**Section 370.20 Definitions**

As used in this Part, the following definitions apply:

"Accreditation body" or "body" means an entity that has been approved by FDA to accredit mammography facilities.

"Action limits" or "action levels" means the minimum and maximum values of a quality assurance measurement that can be interpreted as representing acceptable performance with respect to the parameter being tested. Values less than the minimum or greater than the maximum action limit or level indicate that corrective action shall be taken by the facility. Action limits or levels are also sometimes called control limits or levels.

"Adverse event" means an undesirable experience associated with mammography activities that include but are not limited to:

Poor image quality;

Failure to send mammography reports within 30 days to the referring physician or in a timely manner to the self-referred patient; and

Use of personnel that do not meet the requirements of Section 370.70 of this Part.

"Agency" means the Illinois Emergency Management Agency.

"Air kerma" means kerma in a given mass of air. The unit used to measure the quantity of air kerma is the Gray (Gy). For x-rays with energies less than 300 kiloelectronvolts (keV), 1 Gy = 100 rad.

"Breast implant" means a prosthetic device implanted in the breast.

"Calendar quarter" means any one of the following time periods during a given year: January 1 through March 31, April 1 through June 30, July 1 through September 30 or October 1 through December 31.

"Category I" means medical educational activities that have been designated as Category I by the Accreditation Council for Continuing Medical Education (ACCME), the American Osteopathic Association (AOA), a state medical society or an equivalent organization.

"Certificate" means the certificate described in Section 370.50 of this Part.

"Certification" means the process of approval of a facility by the Agency to provide mammography services.

"Clinical image" means a mammogram.

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

"Continuing education unit" or "continuing education credit" means one contact hour of training.

"Contact hour" means an hour of training received through direct instruction.

"Diagnostic mammography" means mammography performed on a patient with:

clinical signs, symptoms or physical findings suggestive of breast cancer;

an abnormal or questionable screening mammogram;

a history of breast cancer with breast conservation surgery regardless of absence of clinical breast signs, symptoms or physical findings; or

augmented breasts regardless of absence of clinical breast signs, symptoms or physical findings.

AGENCY NOTE: Diagnostic mammography is also called problem-solving mammography or consultative mammography. This definition excludes mammography performed during invasive interventions for localization or biopsy procedures.

"Direct instruction" means:

Face-to-face interaction between instructor and students, as when the instructor provides a lecture, conducts demonstrations or reviews student performance; or

The administration and correction of student examinations by an instructor with subsequent feedback to the students.

"Direct supervision" means that:

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

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

"Director" means the Director of the Illinois Emergency Management Agency.

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

"Facility" or "mammography installation" means a hospital, outpatient department, clinic, radiology practice, mobile unit, office of a physician or other facility that conducts mammography activities, including operation of equipment to produce a mammogram, processing of the mammogram, initial interpretation of the mammogram and maintaining viewing conditions for that interpretation.

"First allowable time" means the earliest time a resident physician is eligible to take the diagnostic radiology boards from an FDA-designated certifying body.

"FDA" means the U.S. Food and Drug Administration.

"Interim regulations" means the regulations entitled "Requirements for Accrediting Bodies of Mammography Facilities" (58 FR 67558-67565) and "Quality Standards and Certification Requirements for Mammography Facilities" (58 FR 67565-67572), published by FDA on December 21, 1993, and amended on September 30, 1994 (59 FR 49808-49813). These regulations established the standards that had to be met by mammography facilities in order to lawfully operate between October 1, 1994 and April 28, 1999.

"Interpreting physician" means a licensed physician who interprets mammograms and who meets the requirements of Section 370.70(a) of this Part.

"Lead interpreting physician" means the interpreting physician assigned the general responsibility for ensuring that a facility's quality assurance program meets all of the requirements of Sections 370.100, 370.110, 370.120(b) and (c) and 370.130 of this Part. The administrative title and other supervisory responsibilities of the individual, if any, are left to the discretion of the facility.

"Mammogram" means radiographic image produced through mammography.

"Mammographic modality" means a technology for radiography of the breast. Examples are screen-film mammography and digital mammography.

"Mammography" means radiography of the breast.

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

"Mammography medical outcomes audit" means a systematic collection of mammography results and the comparison of those results with outcomes data.

"Mammography unit" or "units" means an assemblage of components for the production of x-rays for use during mammography, including, at a minimum, an x-ray generator, an x-ray control, a tube housing assembly, a beam limiting device and the supporting structures for these components.

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

"Medical physicist" means a person trained in evaluating the performance of mammography equipment and facility quality assurance programs and who meets the qualifications set forth in Section 370.70(c) of this Part.

"MQSA" means the federal Mammography Quality Standards Act of 1992, as amended by the Mammography Quality Standards Reauthorization Act of 1998.

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

"Patient" means any individual who undergoes a mammography evaluation in a facility.

"Phantom" means a test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer. It is equivalent to a nominal 4.2 centimeter compressed breast of average density (i.e., 50 percent adipose and 50 percent glandular tissue) and shall contain the following objects:

Spherical masses, composed of phenolic plastic, with thicknesses of: 2.00, 1.00, 0.75, 0.50 and 0.25 millimeter;

Specks, composed of aluminum oxide, with diameters of: 0.54, 0.40, 0.32, 0.24 and 0.16 millimeter;

Fibers, composed of nylon, with thicknesses of: 1.56, 1.12, 0.89, 0.75, 0.54 and 0.40 millimeter.

AGENCY NOTE: The Mammographic Accreditation Phantom Model 156, manufactured by Radiation Measurements, Inc., meets the above criteria and was chosen for use by the American College of Radiology's Mammography Accreditation Program.

"Phantom image" means a radiographic image of a phantom.

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

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

"Provisional certificate" means the provisional certificate described in Section 370.50(b) of this Part.

"Qualified instructor" means an individual whose training and experience adequately prepares him or her to carry out specified training assignments. Interpreting physicians, radiologic technologists or medical physicists who meet the requirements of Section 370.70 of this Part would be considered qualified instructors in their respective areas of mammography. Other examples of individuals who may be qualified instructors for the purpose of providing training to meet the requirements of this Part include, but are not limited to, instructors in a post-high school training institution and manufacturer's representatives.

"Quality control technologist" means an individual meeting the requirements of Section 370.100(a)(4) of this Part who is responsible for those quality assurance responsibilities not assigned to the lead interpreting physician or to the medical physicist.

"Radiologic technologist" means an individual specifically trained in the use of radiographic equipment and the positioning of patients for radiographic examinations and when performing mammography without direct supervision, also meets the requirements set forth in Section 370.70(b) of this Part.

"Screening mammography" means mammography performed on an asymptomatic patient to detect the presence of breast cancer at an early stage.

"Serious adverse event" means an adverse advent that may significantly compromise clinical outcomes, or an adverse event for which a facility fails to take appropriate corrective action in a timely manner.

"Serious complaint" means a report of a serious adverse event.

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

"Survey" means an onsite physics consultation and evaluation of a facility quality assurance program performed by a medical physicist.

"Time cycle" means the film development time.

"Traceable to a national standard" means an instrument is calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program with NIST at least once every 2 years and the results of the proficiency test conducted within 24 months of calibration show agreement within plus or minus 3 percent of the national standard in the mammography energy range.

(Source: Amended at 29 Ill. Reg. 20963, effective December 16, 2005)