

## PART IX DEFINITIONS

As used in these regulations, the following definitions apply:

9.1 "Absorbed Dose" is the energy imparted to matter by ionizing radiation per unit mass of irradiated material at the place of interest. The special units of absorbed dose are the rad or the gray.

9.2 "Accessible Surface" means the external surface of the enclosure or housing provided by the manufacturer.

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

9.4 "Act" means Act No. 223, Atomic Energy and Radiation Control Act enacted by the 1967 Session South Carolina Legislature. [Section 13-7-40 *et seq.*, S.C. Code of Laws (1976, as amended)].

9.5 "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.

9.6 "Added filtration" means any filtration which is in addition to the inherent filtration.

9.7 "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

9.8 "Adult" means an individual 18 or more years of age.

9.9 "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), 1Gy=100rad.

9.10 "ALARA" (acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits in the Rules in this Chapter as is practical consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of sources of radiation in the public interest.

9.11 "Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question.

9.12 "Analytical x-ray equipment" means any machine utilizing x-rays for examination of the microscopic structure, or elemental or chemical composition of materials. This includes x-ray equipment used for x-ray diffraction, fluorescence analysis, or spectroscopy.

9.13 "Analytical X-ray System" means a group of local and remote components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials. Local components

include those that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding. Remote components include power supplies, transformers, amplifiers, readout devices, and control panels.

9.14 "Annually" means at intervals not to exceed 12 consecutive months.

9.15 "Applicator" means a structure which determines the extent of the treatment field at a given distance from the virtual source.

9.16 "Assembler" means any person engaged in the business of assembling, reassembling, replacing, installing, or reinstalling one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system, his employee, or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

9.17 "Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.

9.18 "Authorized representative" means an employee of the Department, or an individual outside the Department when the individual is specifically so designated by the Department.

9.19 "Automatic exposure control" means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (See also "Phototimer").

9.20 "Average Glandular dose" means, in mammography, the value in millirad for a given breast or phantom thickness which estimates the average absorbed dose to the glandular tissue extrapolated from free air exposures and based on fixed filter thickness and target material.

9.21 "Background radiation" means radiation from cosmic sources, naturally occurring radioactive materials, including radon (except as a decay product of source or special nuclear material) and global fallout as it exists in the environment from the testing of nuclear explosive devices. "Background radiation" does not include sources of radiation regulated by the agency.

9.22 "Barrier" (See "Protective Barrier").

9.23 "Beam Axis" means a line from the source through the centers of the x-ray fields.

9.24 "Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray field.

9.25 "Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.

9.26 "Beam scattering foil" means a foil used in order to scatter a beam of electrons.

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

9.28 "Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet so shielded that every location on the exterior meets the dose limits as specified in Part III of these Regulations.

9.29 "Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure which is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and

exclude personnel from its interior during x-ray production. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.

9.30 "Calendar Quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January; and subsequent calendar quarters shall be such that no day is included in more than one calendar quarter or omitted from inclusion within a calendar quarter. No registrant shall change the method observed by him of determining calendar quarters for purposes of these regulations, except at the beginning of a calendar year. For the purpose of Part V, "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.

9.31 "Calibration" means:

a) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or

b) the strength of a source of radiation relative to a standard.

9.32 "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.

9.33 "C-Arm" means an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship.

9.34 "Central axis of the Beam" means a line passing through the virtual source and the center of the plane figure formed by the edge of the first beam-limiting device.

9.35 "Cephalometric" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

9.36 "Certifiable cabinet x-ray system" means an existing uncertified x-ray system that has been modified to meet the certification requirements specified in 21 CFR 1020.40.

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

9.38 "Certified cabinet x-ray system" means an x-ray system that has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40.

9.39 "Certified components" means components of x-ray systems which are subject to the Regulations for the Administration and Enforcement of the Radiation Control for Health and Safety Act of 1968, promulgated under Public Law 90-602.

9.40 "Certified system" means any x-ray system which has one or more certified component(s).

