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3701:1-37-11 Relief from fingerprinting, identification, and criminal history records checks and other elements of background investigations for designated categories of individuals permitted unescorted access to certain radioactive materials.

(A) Fingerprinting, and the identification and criminal history records checks required by section 149 of the Atomic Energy Act of 1954, as amended, and this chapter, and other elements of the background investigation are not required for the following individuals prior to granting unescorted access to category one or category two quantities of radioactive materials:

(1) An employee of the U.S. nuclear regulatory commission or of the executive branch of the U.S. government who has undergone fingerprinting for a prior U.S. government criminal history records check;

(2) A member of congress;

(3) An employee of a member of congress or congressional committee who has undergone fingerprinting for a prior U.S. government criminal history records check;

(4) The governor of a state or his or her designated state employee representative;

(5) Federal, state, or local law enforcement personnel;

(6) State radiation control program directors and state homeland security advisors or their designated state employee representatives;

(7) Agreement state employees conducting security inspections on behalf of the U.S. nuclear regulatory commission under an agreement executed under section 274.i. of the Atomic Energy Act;

(8) Representatives of the international atomic energy agency (IAEA) engaged in activities associated with the U.S./IAEA safeguards agreement who have been certified by the U.S. nuclear regulatory commission;

(9) Emergency response personnel who are responding to an emergency;

(10) Commercial vehicle drivers for road shipments of category one and two quantities of radioactive material;

(11) Package handlers at transportation facilities such as freight terminals and railroad yards;

(12) Any individual who has an active federal security clearance, provided that he or she makes available the appropriate documentation. Written confirmation from the agency/employer that granted the federal security clearance or reviewed the criminal history records check must be provided to the licensee. The licensee shall retain this documentation for a period of three years from the date the individual no longer

requires unescorted access to category one or category two quantities of radioactive material; and

(13) Any individual employed by a service provider licensee for which the service provider licensee has conducted the background investigation for the individual and approved the individual for unescorted access to category one or category two quantities of radioactive material. Written verification from the service provider must be provided to the licensee. The licensee shall retain the documentation for a period of three years from the date the individual no longer requires unescorted access to category one or category two quantities of radioactive material.

(B) Fingerprinting, and the identification and criminal history records checks required by section 149 of the Atomic Energy Act of 1954, as amended, are not required for an individual who has had a favorably adjudicated U.S. government criminal history records check within the last five years, under a comparable U.S. government program involving fingerprinting and an FBI identification and criminal history records check provided that he or she makes available the appropriate documentation. Written confirmation from the agency/employer that reviewed the criminal history records check must be provided to the licensee. The licensee shall retain this documentation for a period of three years from the date the individual no longer requires unescorted access to category one or category two quantities of radioactive material. These programs include, but are not limited to:

(1) National agency check;

(2) Transportation worker identification credentials (TWIC) under 49 CFR 1572, as published in Code of Federal Regulations, October 1, ~~2012~~2014;

(3) Bureau of alcohol, tobacco, firearms, and explosives background check and clearances under 27 CFR 555, as published in Code of Federal Regulations, April 1, ~~2013~~2014;

(4) Health and human services security risk assessments for possession and use of select agents and toxins under ~~10~~42 CFR 73, as published in Code of Federal Regulations, ~~January 1, 2012~~October 1, 2014;

(5) Hazardous material security threat assessment for hazardous material endorsement to commercial driver's license under 49 CFR 1572 as published in Code of Federal Regulations, October 1, ~~2012~~2014; and

(6) Customs and border protection's free and secure trade (FAST) program.

3701:1-37-15 General security program requirements.

(A) Security plan:

(1) Each licensee identified in paragraph (A) of rule 3701:1-37-14 of the Administrative Code shall develop a written security plan specific to its facilities and operations. The purpose of the security plan is to establish the licensee's overall security strategy to ensure the integrated and effective functioning of the security program required by this chapter. The security plan must, at a minimum:

(a) Describe the measures and strategies used to implement the requirements of this chapter; and

(b) Identify the security resources, equipment, and technology used to satisfy the requirements of this chapter.

(2) The security plan must be reviewed and approved by the individual with overall responsibility for the security program.

(3) A licensee shall revise its security plan as necessary to ensure the effective implementation of Ohio department of health requirements. The licensee shall ensure that:

(a) The revision has been reviewed and approved by the individual with overall responsibility for the security program; and

(b) The affected individuals are instructed on the revised plan before the changes are implemented.

(4) The licensee shall retain a copy of the current security plan as a record for three years after the security plan is no longer required. If any portion of the plan is superseded, the licensee shall retain the superseded material for three years after the record is superseded.

(B) Implementing procedures:

(1) The licensee shall develop and maintain written procedures that document how the requirements of this chapter and the security plan will be met.

(2) The implementing procedures and revisions to these procedures must be approved in writing by the individual with overall responsibility for the security program.

(3) The licensee shall retain a copy of the current procedure as a record for three years after the procedure is no longer needed. Superseded portions of the procedure must be retained for three years after the record is superseded.

