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

10A NCAC 15 .0802 DEFINITIONS

~~(a) "Analytical x-ray equipment" means equipment used for x-ray diffraction or fluorescence analysis.~~

~~(b) "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.~~

~~(c) "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.~~

~~(d) "Normal operating procedures" mean operating procedures for conditions suitable for analytical purposes with shielding and barriers in place. These do not include maintenance but do include routine alignment procedures. Routine and emergency radiation safety considerations are part of these procedures.~~

~~(e) "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.~~

~~(f) "Primary beam" means ionizing radiation which passes through an aperture of the source housing by a direct path from the x-ray tube or a radioactive source located in the radiation source housing.~~

(a) In addition to terms found in Rule .0104 of this Chapter the following definitions shall apply to this Section:

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

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

(3) "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 solely for the purpose of remotely detecting explosive devices.

(5) "Certified bomb technician" means a member of an accredited bomb squad who has successfully 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 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 as incorporated by reference in Rule .0117 of

this Chapter, as being manufactured and assembled pursuant to the provisions of 21 CFR 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 upon which are mounted the switches, knobs, pushbuttons, and other hardware 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 fully contained in a chamber, coupled chambers, or other beam-path-confinement 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) "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.

(13) "Hand-held x-ray system" means any device or equipment that is portable and used for similar purposes as analytical x-ray 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 are not contained in a cabinet and are not permanent installations.

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

(17) "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.

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

(20) “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) “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) “Portable RGD” means RGD equipment designed to be carried.

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

(25) “Radiation generating device (RGD)” means any system, device, subsystem, or machine component that may generate by electronic 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:

(A) analytical x-ray machines;

(B) certified and certifiable cabinet x-ray systems;

(C) gauging devices using x-ray sources;

(D) hybrid gauging devices;

(E) e-beam welders;

(F) baggage scanners;

(G) industrial radiography RGDs; and

(H) permanent radiographic installations.

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

(27) “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.

(28) “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) “Source” means the point of origin of the radiation, such as the focal spot of an x-ray tube.

(30) “Stationary RGD” means RGD equipment that is installed or placed in a fixed location.

(31) “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.

(32) “X-ray generator” means the part of an x-ray system which 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.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0802 Eff. February 1, ~~2015.~~ 2015;
Amended Eff. October 1, 2015.