9.41 "Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

9.42 "Change of Status" means transfer of ownership, change of address, or disposal of any X-ray system.

9.43 "Clinical image" means a mammogram.

9.44 "Coefficient of Variation" or "C" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$c = s/\bar{X} = 1/\bar{X} * \sum (X_i - \bar{X})^2 / n - 1$$

where:

s = Estimated standard deviation of the population.

$\bar{X}$  = Mean value of observations in sample.

X<sub>i</sub> = i<sup>th</sup> observation in sample.

n = Number of observations in sample.

9.45 "Collimator" means a device or mechanism by which the x-ray beam is restricted in size.

9.46 "Committed dose equivalent" means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

9.47 "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).

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

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

9.50 "Controlled area" means an area outside of a restricted area but inside the site boundary, access to which can be limited by the registrant for any reason.

9.51 "Coulomb per Kilogram" (C/kg) is the unit of exposure. One Roentgen is equal to 2.58 x 10<sup>-4</sup> Coulomb per kilogram. Submultiples of this unit are the milliCoulomb per kilogram (mC/kg) and the microCoulomb per kilogram (uC/kg).

9.52 "CT" (See "Computed Tomography")

9.53 "CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in 8.173.

9.54 "CT Gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

9.55 "Computed Tomography" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

9.56 "Contact Therapy System" means an x-ray system used for therapy with the x-ray tube port placed in contact with or within 5 centimeters of the surface being treated.

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

9.58 "Cooling Curve" means the graphical relationship between heat units stored and cooling time.

9.59 "Dead-man Switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

9.60 "Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

9.61 "Deep-dose equivalent" ( $H_d$ ), which applies to external whole-body exposure, is the equivalent at a tissue depth of 1 cm ( $1000 \text{ mg/cm}^2$ ).

9.62 "Department" means the South Carolina Department of Health and Environmental Control.

9.63 "Detector" (See "Radiation detector")

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

- (a) Clinical signs, symptoms or physical findings suggestive of breast cancer;
- (b) An abnormal or questionable screening mammogram;
- (c) A history of breast cancer with breast conservation surgery regardless of absence of clinical breast signs, symptoms or physical findings; or
- (d) Augmented breast regardless of absence of clinical breast signs, symptoms or physical findings.

9.65 "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

9.66 "Diagnostic x-ray imaging system" means an assemblage of components for the generation, emission and reception of x-rays and the transformation, storage and visual display of the resultant x-ray image.

9.67 "Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.

9.68 "Diaphragm" means a device or mechanism by which the x-ray beam is restricted in size.

9.69 "Direct instruction" means face-to-face interaction between instructor(s) and student(s), as when the instructor provides a lecture, conducts demonstrations or reviews student performance; or the administration and correction of student examinations by an instructor(s) with subsequent feedback to the student(s).

9.70 "Direct scattered radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (See "Scattered Radiation").

9.71 "Direct supervision", in Part V, 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.

9.72 "Dose" is a generic term which means absorbed dose, dose equivalent, effective dose equivalent, or total effective dose equivalent as defined in these regulations.

9.73 "Dose Equivalent" ( $H_T$ ) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv).

9.74 "Dose limits" (See Limits)

9.75 "Dose monitoring system" means a system of devices for the detection, measurement, and display of quantities of radiation.

9.76 "Dose monitor unit" means a unit response from the dose monitoring system from which the absorbed dose can be calculated.

9.77 "Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

9.78 "Effective dose equivalent" ( $H_E$ ) is the sum of the products of the dose equivalent to the organ or tissue ( $H_T$ ) and the weighting factors ( $W_T$ ) applicable to each of the body organs or tissues that are irradiated ( $H_E = \sum W_T H_T$ ).

9.79 "Embryo/fetus" means the developing human organism from conception until the time of birth.

9.80 "Entrance or access point" means any location through which an individual could gain access to radiation areas or to a source of radiation. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

9.81 "Entrance exposure rate" means the exposure free in air per unit time at the point where the center of the useful beam enters the patient.

