10A NCAC 15 .0802 is proposed for amendment as follows:

10A NCAC 15 .0802 DEFINITIONS

In addition to terms found in Rule .0104 of this ~~Chapter~~ Chapter, the following definitions shall apply to this Section:

(1) "Accredited bomb squad" means a law enforcement agency utilizing certified bomb technicians.

(2) "Accessible surface" means the external or outside surface of the enclosure or housing provided by the manufacturer or designer of the RGD. This includes the high-voltage generator, doors, access panels, latches, control knobs, and other permanently mounted hardware, and including the plane across the exterior edge of any opening.

~~(2)~~(3) "Analytical RGD equipment" means equipment that uses electronic means to generate ionizing radiation for the purpose of examining the microstructure of ~~materials,~~ materials ~~i.e.~~ using direct x-ray transmission, x-ray diffraction, x-ray fluorescence, and x-ray spectroscopy.

~~(3)~~(4) "Analytical RGD system" means a group of local and remote components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials.

~~(4) "Bomb detection RGDs" means RGDs used for the sole purpose of remotely detecting explosive devices.~~

(5) "Certified bomb technician" means a member of an accredited bomb squad who has completed the FBI Hazardous Devices School. Information pertaining to this program can be found on the school website at http://www.fbi.gov/about-us/cirg/hazardous-devices.

(6) "Certifiable cabinet x-ray system" means an existing uncertified RGD that has been modified to meet the certification requirements specified in 21 CFR ~~1020.40~~ 1020.40, as incorporated by reference in Rule .0117 of this Chapter.

(7) "Certified cabinet x-ray system" means an RGD utilized in an enclosed, interlocked cabinet, such that the radiation machine will not operate unless all openings are securely closed. These systems shall be certified in accordance with 21 CFR ~~1010.2~~ 1010.2, as incorporated by reference in Rule .0117 of this Chapter, as being manufactured and assembled pursuant to the provisions of 21 CFR ~~1020.40~~ 1020.40, as incorporated by reference in Rule .0117 of this Chapter.

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

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

(10) "Electron Beam Device" means any device using electrons below 1MeV to heat, join, or otherwise irradiate materials.

(11) "Enclosed beam RGD" means an RGD with all possible x-ray beam paths contained in a chamber, coupled chambers, or other beam-path-confinement ~~devices~~ devices, to prevent any part of the body from intercepting the beam during normal operations. Normal access to the primary beam path, such as a sample chamber door, shall be interlocked with the high voltage of the x-ray tube or the shutter

for the beam to be considered "enclosed." An open-beam device placed in an interlocked enclosure is considered an "enclosed beam" unless there are provisions for routine bypassing of the interlocks.

(12) "Emergency procedure" means the written pre-planned steps to be taken in the event of actual or suspected exposure of an individual exceeding administrative or regulatory limits. This procedure shall include the names and telephone numbers of individuals to be contacted as well as directives for processing individual monitoring devices.

~~(12)~~(13) "Fail-safe characteristics" means a design feature that causes the radiation beam to terminate, port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device. For example, if an "X-ray On" light indicator or shutter indicator or interlock fails, the radiation beam shall terminate.

(14) "Gauging device" means a mechanism containing a source of ionizing radiation that is designed and manufactured for the purpose of determining or controlling thickness, density, level, interface location, or qualitative or quantitative composition of materials. It may include components such as radiation shields, useful-beam controls, and other safety features in order to meet the requirements or specifications.

(15) "General-use system" means a security screening system that delivers an effective dose of 25 microrem (0.25 microSv) or less per screening.

~~(13)~~(16) "Hand-held x-ray system" means any device or equipment that is portable and used for similar purposes as analytical RGD equipment.

~~(14) "Hybrid gauge" means an x-ray gauge device utilizing both x-ray and radioactive sources.~~

~~(15) "Industrial radiography" means RGDs used to make radiographic images to examine the structure of materials by nondestructive methods. These RGDs shall not be contained in a cabinet and are not permanent installations.~~

(17) "Inspection Zone" means the area established for the purpose of controlling access where screening is performed. Areas controlled due to the presence of radiation may include areas of ingress, egress, gates, portals, and traffic paths. The area outside of the inspection zone shall not exceed the limits of Rule .1601(a)(13) of this Section.

(18) "Interlock" means a feature designed to prevent access to an area of radiation hazard by preventing entry or by automatically removing the hazard.

~~(16)~~(19) "Ion implantation equipment, low-energy" means any enclosed device operating below 1MeV used to accelerate elemental ions and implant them in other materials.