(C) Training:

(1) Each licensee shall conduct training to ensure that those individuals implementing the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively. The training must include instruction in:

(a) The licensee's security program and procedures to secure category one or category two quantities of radioactive material, and in the purposes and functions of the security measures employed;

(b) The responsibility to report promptly to the licensee any condition that causes or may cause a violation of department requirements;

(c) The responsibility of the licensee to report promptly to the local law enforcement agency (LLEA) and licensee any actual or attempted theft, sabotage, or diversion of category one or category two quantities of radioactive material; and

(d) The appropriate response to security alarms.

(2) In determining those individuals who shall be trained on the security program, the licensee shall consider each individual's assigned activities during authorized use and response to potential situations involving actual or attempted theft, diversion, or sabotage of category one or category two quantities of radioactive material. The extent of the training must be commensurate with the individual's potential involvement in the security of category one or category two quantities of radioactive material.

(3) Refresher training must be provided at a frequency not to exceed twelve months and when significant changes have been made to the security program. This training must include:

(a) Review of the training requirements of paragraph (C) of this rule and any changes made to the security program since the last training;

(b) Reports on any relevant security issues, problems, and lessons learned;

(c) Relevant results of Ohio department of health inspections; and

(d) Relevant results of the licensee's program review and testing and maintenance.

(4) The licensee shall maintain records of the initial and refresher training for three years from the date of the training. The training records must include dates of the training, topics covered, a list of licensee personnel in attendance, and related information.

(D) Protection of information:

(1) Licensees authorized to possess category one or category two quantities of radioactive material shall limit access to and unauthorized disclosure of their security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.

(2) Efforts to limit access shall include the development, implementation, and maintenance of written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, the security plan and implementing procedures.

(3) Before granting an individual access to the security plan or implementing procedures, licensees shall:

(a) Evaluate an individual's need to know the security plan or implementing procedures; and

(b) If the individual has not been authorized for unescorted access to category one or category two quantities of radioactive material, safeguards information, or safeguards information- modified handling, the licensee must complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in rule 3701:1-37-09 of the Administrative Code.

(4) Licensees need not subject the following individuals to the background investigation elements for protection of information:

(a) The categories of individuals listed in rule 3701:1-37-11 of the Administrative Code; or

(b) Security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in rule 3701:1-37-09 of the Administrative Code, has been provided by the security service provider.

(5) The licensee shall document the basis for concluding that an individual is trustworthy and reliable and should be granted access to the security plan or implementing procedures.

(6) Licensees shall maintain a list of persons currently approved for access to the security plan or implementing procedures. When a licensee determines that a person no longer needs access to the security plan or implementing procedures or no longer meets the access authorization requirements for access to the information, the licensee shall remove the person from the approved list as soon as possible, but no later than seven working days, and take prompt measures to ensure that the individual is unable to obtain the security plan or implementing procedures.

(7) When not in use, the licensee shall store its security plan and implementing procedures in a manner to prevent unauthorized access. Information stored in nonremovable electronic form must be password protected.

(8) The licensee shall retain as a record for three years after the document is no longer needed:

(a) A copy of the information protection procedures; and

(b) The list of individuals approved for access to the security plan or implementing procedures.

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DRAFT - NOT FOR FILING

3701:1-37-26 Advance notification of shipment of category one quantities of radioactive material.

As specified in paragraphs (A) and (B) of this rule, each licensee shall provide advance notification to the director and the governor of a state, or the governor's designee, of the shipment of licensed material in a category one quantity, through or across the boundary of the state, before the transport, or delivery to a carrier for transport of the radioactive material outside the confines of the licensee's facility or other place of use or storage.

(A) Procedures for submitting advance notification:

(1) The notification must be made to the U.S. nuclear regulatory commission (NRC) and to the office of each appropriate governor or governor's designee. The contact information, including telephone and mailing addresses, of governors and governor's designees, is available on the NRC website at http://nrc-stp.ornl.gov/special/designee.pdf. A list of the contact information is also available upon request from the "director, Division of Intergovernmental Liaison and Rulemaking, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001." Notifications to the NRC must be to the NRC's "Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001." The notification to the NRC may be made by e-mail to RAMQC SHIPMENTS@nrc.gov or by fax to (301)816-5151.

(2) A notification delivered by mail must be postmarked at least seven days before transport of the shipment commences at the shipping facility.

(3) A notification delivered by any means other than mail must reach the director at least four days before the transport of the shipment commences and must reach the office of the governor or the governor's designee at least four days before transport of a shipment within or through the state.

(B) Information to be furnished in advance notification of shipment: Each advance notification of shipment of category one quantities of radioactive material must contain the following information, if available at the time of notification:

(1) The name, address, and telephone number of the shipper, carrier, and receiver of the category one radioactive material;

(2) The license numbers of the shipper and receiver;

(3) A description of the radioactive material contained in the shipment, including the radionuclides and quantity;

(4) The point of origin of the shipment and the estimated time and date that shipment will commence;

(5) The estimated time and date that the shipment is expected to enter each state along the route;

(6) The estimated time and date of arrival of the shipment at the destination; and

(7) A point of contact, with a telephone number, for current shipment information.

(C) Revision notice:

(1) The licensee shall provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the governor of the state or the governor's designee and to the NRC's "Director of Nuclear Security, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001."