9.82 "ESE" means the exposure at skin entrance where the center of the useful beam enters the patient.

9.83 "Equipment" (See "X-ray system").

9.84 "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.

9.85 "Exposure" is the amount of ionization per unit mass of air due to x-rays. It is the quotient of  $dQ$  by  $dm$  where " $dQ$ " is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass " $dm$ " are completely stopped in air. The special units of exposure are the Roentgen (R), or the coulomb per kilogram.

9.86 "Exposure rate" means the exposure per unit of time, such as R/min and mR/h.

9.87 "External dose" means that portion of the dose equivalent received from radiation sources outside the body.

9.88 "Extremities" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

9.89 "Eye dose equivalent" applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm<sup>2</sup>)

9.90 "Facility" means the location at which one or more x-ray machines are installed or located within one building, vehicle, or under one roof and are under the same administrative control.

9.91 "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.

9.92 "Fail-safe characteristics" means a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

9.93 "FDA" means the Food and Drug Administration.

9.94 "Field emission equipment" means equipment which uses an x-ray tube in which an electron emission from the cathode is due solely to the action of an electric field.

9.95 "Field-flattening filter" means a filter used to provide dose uniformity over the area of a useful beam of x-rays at a specified depth.

9.96 "Field Radiography" means the examination of the macroscopic structure of materials by nondestructive methods of utilizing sources of radiation in a non-fixed or non-permanent location.

9.97 "Field size" means the dimensions along the major axes of an area in a plane perpendicular to the central axis of the useful beam of incident radiation at the normal treatment distance and defined by the intersection of the major axes and the 50 percent isodose line. Material shall be placed in the beam such that dose maximum is produced at the normal treatment distance when field size is being determined.

9.98 "Filter" means material placed in the useful beam to preferentially absorb selected radiation.

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

9.100 "Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

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

9.102 "Fog test" means an evaluation of increased density and reduced contrast on film which has not been exposed to the radiation field. This is usually done by processing unexposed film and measuring the density.

9.103 "Gantry" means that part of the system supporting and allowing possible movements of the radiation head.

9.104 "Gauge" means a mechanism designed and manufactured for the purpose of determining or controlling thickness, density, level, interface location, or qualitative or quantitative chemical composition.

It may include components such as radiation shields and useful beam controls incorporated into the gauge in order to meet the requirements or specifications of this regulation.

9.105 "General purpose radiographic x-ray system" means any radiographic x-ray which, by design, is not limited to radiographic examination of specific anatomical regions.

9.106 "Gonadal shield" means a protective barrier for the testes or ovaries.

9.107 "The "Gray" is the unit of absorbed dose. It is equal to 1 joule per kilogram. One rad is equal to  $1 \times 10^{-2}$  Gray. Submultiples included in this document are the milliGray (Gy) and the microGray (uGy).

9.108 "Half-value layer (HVL)" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

9.109 "Healing arts" means any system, treatment, operation, diagnosis, prescription, or practice for the ascertainment, cure, relief, palliation, adjustment, or correction of any human disease, ailment, deformity, injury, or unhealthy or abnormal physical or mental condition.

9.110 "Healing arts screening" means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

9.111 "Health Professions" means the professional persons authorized by the laws of the State to use x-rays in the diagnosis or treatment of human or animal disease.

9.112 "Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp x mA x second.

9.113 "High radiation area" means any area, accessible to individuals, in which there exists radiation at such levels that the whole body could receive in any one hour, a dose in excess of 0.1 rem (mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

9.114 "HVL" (See "Half-value layer").

9.115 "Image intensifier" means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

9.116 "Image receptor" means any device, such as radiographic film, which transforms incident photons either into a visible image or into another form which can be made into a visible image by further transformations.

9.117 "Image receptor support" means, for mammographic systems, that part of the system designed to support the image receptor during mammography.

9.118 "Individual" means any human being.

9.119 "Individual monitoring" means:

- (a) the assessment of dose equivalent by the use of devices designed to be worn by an individual; or
- (b) the assessment of dose equivalent by the use of survey data.