~~(17)~~(20) "Leakage radiation" means radiation emanating from the source assembly housing except for:

(A) the primary beam;

(B) scatter radiation emanating from other components (e.g., shutter or collimator); and

(C) radiation produced when the beam on switch or timer is not activated.

(21) "Limited-use system" means a screening system that is capable of delivering an effective dose greater than 25 microrem (0.25 microSv) per screening but shall not exceed an effective dose of 1 mrem (10 microSv) per screening.

~~(18)~~(22) "Local components" means part of an RGD x-ray system and include areas that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding, but do not include power supplies, transformers, amplifiers, readout devices, and control panels.

~~(19)~~(23) "Mobile RGD" means RGD equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

~~(20)~~(24) "Normal operating procedures" means step-by-step instructions necessary to accomplish a task. These procedures shall include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant, and data recording procedures that are related to radiation safety.

~~(21)~~(25) "Open-beam RGD" means a device or system designed in such a way that the primary beam is not completely enclosed during normal operation and used for analysis, gauging, or imaging in which an individual could accidentally place some part of their body in the primary beam or stray radiation path during normal operation.

~~(22) "Permanent radiographic installation" means an RGD utilized in an enclosed shielded room, cell, or vault that allows entry when the RGD is not energized.~~

~~(23)~~(26) "Portable RGD" means RGD equipment designed to be carried.by hand.

~~(24)~~(27) "Primary beam" means radiation that passes through an aperture of the source assembly housing by a direct path from the radiation source.

~~(25)~~(28) "Radiation generating device (RGD)" means any system, device, subsystem, or machine component that may ~~generate~~ generate, by electronic ~~means~~ means, x-rays or particle radiation above 5 keV, but below 1 MeV, and not used for healing arts on humans or animals. ~~Examples of~~ RGDs ~~are the following~~ may be used as a:

(A) ~~analytical RGD equipment~~ mobile RGD;

(B) ~~certified and certifiable cabinet x-ray systems~~ portable RGD; or

(C) ~~gauging devices using x-ray sources;~~ stationary RGD.

~~(D) hybrid gauging devices;~~

~~(E) e-beam welders;~~

~~(F) baggage scanners;~~

~~(G) industrial radiography RGDs; and~~

~~(H) permanent radiographic installations.~~

~~(26)~~(29) "Remote components" means parts of an RGD x-ray system that are not struck by ~~x-rays~~ x-rays, such as power supplies, transformers, amplifiers, readout devices, and control panels.

(30) “Safety Device” means a device, interlock or system that prevents the entry of any portion of an individual’s body into the primary x-ray beam or that will cause the beam to shut off upon entry into its path.

~~(27)~~(31) "Scattered radiation" means radiation, other than leakage radiation, that during passage through matter, has been deviated in direction or has been modified by a decrease in energy.

(32) “Screening” means the sum of scans necessary for a security screening system to image concealed objects as intended by the system design under normal operating conditions.

(33) "Security screening device" means a non-human use open-beam device designed for the detection of contraband or weapons concealed in baggage, mail, packages, or other structures. These devices include bomb detection devices used for the sole purpose of detecting explosive devices.

(34) "Security screening system" means a system specifically designed to detect contraband and weapons concealed on a person and is used for the sole purpose of public safety and security evaluation by law enforcement.

~~(28)~~(35) "Shutter" means an adjustable device, generally made of lead or other high atomic number material, fixed to a source assembly housing to intercept, block, or collimate the primary beam.

~~(29)~~(36) "Source" means the point of origin of the radiation, such as the focal spot of an x-ray tube.

~~(30)~~(37) "Stationary RGD" means RGD equipment that is installed or placed in a fixed location.

~~(31)~~(38) "Stray radiation" means the sum of leakage and scatter radiation emanating from the source assembly or other components except for the primary beam, and radiation produced when the beam on switch or timer is not activated.

(39) "Warning device" means an audible or visible signal that warns individuals of a potential radiation hazard.

~~(32)~~(40) "X-ray generator" means the part of an x-ray system that provides the accelerating (high) voltage and current for the x-ray tube.

~~(33) "X-ray gauge" means an x-ray producing device designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level, or interface location of manufactured products.~~

(41) "X-ray source housing" means the portion of an RGD system which contains the x-ray tube and emitting target. The housing often contains radiation shielding material or inherently provides shielding.

History Note: *Authority G.S. 104E-7;*
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