(2) A licensee shall promptly notify the governor of the state or the governor's designee of any such changes to the information provided in accordance with paragraphs (B) and (C)(1) of this rule. The licensee shall also immediately notify the NRC's "Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001" of any such changes.

(D) Cancellation notice: each licensee who cancels a shipment for which the advance notification has been sent shall send a cancellation notice to the governor of each state or to the governor's designee previously notified and to the NRC's "Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001." The licensee shall send the cancellation notice before the shipment would have commenced or as soon thereafter as possible. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being canceled.

(E) Records: the licensee shall retain a copy of the advance notification and any revision and cancellation notices as a record for three years.

(F) Protection of information: state officials, state employees, and other individuals, whether or not licensees of the U.S. nuclear regulatory commission or an agreement state, who receive schedule information of the kind specified in paragraph (B) of this rule shall protect that information against unauthorized disclosure as specified in paragraph (D) of rule 3701:1-37-15 of the Administrative Code.

3701:1-38-01 Definitions.

(A) As used in this chapter and all other rules promulgated pursuant to Chapter 3748. of the Revised Code:

(1) "A_1" means the maximum activity of special form radioactive material permitted in a type A package. These values are listed in rule 3701:1-50-25 of the Administrative Code, or may be derived in accordance with the procedure prescribed in rule 3701:1-50-25 of the Administrative Code.

(2) "A_2" means the maximum activity of radioactive material, other than special form, low specific activity and surface contaminated object material, permitted in a type A package. These values are listed in rule 3701:1-50-25 of the Administrative Code, or may be derived in accordance with the procedure prescribed in rule 3701:1-50-25 of the Administrative Code.

(3) "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray, or Gy, and the rad.

(4) "Accelerator or charged particle accelerator" means any of a class of radiation generating equipment designed to electronically accelerate atomic or sub-atomic particles for subsequent bombardment of targets.

(5) "Accelerator-produced radioactive material" means any material made radioactive by a particle accelerator.

(6) "Activity" means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel, or Bq, and the curie, or Ci.

(7) "Address of use" means the building or buildings that are identified on the license or registration and where the source of radiation may be received, used, prepared, or stored, except for temporary job sites.

(8) "Administrative controls" means mechanisms used to protect health and minimize damage to life and property through the use of written policies, procedures, instructions, training, observation of work practices, and related compliance audits.

(9) "Administrative monetary penalty" means a monetary penalty assessed by the director under section 3748.05 of the Revised Code and in compliance with rules adopted thereunder, to emphasize the need for lasting remedial action and to deter future violations.

(10) "Adult" means an individual eighteen or more years of age.

(11) "Agreement state" means any state with which the United States nuclear regulatory commission or the atomic energy commission has entered into an effective agreement under subsection 274B of the Atomic Energy Act. Non-agreement state means any other state.

(12) "Airborne radioactive material" means radioactive material dispersed in the air

in the form of dusts, fumes, particulates, mists, vapors, or gases.

(13) "Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive materials, composed wholly or partly of licensed material, exist in concentrations:

(a) In excess of the derived air concentrations (DACs) specified in appendix C to rule 3701:1-38-12 of the Administrative Code, or

(b) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 per cent of the annual limit on intake or twelve DAC-hours.

(14) "Air-purifying respirator" means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

(15) "ALARA" or "as low as is reasonably achievable" means every reasonable effort to maintain exposures to radiation as far below the dose limits 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 benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials and registered activities in the public interest.

(16) "Alert" means events may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by off-site response organizations to protect persons off-site.

(17) "Annual limit on intake" or "ALI" means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 sievert (five rem) or a committed dose equivalent of 0.5 sievert (fifty rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in appendix C to rule 3701:1-38-12 of the Administrative Code.

(18) "Annually" means either

(a) At intervals not to exceed one year; or

(b) Once per year, at about the same time each year, plus or minus one month.

(19) "Area of use" means a portion of an address of use that has been set aside for the purpose of receiving, preparing, using, or storing sources of radiation.

(20) "Assigned protection factor" or "APF" means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

(21) "Atmosphere-supplying respirator" means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied air respirators, or SARs, and self-contained breathing apparatus, or SCBA, units.

(22) "Atomic energy commission" or "AEC" means the federal agency created by the Atomic Energy Act of 1954, as amended, and was the predecessor agency to the current United States nuclear regulatory commission created by the Energy Reorganization Act of 1974.

(23) "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 or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. "Background radiation" does not include radiation from radioactive materials regulated by the department.

(24) "Becquerel" or "Bq" means the SI unit of activity. One becquerel is equal to one disintegration per second.

(25) "Bioassay" or "radiobioassay" means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body.

(26) "Byproduct material" means

(a) Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear materials; or

(b) The tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from solution extraction processes. Underground ore bodies depleted by such solution extraction do not constitute byproduct material within the definition.

(27) "Chelating agent" means a chemical compound or mixture that enhances the removal of radioactive material from the body, water or similar applications. Typical chelating agents include amine polycarboxylic acids such as EDTA or DTPA; hydroxy-carboxylic acids; and polycarboxylic acids such as citric acid, carbolic acid, and gluconic acid.