9.120 "Individual Monitoring Devices" or "individual monitoring equipment" means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescent dosimeters (TLDs), and pocket ionization chambers.

9.121 "Industrial x-ray equipment" means any machine utilizing x-rays for examination of the macroscopic structure of materials. This includes x-ray equipment used for cabinet radiography, shielded room radiography, field radiography, and gauges.

9.122 "Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

9.123 "Inoperative" means any x-ray machine or device that is temporarily or permanently rendered incapable of producing x-rays.

9.124 "Inspection" means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the Department.

9.125 "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.

9.126 "Interlock" means a device for precluding access to a high radiation area by automatically reducing the exposure rate upon entry by personnel.

9.127 "Interpreting physician" means a licensed physician who interprets mammograms and who meets the requirements of Section 5.7.1 and 5.25.1.1.

9.128 "Irradiation" means the exposure of matter to ionizing radiation.

9.129 "Isocenter" means the intersection of the collimator axis of rotation and the gantry axis of rotation.

9.130 "Kilovolts peak" (See "Peak tube potential").

9.131 "kV" means kilovolts.

9.132 "kVp" (See "Peak tube potential").

9.133 "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 5.9, 5.10.1, 5.10.2, 5.10.4, 5.10.5, 5.10.6 and 5.10.7 of this Part. The administrative title and other supervisory responsibilities of the individual, if any, are left to the discretion of the facility.

9.134 "Leakage radiation (non-diagnostic)" means all radiation coming from within the tube housing complex except the useful beam(s).

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

- 1) the useful beam, and
- 2) radiation produced when the exposure switch or timer is not activated.

9.136 "Leakage technique factors" means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:

1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliampere seconds, or the minimum obtainable from the unit, whichever is larger.

2) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.

3) For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

9.137 "Licensed practitioner" means an individual with professional specialization who has met the criteria as outlined by the South Carolina Department of Labor, Licensing, and Regulation.

9.138 "Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

9.139 "Limits" or "Dose Limits" means the permissible upper bounds of radiation doses.

9.140 "Linear attenuation coefficient" or " $\mu$ " means the quotient of  $dN/N$  divided by  $dl$  when  $dN/N$  is the fraction of uncharged ionizing radiation that experience interactions in traversing a distance  $dl$  in a specified material.

9.141 "Line voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation.

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

$V_n$  = No load line potential and

$V_l$  = Load line potential.

9.142 "mA" means milliAmpere.

9.143 "Mammogram" means a radiographic image produced through mammography.

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

9.145 "Mammography" means radiography of the breast.

9.146 "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.

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

9.148 "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.

9.149 "mAs" means milliAmpere second.

9.150 "Maximum line current" means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.

9.151 "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.

9.152 "Medical device" means an instrument, tool, machine, test kit, or implant that is used to prevent, diagnose, or treat disease or other medical conditions.

9.153 "Medical physicist", for the purpose of Part V, means a person trained in evaluating the performance of mammography equipment and facility quality assurance programs and who meets the qualifications set forth in RHB 5.7.3.

9.154 "Member of the public" means an individual in a controlled or unrestricted area; however, an individual is not a member of the public during any period in which the individual receives an occupational dose.

9.155 "Minor" means an individual less than 18 years of age.

9.156 "Misadministration" means the administration of:

9.156.1 Radiation to the wrong patient, wrong treatment site, or wrong mode of treatment;

9.156.2 Performance of a diagnostic or therapeutic procedure other than that ordered by the prescribing physician.

9.156.3 A therapeutic radiation dose from a source such that errors in the source calibration, time of exposure, or treatment geometry result in a calculated total treatment dose differing from the total prescribed treatment dose by more than 20 percent.

9.156.4 When the treatment consists of three or fewer fractions, a therapeutic radiation dose from a source such that errors in the source calibration, time of exposure, or treatment geometry result in a calculated total treatment dose differing from the total prescribed treatment dose by more than 10 percent.

