall be made individually and collectively for all interpreting physicians at the facility. In  
2125        addition, any cases of breast cancer among women imaged at the facility that subsequently become  
2126        known to the facility shall prompt the facility to initiate followup on surgical and/or pathology results and  
2127        review of the mammograms taken prior to the diagnosis of a malignancy.

2128

2129        **(3) Frequency of audit analysis. The facility's first audit analysis shall be initiated no later than 12**  
2130        months after the date the facility becomes authorized, ~~or 12 months after April 28, 1999, whichever date is~~  
2131        ~~the latest.~~ This audit analysis shall be completed within an additional 12 months to permit completion of  
2132        diagnostic procedures and data collection. Subsequent audit analyses will be conducted at least once  
2133        every 12 months.

2134

2135        **(4) Audit interpreting physician. Each facility shall designate at least one interpreting physician to**

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2136 review the medical outcomes audit data at least once every 12 months. This individual shall record the  
2137 dates of the audit period(s) and shall be responsible for analyzing results based on this audit. This  
2138 individual shall also be responsible for documenting the results and for notifying other interpreting  
2139 physicians of their results and the facility aggregate results. If followup actions are taken, the audit  
2140 interpreting physician shall also be responsible for documenting the nature of the followup.

2141

2142 **R325.5664. Mammographic procedure and techniques for mammography of patients with**  
2143 **breast implants.**

2144

2145 **Rule 664. (1) Each facility shall have a procedure to inquire whether or not the patient has breast**  
2146 **implants prior to the actual mammographic exam.**

2147

2148 **(2) Except where contraindicated, or unless modified by a physician's directions, patients with breast**  
2149 **implants undergoing mammography shall have mammographic views to maximize the visualization of**  
2150 **breast tissue.**

2151

2152 **R325.5665. Consumer complaint mechanism.**

2153

2154 **Rule 665. Each facility shall:**

2155 **(a) Establish a written and documented system for collecting and resolving consumer complaints;**

2156 **(b) Maintain a record of each serious complaint received by the facility for at least 3 years from the**  
2157 **date the complaint was received;**

2158 **(c) Provide the consumer with adequate directions for filing serious complaints with the facility's**  
2159 **accreditation body if the facility is unable to resolve a serious complaint to the consumer's satisfaction;**

2160 **(d) Report unresolved serious complaints to the accreditation body in a manner and timeframe**  
2161 **specified by the accreditation body.**

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2163 **R325.5666. Clinical image quality.**

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**Rule 666.** Clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by that facility's accreditation body.

**R325.5667. Additional mammography review and patient notification.**

**RULE 667. (1)** If the department believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by the department, for review by the accreditation body or other entity designated by the department. This additional mammography review will help the agency to determine whether the facility is in compliance with this section and, if not, whether there is a need to notify affected patients, their physicians, or the public that the reliability, clarity, and accuracy of interpretation of mammograms has been compromised.

**(2)** If the department determines that the quality of mammography performed by a facility, whether or not authorized, was so inconsistent with the quality standards established in this section as to present a significant risk to individual or public health, the department may require such facility to notify patients who received mammograms at such facility, and their referring physicians, of the deficiencies presenting such risk, the potential harm resulting, appropriate remedial measures, and such other relevant information as the department may require. Such notification shall occur within a timeframe and in a manner specified by the department.