(28) "Chiropractor" means an individual licensed by the state of Ohio to practice chiropractic medicine pursuant to Chapter 4734. of the Revised Code.

(29) "Class" or "lung class" or "inhalation class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for class D, days, of less than ten days, for class W, weeks, from ten to one hundred days, and for class Y, years, of greater than one hundred days.

(30) "Collective dose" means the sum of the individual doses received in a given

period of time by a specified population from exposure to a specified source of radiation.

(31) "Commencement of construction" means taking any action defined as "construction" or any other activity at the site of a facility subject to the rules promulgated pursuant to Chapter 3748. of the Revised Code that has a reasonable nexus to radiological health and safety.

(32) "Committed dose equivalent" or "$H_{T,50}$" 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 fifty year period following the intake.

(33) "Committed effective dose equivalent" or "$H_{E,50}$" means the sum of the products of the weighting factors applicable to each of the body organs or tissues, W_T, that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,\ 50} = W_T H_{T,50}$).

(34) "Consortium" means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a medical facility.

(35) "Constraint" or "dose constraint" means a value above which specified licensee actions are required.

(36) "Construction" means the installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to the rules promulgated pursuant to Chapter 3748. of the Revised Code that are related to radiological safety or security. The term "construction" does not include:

(a) Changes for temporary use of the land for public recreational purposes;

(b) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;

(c) Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;

(d) Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to the rules promulgated pursuant to Chapter 3748. of the Revised Code;

(e) Excavation;

(f) Erection of support buildings (e.g. construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the

construction of the facility;

(g) Building of service facilities (e.g. paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);

(h) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or

(i) Taking any other action that has no reasonable nexus to radiological health and safety.

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

(38) "Critical group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

(39) "Curie" or "Ci" means a unit of activity. One curie equals 3.7×10^{10} disintegrations per second equals 3.7×10^{10} becquerels equals 2.22×10^{12} disintegrations per minute.

(40) "Cyclotron" means a particle accelerator in which the charged particles travel in an outward spiral or circular path. A cyclotron accelerates charged particles at energies usually in excess of ten megaelectron volts and is commonly used for production of short half-life radionuclides for medical use.

(41) "Declared pregnant woman" means a woman who has voluntarily informed the licensee or registrant, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

(42) "Decommission" means to safely remove any licensed operation from service and reduce residual radioactivity to a level that permits release of the licensee's property for unrestricted use and termination of the license. Termination of a license under conditions other than unrestricted use is not permitted by Chapter 3748. of the Revised Code.

(43) "Dedicated check source" means a radioactive source that is used to assure the consistent performance of a radiation detection or measurement device over several months or years.

(44) "Deep dose equivalent" or "H_d" applies to external whole body exposure, and means the dose equivalent at a tissue depth of one centimeter, one thousand milligram per square centimeter.

(45) "Demand respirator" means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

(46) "Dentist" means an individual licensed by the state of Ohio to practice dentistry under Chapter 4715. of the Revised Code.

(47) "Department" means the Ohio department of health.

(48) "Depleted uranium" means the source material uranium in which the isotope uranium-235 is less than 0.711 weight per cent of the total uranium present. Depleted uranium does not include special nuclear material.

(49) "Derived air concentration" or "DAC" means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of two thousand hours under conditions of light work, results in an intake of one ALI. The condition of light work is inhaling 1.2 cubic meters of air per hour for two thousand hours in a year. DAC values are given in appendix C to rule 3701:1-38-12 of the Administrative Code.

(50) "Derived air concentration-hour or DAC-hour" means the product of the concentration of radioactive material in air, which is expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee or registrant may take two thousand DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (five rem).

(51) "Direct reading dosimeter" means a device that measures radiation dose that does not require another device to read the measured radiation dose. Examples of direct reading dosimeters include pocket dosimeters and electronic dosimeters.

(52) "Director" means the director of health or a designee or authorized representative of the director.

(53) "Discipline" means a branch of knowledge or of teaching.

(54) "Discrete source" means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

(55) "Disposable respirator" means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus.

(56) "Dose" or "radiation dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed effective dose equivalent, or total effective dose equivalent as defined in other paragraphs of this rule.

(57) "Dose equivalent" or "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 sievert and rem.

(58) "Dose limits" or "limits" means the permissible upper bounds of radiation doses established in accordance with these regulations but excludes background radiation and medical exposure.

(59) "Dosimetry processor" means a person that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the

monitoring devices.

(60) "Effective dose equivalent" or "H_E" means the sum of the products of the dose equivalent to each organ or tissue, H_T, and the weighting factor, W_T, applicable to each of the body organs or tissues that are irradiated: ($H_E = \Sigma W_T H_T$).

(61) "Embryo" or "fetus" means the developing human organism from conception until time of birth.

(62) "Engineering controls" means mechanisms used to protect health and minimize damage to life and property through engineering specifications, design, and construction of the product or facility including all of the security and safety features. This includes, but is not limited to, auxiliary security and safety features such as additional external shielding, barriers, and operational interlocks with associated processes.