9.156.5 When the calculated weekly treatment dose exceeds the weekly prescribed dose by 30 percent or more of the weekly prescribed dose.

9.157 "Mobile x-ray equipment" (See "X-ray equipment").

9.158 "Monitoring", "radiation monitoring" or "radiation protection monitoring" means the measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.

9.159 "MQSA" means the federal Mammography Quality Standards Act of 1992.

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

9.161 "Nonstochastic effect" means health effects, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of nonstochastic effect (also called a deterministic effect).

9.162 "Moving beam therapy" means radiation therapy with relative displacement of the useful beam or the patient during irradiation. It includes arc therapy, skip therapy, conformational therapy, and rotational therapy.

9.163 "Normal treatment distance" means:

1) For electron irradiation, the distance from the scattering foil or exit window of the electron beam to the surface along the central axis of the useful beam, or from the virtual source to the surface along the central axis of the useful beam as specified by the manufacturer.

2) For x-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be specified by the manufacturer.

9.164 "Occupational dose" means the dose received by an individual in a restricted area or in the course of employment in which the individual's assigned duties involve exposure to radiation, whether in the possession of the registrant or other person. Occupational dose does not include dose received from background radiation, as a patient from medical practices, from voluntary participation in medical research programs, or as a member of the general public.

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

9.166 "Operating Conditions" means circumstances required to maintain a radiation protection program sufficient to ensure compliance with the provisions of this Regulation. Conditions include, but are not limited to, patient holding, pregnant workers, use of shielding and barriers, pregnant patients, use of personnel monitoring devices, employee training, and quality assurance methods.

9.167 "Operating procedures" means detailed written instructions including, but not limited to, use of the x-ray equipment, use of shielding and barriers, quality assurance methods, occasions and methods for conducting area surveys, use of personnel monitoring devices, and alignment, calibration, or preventative maintenance of x-ray equipment. Routine and emergency radiation safety considerations are part of these procedures. Emergency procedures shall include methods of notifying proper persons in the event of an emergency, to include the listing of names, addresses and phone numbers.

9.168 "Operative" means any x-ray machine or device that is capable of producing x-rays.

9.169 "Out of State Facility" means any person proposing to bring an x-ray machine into the State for any temporary use.

9.170 "Patient" means an individual or animal subjected to healing arts examination, diagnosis, or treatment, including a mammography evaluation.

9.171 "PBL" (See "Positive Beam Limitation").

9.172 "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

9.173 "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other state or political subdivision or agency thereof, and any legal successor, representative, agent or agency of the foregoing, other than entities over which a federal government agency has exclusive jurisdiction.

9.174 "Personnel monitoring equipment" means devices designed to be carried or worn by an individual for the purpose of measuring the dose which an individual receives (e.g., film badges, pocket chambers, pocket dosimeters).

9.175 "Phantom" in Part VI, means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number ( $Z$ ) and the density of the material be similar to that of the tissue.

9.176 "Phantom" in Part V, 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. This definition does not apply to phantoms used for Quality Assurance testing of stereotactic biopsy units. 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:

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

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

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

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

9.178 "Phototimer" means a method for controlling radiation exposure to image receptors by measuring the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (See "Automatic exposure control").

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

9.180 "PID" (See "Position indicating device").

9.181 "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

9.182 "Portable x-ray equipment" (See "X-ray equipment").

9.183 "Position indicating device" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

9.184 "Positive Beam Limitation" means the automatic or semiautomatic adjustment of an x-ray beam to the selected image receptor size, whereby exposures cannot be made without such adjustments.

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

9.186 "Primary beam" means ionizing radiation which passes through an aperture of the source housing by a direct path from the x-ray tube located in the radiation source housing.

9.187 "Primary dose monitoring system" means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been acquired.

9.188 "Primary protective barrier" (See "Protective barrier").

9.189 "Protective apron" means an apron made of radiation absorbing material used to reduce radiation exposure.

9.190 "Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

1) "Primary protective barrier" means the material, excluding filters, placed in the useful beam, to protect anyone other than the patient from radiation exposure.

2) "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.

9.191 "Protective glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.

9.192 "Provisional certificate" means the provisional certificate described in RHB 5.3.3.

9.193 "Public dose" means the dose received by a member of the public from exposure to radiation by a registrant, or to another source of radiation either within a registrant's controlled area or in unrestricted areas. It does not include occupational dose or doses received from background radiation, as a patient from medical practices, or from voluntary participation in medical research programs.

9.194 "Qualified expert" means an individual who has demonstrated to the satisfaction of the Department that such individual possesses the knowledge, training and experience to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs.

9.195 "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 5.7 and 5.25.1 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.

9.196 "Quality Assurance" is a program designed to produce high quality radiographs at minimal cost and minimal patient exposure.

9.197 "Quality Control" is the routine measurement of image quality and the performance of the diagnostic x-ray imaging system, from x-ray beam output to the viewing of radiographs, and the continual adjustment of that performance to an optimal and consistent level.

9.198 "Quality control technologist" means an individual meeting the requirements of RHB 5.7.2 who is responsible for those quality assurance responsibilities not assigned to the lead interpreting physician or to the medical physicist.

9.199 "Quality Factor" (Q) means the modifying factor that is used to derive dose equivalent from absorbed dose. Quality factors are provided in the definition of rem.

9.200 The "rad" is a measure of the absorbed dose of any radiation to body tissue in terms of the energy absorbed per unit mass of the tissue. One rad is the absorbed dose corresponding to 100 ergs per gram of tissue. (One millirad {mrad} = 0.001 rad.)

9.201 "Radiation" means ionizing radiation, including gamma rays, x-rays, alpha particles, beta particles, high speed electrons, neutrons, high speed protons, and other atomic particles, but not sound or radio waves, or visible, infrared, or ultraviolet light.

9.202 "Radiation area" means any area accessible to individuals in which there exists radiation at such levels that the whole body could receive in any one hour, a dose in excess of 5 millirem (.05 mSv) at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

9.203 "Radiation detector" means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

9.204 "Radiation dose" means dose.

9.205 "Radiation Installation" is any location or facility where radiation machines are used.

9.206 "Radiation Safety Officer" means one who has the knowledge and responsibility to apply appropriate radiation protection regulations, and is approved in writing by the registrant.

9.207 "Radiation therapy simulation system" means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

9.208 "Radiograph" means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

9.209 "Radiographer" means any individual who performs or who, in attendance at the site where sources of radiation are being used, personally supervises field radiography operations, and who is responsible to the registrant for assuring compliance with the requirements of these regulations.

9.210 "Radiographer's Assistant" means any individual who, under the personal supervision of a radiographer, uses sources of radiation, related handling tools, or survey instruments in field radiography.

9.211 "Radiographic imaging system" means any system whereby a permanent or temporary image is recorded on an image receptor by the action of ionizing radiation.

9.212 "Radiological physicist" means an individual who is certified by the American Board of Radiology in therapeutic radiological physics, radiological physics, or x- and gamma ray physics; or certified by the American Board of Medical Physicists in radiation oncology physics, or have the equivalent training experience as approved, or have the following minimum training and experience:

9.212.1 A Master's or a Doctoral degree in Physics, Biophysics, Radiological Physics, or Health Physics or Medical Physics; one year full-time training in therapeutic radiological physics;

9.212.2 One year full-time experience in a therapeutic facility where the individual's duties involve calibration and spot checks of a medical accelerator, and includes personal calibration and spot check of at least one machine.

9.213 "Radiologic technologist", in Part V, 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 RHB 5.7.2.

9.214 "Rating" means the operating limits as specified by the component manufacturer.

9.215 "Recording" means producing a permanent form of an image resulting from x-ray photons.

9.216 "Registrant" means any person who is registered with the Department or is legally obligated to register with the Department pursuant to the Act and these regulations.

9.217 "Registration" means registering with the Department in accordance with these regulations and the Act.