(63) "Entrance" or "access point" means any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed radioactive materials or registered radiation generating equipment. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

(64) "Explosive material" means any chemical compound, mixture or device which produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

(65) "Exposure" means being exposed to sources of ionizing radiation.

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

(67) "Extremity" means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

(68) "Eye dose equivalent" means the same as lens dose equivalent.

(69) "Facility" means all buildings, equipment, structures and other stationary items that, in addition to the meaning defined in division (H) of section 3748.01 of the Revised Code, are:

(a) Located on a single site or on contiguous or adjacent sites and are operated by the same person and have common corporate or business interests; or

(b) Portions of a building or structure which are operated by the same person and have common corporate or business interests.

(70) "Filtering facepiece" or "dust mask" means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

(71) "Fissile material" means the radionuclides uranium-233, uranium-235, plutonium-239, and plutonium-241, or any combination of these radionuclides. Fissile material means the fissile nuclides themselves, not material containing fissile nuclides. Unirradiated natural uranium and depleted uranium and natural

uranium or depleted uranium that has been irradiated in thermal reactors only, are not included in this definition. Certain exclusions from fissile material controls are provided in rule 3701:1-50-13 of the Administrative Code.

(72) "Fit factor" means quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

(73) "Fit test" means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

(74) "Generally applicable environmental radiation standards" means standards issued by the United States environmental protection agency under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

(75) "Gray" or "Gy" means the SI unit of absorbed dose. One gray is equal to an absorbed dose of one joule per kilogram (one hundred rads).

(76) "Handler" means a facility that handles sources of radiation unless possession is solely for the purpose of transportation.

(77) "Hazardous waste" means those wastes designated as hazardous by rule 3745-51-03 of the Administrative Code.

(78) "Helmet" means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

(79) "High radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of one millisievert (0.1 rem) in one hour at thirty centimeters from the radiation source or thirty centimeters from any surface that the radiation penetrates.

(80) "Hood" means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

(81) "Individual" means any human being.

(82) "Individual monitoring" means

(a) The assessment of dose equivalent by the use of devices designed to be worn by an individual;

(b) The assessment of committed effective dose equivalent by bioassay or by determination of the time-weighted air concentrations to which an individual has been exposed, i.e. DAC-hours; or

(c) The assessment of dose equivalent by the use of survey data.

(83) "Individual monitoring devices" means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges; thermoluminescent dosimeters; optically stimulated luminescent dosimeters;

pocket ionization chambers; and personal air sampling devices.

(84) "Industrial radiography" means the examination of the structure of materials by nondestructive methods, utilizing sealed sources of radioactive material or radiation-generating equipment.

(85) "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

(86) "Irradiator" means a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding five grays (five hundred rads) per hour exist at one meter from the sealed radioactive source in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

(87) "Lens dose equivalent" or "eye dose equivalent" means the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeters; i.e. three hundred milligrams per square centimeter.

(88) "License" means a license issued by the nuclear regulatory commission, the director, or another agreement state in accordance with rules adopted by those organizations.

(89) "Licensee" means a person to whom a license is issued.

(90) "Licensed activity" means an activity authorized by a radioactive material license which is essential to achieving the purpose for which the license was issued or amended.

(91) "Licensed material" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license.

(92) "Loose-fitting facepiece" means a respiratory inlet covering that is designed to form a partial seal with the face.

(93) "Lost or missing licensed source of radiation" means a licensed source of radiation whose location is unknown. It includes material that has been shipped but has not reached its destination and whose location cannot be readily traced in the transportation system.

(94) "Low-level radioactive waste" or "LLRW," also "low-level waste," or "LLW" means radioactive waste which is not high-level radioactive waste, spent nuclear fuel, NARM, or byproduct material as defined in section 11 E. (2) of the Atomic Energy Act of 1954, as amended, but is radioactive material that the United States nuclear regulatory commission classifies as low-level radioactive waste.

(95) "Low specific activity material" or "LSA" means radioactive material with limited specific activity which is nonfissile or is excepted under rule 3701:1-50-13 of the Administrative Code, and which satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. LSA must be in one of three groups:

(a) LSA - I.

(i) Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radioactive radionuclides which are not intended to be processed for the use of these radionuclides;

(ii) Solid unirradiated natural uranium or depleted uranium or natural thorium or their solid or liquid compounds or mixtures;

(iii) Radioactive material for which the A_2 value is unlimited; or

(iv) Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed thirty times the value for exempt material activity concentration determined in accordance with rule 3701:1-50-25 of the Administrative Code.

(b) LSA-II.

(i) Water with tritium concentration up to 0.8 terabecquerels per liter (twenty curies per liter); or

(ii) Other material in which the activity is distributed throughout and the average specific activity does not exceed ($0.0001 \times A_2$) per gram for solids and gases, and ($0.00001 \times A_2$) for liquids.

(c) LSA-III. Solids (e.g., consolidated wastes, activated materials), excluding powders, that satisfy the requirements of 10 C.F.R. 71.77 (as published in the January 1, 2006, Code of Federal Regulations), in which:

(i) The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, etc.);

(ii) The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that even under loss of packaging, the loss of radioactive material per package by leaching, when placed in water for seven days, would not exceed ($0.1 \times A_2$); and

(iii) The estimated average specific activity of the solid does not exceed ($0.002 \times A_2$) per gram.

(96) "Management" means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates.

(97) "Medical institution" means an organization in which more than one medical discipline is practiced.

(98) "Medical use" means the intentional internal or external administration of radioactive material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user.

(99) "Member of the public" means any individual except when that individual is receiving an occupational dose.

(100) "Minor" means an individual less than eighteen years of age.

(101) "Monitoring" or "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.

(102) "NARM" or "naturally occurring or accelerator-produced radioactive material" means naturally occurring or accelerator-produced radioactive material, including naturally occurring material that is technologically enhanced, and those nuclides that are generated in a charged particle accelerator, but does not include source material, byproduct material, or special nuclear material.

(103) "NARM licensing state" means any state with regulations equivalent to the suggested state regulations for control of radiation relating to, and an effective program for, the regulatory control of NARM and which has been granted final designation by the conference of radiation control program directors, inc.

(104) "Nationally tracked source" means a sealed source containing a quantity equal to or greater than "Category 1" or "Category 2" levels of any radioactive material listed in the appendix to rule 3701:1-38-25 of the Administrative Code. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. "Category 1" nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the "Category 1" threshold. "Category 2" nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the "Category 2" threshold but less than the "Category 1" threshold.

(105) "Negative pressure respirator" or "tight fitting respirator" means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

(106) "Nonstochastic effect" or "deterministic 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 a nonstochastic effect.

(107) "NORM" or "naturally occurring radioactive material" means any nuclide that is radioactive in its natural physical state, but does not include source material, byproduct material, or special nuclear material.

(108) "Normal form radioactive material" means radioactive material that has not been demonstrated to qualify as special form radioactive material.

(109) "Nuclear regulatory commission" means the federal agency established by Title II of the Energy Reorganization Act of 1974, as amended, comprising the members of the commission and all offices, employees, and representatives authorized to act in any case or matter related to licensing and related regulatory function previously assigned to the AEC by the Atomic Energy Act of 1954, as amended.

(110) "Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to

radiation or radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposures to individuals administered radioactive materials and released in accordance with rule 3701:1-58-30 of the Administrative Code or equivalent United States nuclear regulatory commission or agreement state regulations, from voluntary participation in medical research programs, or as a member of the public.

(111) "Package" means the packaging together with its radioactive contents as presented for transport.

(a) Fissile material package or type AF package, type BF package, type B(U)F package, or type B(M)F package means a fissile material packaging together with its fissile material contents.

(b) Type A package means a type A packaging together with its radioactive contents. A type A package is defined and must comply with the United States department of transportation regulations in 49 C.F.R. 173 (as published in the October 1, 2005, Code of Federal Regulations).

(c) Type B package means a type B packaging together with its radioactive contents. On approval, a type B package design is designated by the United States nuclear regulatory commission as B(U) unless the package has a maximum normal operating pressure of more than seven hundred kilopascals (one hundred pounds per square inch) gauge or a pressure relief device that would allow the release of radioactive material to the environment under the tests specified in 10 C.F.R. 71.73 (hypothetical accident conditions) (as published in the January 1, 2006, Code of Federal Regulations), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see United States department of transportation regulations in 49 C.F.R. 173 (as published in the October 1, 2005 Code of Federal Regulations). A type B package approved before September 6, 1983, was designated only as type B. Limitations on its use are specified in 10 C.F.R. 71.19 (as published in the January 1, 2006, Code of Federal Regulations).

(112) "Packaging" means the assembly of components necessary to ensure compliance with the packaging requirements of rule 49 C.F.R. 173 Subpart I (as published in the October 1, 2005, Code of Federal Regulations). It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system and auxiliary equipment may be designated as part of the packaging.

(113) "Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of one megaelectron volt. For purposes of this definition, "accelerator" is an equivalent term.

(114) "Person" means any individual, corporation, association, business enterprise, or other legal entity either public or private and any legal successor, representative, agent, or agency of that individual, corporation, association, business enterprise, or other legal entity. Person also includes the United States, states, political subdivisions of states, and any department, agency, or instrumentality of the United States or a state, except the U.S. department of energy or the U.S. nuclear regulatory commission where the state regulation of radioactive material by either of those agencies is prohibited by federal law.

(115) "Personnel dosimeter", means a device that measures radiation dose that is processed and evaluated by an accredited "National Voluntary Laboratory Accreditation Program" (NVLAP) processor. Examples of personnel dosimeters include film badges, thermo-luminescent dosimeters (TLD), and optically stimulated luminescence (OSL) dosimeters.

(116) "Pharmacist" means a person who is licensed by the state of Ohio to practice pharmacy pursuant to Chapter 4731. of the Revised Code.

(117) "Physician" means a person who is licensed pursuant to Chapter 4731. of the Revised Code to practice medicine or surgery or osteopathic medicine or surgery.

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

(119) "Podiatrist" means an individual licensed by the state of Ohio to practice podiatry pursuant to Chapter 4731. of the Revised Code.