9.218 "Rem" is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 sievert). The quality factors for converting absorbed dose to dose equivalent are as follows:

#### QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

TYPE OF RADIATION	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent*
X-, gamma, or beta radiation	1	1 a Unit Dose Equivalent*
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05

Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

\*Absorbed dose in rad equal to 1 rem or the absorbed dose in gray equal to 1 sievert.

9.219 "Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady step midscale reading.

9.220 "Restricted area" (controlled area) means any area, access to which is controlled by the registrant for purposes of protection of individuals from exposure to radiation. A "restricted area" shall not include any areas used for residential quarters, although a separate room or rooms in a residential building may be set apart as a restricted area.

9.221 "Roentgen" (R) is the special unit of exposure. One Roentgen equals  $2.58 \times 10^{-4}$  Coulombs/kilogram of air. (See exposure.)

9.222 "Safety device" means a device which prevents the entry of any portion of an individual's body into the primary x-ray beam path or which causes the beam to be shut off upon entry into its path.

9.223 "Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

9.224 "Scan increment" means the amount of relative displacement of the patient with respect to the CT x-ray system or between successive scans measured along the direction of such displacement.

9.225 "Scan sequence" means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

9.226 "Scan time" means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

9.227 "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction (See "Direct scattered radiation").

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

9.229 "Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary system.

9.230 "Secondary protective barrier" (See "Protective barrier").

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

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

9.233 "Shadow tray" means a device attached to the radiation head to support auxiliary beam blocking material.

9.234 "Shallow-dose equivalent" ( $H_s$ ), which applies to the external exposure of the skin or an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter ( $7 \text{ mg/cm}^2$ ) averaged over an area of 1 square centimeter.

9.235 "Shielded room radiography" means industrial radiography using radiation machines, which is conducted in an enclosed room, the interior of which is not occupied during radiographic operations, which is so shielded that every location on the exterior meets conditions for an unrestricted area and the only access to which is through openings which are interlocked so that the radiation machine will not operate unless all openings are securely closed.

9.236 "Shutter" means a device attached to the tube housing assembly which can totally intercept the entire cross sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

9.237 "SID" (see Source to Image Receptor Distance).

9.238 "Sievert (Sv)" is the unit of dose equivalent. The dose equivalent in Sieverts is equal to the absorbed dose in grays multiplied by the quality factor. ( $1 \text{ Sv} = 100 \text{ rems}$ ). Submultiples included in this document are the milliSievert (mSv) and the microSievert (uSv).

9.239 "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the registrant.

9.240 "Source" means the focal spot of the x-ray tube.

9.241 "Source to image receptor distance (SID)" means the distance from the source to the center of the input surface of the image receptor.

9.242 "Source of radiation" means any device or equipment emitting or capable of producing x-ray radiation.

9.243 "Special procedures" means the application of special x-ray equipment and specialized techniques to obtain required diagnostic information. This usually provides enhanced detail of a given anatomical structure but with reduced visualization of others. Special procedures include, but are not limited to, angiography, cardiac catheterization, myelogram, and surgery.

9.244 "Special purpose x-ray system" means any radiographic x-ray system which is limited, by design, to radiographic examinations of specified anatomical regions. Special purpose x-ray systems include, but are not limited to, mammography units, dedicated chest units, cystography units, and head and skull units.

9.245 "Spot check" means a procedure which is performed to assure that a previous calibration continues to be valid.

9.246 "Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

9.247 "Spot film device" means a device intended to transport or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

9.248 "SSD" means the distance between the source and the skin entrance plane of the patient.

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

9.250 "Stationary x-ray equipment" (See "X-ray equipment").

9.251 "Stochastic effects" means health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects (also called a probabilistic effect).

9.252 "Stray radiation" means the sum of leakage and scattered radiation.

9.253 "Supervision" means the delegating of the task of applying radiation pursuant to this part by persons, not licensed in the healing arts or veterinary medicine, who provide services under the practitioner's control. The licensed practitioner assumes full responsibility for these tasks and must assure that the tasks will be administered correctly.

9.254 "Survey" means an evaluation of the use, of sources of radiation under a specific set of conditions to determine actual or potential radiation hazards. When appropriate, such evaluation includes, but is not limited to tests, physical examination, and measurements of levels of radiation.

9.255 "Survey" in Part V, means an onsite physics consultation and evaluation of a facility's quality assurance program performed by a medical physicist.

9.256 "Target" means that part of a radiation head which by design intercepts a beam of accelerated particles with subsequent emission of other radiation.

9.257 "Technique factors" means the following conditions of operations:

- 1) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;
- 2) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses;
- 3) For CT x-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;
- 4) For CT x-ray systems not designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and
- 5) For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

9.258 "Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

9.259 "Test" means a method for determining the characteristics or condition of sources of radiation or components thereof.

9.260 "Therapeutic-type-protective tube housing" (1) For x-ray therapy equipment not capable of operating at 500 kVp or above, the following definition applies: An x-ray tube housing so constructed that the leakage radiation at a distance of one meter from the source does not exceed one Roentgen in an hour when the tube is operated at its maximum rated continuous current for the maximum rated tube potential. (2) For x-ray therapy equipment capable of operation at 500 kVp or above, the following definition applies: An x-ray tube housing so constructed that leakage radiation at a distance of one meter from the source does not exceed an exposure of one Roentgen in an hour or 0.1 percent of the useful beam dose rate at one meter at its maximum rated continuous current for the maximum rated accelerating potential.

9.261 "Time cycle" means the film development time.

9.262 "Tomogram" means the depiction of the x-ray attenuation properties of a section through the body.

9.263 "Total Effective Dose Equivalent" (TEDE) means the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

9.264 "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.

9.265 "Tube" means an x-ray tube, unless otherwise specified.

9.266 "Tube housing-apparatus complex" means those parts of an analytical x-ray device in which x-rays are produced and utilized for a useful purpose. This includes the x-ray tube housing, shutter or port assemblies, collimators, cameras, goniometers, and electronic radiation detectors.

9.267 "Tube housing assembly" means the tube housing with tube installed. It includes high voltage or filament transformers and other appropriate elements when such are contained within the tube housing.

9.268 "Unrestricted area" (uncontrolled area) means any area to which access is not controlled by the registrant for purposes of protection of individuals from exposure to radiation, and any area used for residential quarters.

9.269 "Vendor" means a person who is engaged in the business of selling, leasing, installing, or offering to sell, lease, or install x-ray machines or machine components or is engaged in the business of furnishing or offering to furnish x-ray machine services, which includes, but is not limited to, reinstalling, reassembling, leasing, servicing, maintenance, calibration, and repair of x-ray equipment, facility and shielding design, radiation surveys, instrument calibration, personnel dosimetry, processor cleaning and maintenance, and health physics consultations.

9.270 "Very high radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in 1 hour at 1 meter from a radiation source or from any surface that the radiation penetrates. At very high doses received at high

dose rates, units of absorbed dose (e.g., rads and grays) are appropriate, rather than units of dose equivalent (e.g., rems and sieverts).

9.271 "Virtual source" means a point from which radiation appears to originate.

9.272 "Whole body" means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

9.273 "Worker" means an individual engaged in work under a license or registration issued by the agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

9.274 "X-ray equipment" means an x-ray system, subsystem, or component thereof.

9.274.1 Mobile means X-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

9.274.2 Portable means X-ray equipment designed to be hand carried.

9.274.3 Stationary means X-ray equipment designed which is installed in a fixed location.

9.274.4 Transportable means X-ray equipment installed in a vehicle or trailer.

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

9.276 "X-ray control" means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

9.277 "X-ray subsystem" means any combination of two or more components of an x-ray system.

9.278 "X-ray tube" means any electron tube which is designed to be used primarily for the production of x-rays.

9.279 "Year" means the period of time beginning in January used to determine compliance with the provisions of this part. The registrant may change the starting date of the year used to determine compliance by the registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.