(120) "Positive pressure respirator" means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

(121) "Positron Emission Tomography (PET) radionuclide production facility" means a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

(122) "Powered air-purifying respirator" or "PAPR" means an air-purifying respirator that uses a blower to force the ambient air through air purifying elements to the inlet covering.

(123) "Pressure demand respirator" means a positive pressure atmosphere supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

(124) "Public dose" means the dose received by a member of the public from exposure to radiation and/or radioactive material released by the licensee, or to any other source of radiation under the control of a licensee or registrant. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposures to individuals administered radioactive materials and released in accordance with rule 3701:1-58-30 of the Administrative Code or equivalent United States nuclear regulatory commission or agreement state regulations, or from voluntary participation in medical research programs.

(125) "Pyrophoric material" means any liquid that ignites spontaneously in dry or

moist air at or below 54.4 degrees celsius (one hundred thirty degrees fahrenheit). A pyrophoric solid is any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and when ignited burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

(126) "Qualitative fit test" or "QLFT" means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

(127) "Quality factor" or "Q" means the modifying factor, as listed in paragraphs (A) and (B) of rule 3701:1-38-11 of the Administrative Code, that is used to derive dose equivalent from absorbed dose.

(128) "Quantitative fit test" or "QNFT" means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

(129) "Quarter" or "quarterly" means a period of time equal to one-fourth of the year observed by the licensee or registrant, approximately thirteen consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

(130) "Rad" means the special unit of radiation absorbed dose. One rad is equal to an absorbed dose of one hundred ergs per gram, or 0.01 joule per kilogram, or 0.01 gray.

(131) "Radiation" or "ionizing radiation" means alpha particles, beta particles, gamma rays, x-rays, neutrons, high speed electrons, high speed protons, and other particles capable of producing ions. Radiation does not include nonionizing radiation, such as radio or microwaves, or visible, infrared or ultraviolet light.

(132) "Radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 millisievert (0.005 rem) in one hour at thirty centimeters from the source of radiation or from any surface that the radiation penetrates.

(133) "Radiation-generating equipment" or "RGE" means any manufactured product or device, or component of such a product or device, or any machine or system that during operation can generate or emit radiation, except those that emit radiation only from radioactive material. "Radiation-generating equipment" does not include either of the following:

(a) Diathermy machines;

(b) Microwave ovens, including food service microwave ovens used for commercial and industrial uses, television receivers, electric lamps, and other household appliances and products that generate very low levels of radiation.

(134) "Radiation Safety Officer" or "RSO" means an individual designated by the licensee who has the knowledge and responsibility for the overall radiation safety program at the facility, to include the implementation of the daily

radiation safety operations and compliance with the rules.

(135) "Radioactive material" means any solid, liquid or gaseous material that emits ionizing radiation spontaneously. "Radioactive material" includes accelerator-produced and naturally occurring radioactive materials and byproduct, source, and special nuclear material.

(136) "Radioactive waste" means waste containing regulated radioactive material.

(137) "Radioactivity" means the transformation of unstable atoms by the emission of radiation.

(138) "Radiography" means the same as industrial radiography.

(139) "Reference man" means a hypothetical aggregation of human physical and physiological characteristics arrived at by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base.

(140) "Registrant" means a person required by Chapter 3748. of the Revised Code to register radiation-generating equipment with the director.

(141) "Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rads multiplied by the quality factor (one rem = 0.01 Sv).

(142) "Research and development" means

(a) Theoretical analysis, exploration, or experimentation; or

(b) The extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials and processes. "Research and development" does not include the internal or external administration of sources of radiation to human beings.

(143) "Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of 10 C.F.R. 20 (as published in the January 1, 2006, Code of Federal Regulations).

(144) "Respiratory protective equipment or device" means an apparatus, such as a respirator, used to reduce the individual's intake of airborne radioactive materials.

(145) "Restricted area" means an area access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set

apart as a restricted area.

(146) "Roentgen" means the amount of gamma or x-rays required to produce ions resulting in a charge of 0.000258 coulombs per kilogram of air under standard conditions.

(147) "Sanitary sewerage" means a system of public sewers for carrying off wastewater and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee.

(148) "Sealed source" means radioactive material that is encased in a manner designed to prevent leakage or escape of the radioactive material.

(149) "Sealed source and device registry" means the national registry that contains all the registration certificates, generated by both the United States nuclear regulatory commission and the agreement states, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

(150) "Seismic area" means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in two hundred fifty years is greater than ten per cent, as designated by the United States geological survey.

(151) "Self-contained breathing apparatus" or "SCBA" means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

(152) "Shallow dose equivalent" or "H_S" means the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter, or seven milligrams per square centimeter.

(153) "Sievert" or "Sv" means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor. One sievert equals one hundred rem.

(154) "Site area emergency" means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by off-site response organizations to protect persons off-site.

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

(156) "Site closure and stabilization" means those actions that are taken upon completion of operations that prepare a disposal site for custodial care and that assure that the disposal site will remain stable and will not need ongoing active maintenance.

(157) "Source material" means uranium, thorium, or any combination thereof in any physical or chemical form, or any ores that contain by weight at least one-twentieth of one per cent (0.05 per cent) of uranium, thorium, or any combination thereof. Source material does not include special nuclear material.

(158) "Sources of radiation" means radioactive material or radiation generating

equipment.

(159) "Special form radioactive material" means radioactive material that satisfies the following conditions:

(a) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

(b) The piece or capsule has at least one dimension not less than five millimeters (0.2 inch); and

(c) It satisfies the test requirements specified by the United States nuclear regulatory commission in 10 C.F.R. 71.75 (as published in the January 1, 2006, Code of Federal Regulations). A special form encapsulation designed in accordance with the United States nuclear regulatory commission requirements identified in 10 C.F.R. 71.4, in effect on June 30, 1983, and constructed prior to July 1, 1985, and a special form encapsulation designed in accordance with the requirements of 10 C.F.R. 71.4 in effect on March 31, 1996, and constructed before April 1, 1998, may continue to be used. Any other special form encapsulation must meet the specifications of this definition.

(160) "Special nuclear material" means either of the following:

(a) Plutonium, uranium-233, uranium enriched in the isotope 233, or in the isotope 235, and any other material that the United States nuclear regulatory commission determines to be special nuclear material, but does not include source material pursuant to section 51 of the "Atomic Energy Act of 1954," 68 Stat 919, 42 USCA 2071.

(b) Any material artificially enriched by any of the foregoing but does not include source material.

(161) "Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope uranium-235 in quantities not exceeding three hundred fifty grams of contained uranium-235; uranium-233 in quantities not exceeding two hundred grams; plutonium in quantities not exceeding two hundred grams; or any combination of them in accordance with the following formula: for each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed unity.

(162) "Stochastic effect" 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.

(163) "Supplied-air respirator" or "SAR" or "airline respirator" means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

(164) "Surface contaminated object" or "SCO" means a solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. SCO must be in one of two groups with surface activity

not exceeding the following limits:

(a) SCO-I: a solid object on which:

(i) The non-fixed contamination on the accessible surface averaged over three hundred square centimeters, or the area of the surface if less than three hundred square centimeters, does not exceed four becquerels per square centimeter (10^{-4} microcurie per square centimeter) for beta and gamma and low toxicity alpha emitters, or 0.4 becquerels per square centimeter 10^{-5} microcurie per square centimeter) for all other alpha emitters;

(ii) The fixed contamination on the accessible surface averaged over three hundred square centimeters, or the area of the surface if less than three hundred square centimeters, does not exceed forty thousand becquerels per square centimeter (one microcurie per square centimeter) for beta and gamma and low toxicity alpha emitters, or four thousand becquerels per square centimeter (0.1 microcurie per square centimeter) for all other alpha emitters; and

(iii) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over three hundred square centimeters, or the area of the surface if less than three hundred square centimeters, does not exceed forty thousand becquerels per square centimeter (one microcurie per square centimeter) for beta and gamma and low toxicity alpha emitters, or four thousand becquerels per square centimeter (0.1 microcurie per square centimeter) for all other alpha emitters.

(b) SCO-II: a solid object on which the limits for SCO-I are exceeded and on which:

(i) The non-fixed contamination on the accessible surface averaged over three hundred square centimeters, or the area of the surface if less than three hundred square centimeter, does not exceed four hundred becquerels per square centimeter (10^{-2} microcurie per square centimeter) for beta and gamma and low toxicity alpha emitters, or forty becquerels per square centimeter (10^{-3} microcurie per square centimeter) for all other alpha emitters;

(ii) The fixed contamination on the accessible surface averaged over three hundred square centimeters, or the area of the surface if less than three hundred square centimeters, does not exceed eight hundred thousand becquerels per square centimeter (twenty microcuries per square centimeter) for beta and gamma and low toxicity alpha emitters, or eighty thousand becquerels per square centimeter (two microcuries per square centimeter) for all other alpha emitters; and

(iii) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over three hundred square centimeters, or the area of the surface if less than three hundred square centimeters, does not exceed eight hundred thousand becquerels per square centimeter (twenty microcuries per square centimeter) for beta and gamma and low toxicity alpha emitters, or eighty thousand becquerels per square centimeter (two microcuries per square centimeter) for all

other alpha emitters.

(165) "Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal or presence of radioactive material or other sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of radioactive material, or the sources of radiation and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.

(166) "Tight-fitting facepiece" means a respiratory inlet covering that forms a complete seal with the face.

(167) "Total effective dose equivalent" or "TEDE" means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

(168) "Transport index" means the dimensionless number, rounded up to the next tenth, placed on the label of a package, to designate the degree of control to be exercised by the carrier during transportation. The transport index is the number determined by multiplying the maximum radiation level in millisievert per hour at one meter (3.3 feet) from the external surface of the package by one hundred, which is equivalent to the maximum radiation level in millirem per hour at one meter (3.3 feet).

(169) "Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material, or A_2 for normal form radioactive material, where A_1 and A_2 are given in rule 3701:1-50-25 of the Administrative Code.

(170) "Type B quantity" means a quantity of radioactive material greater than a type A quantity.

(171) "Type B package" is defined under "Package."

(172) "United States department of energy" means the department of energy established by the Department of Energy Organization Act, PL 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the department of energy or its duly authorized representatives, exercises functions formerly vested in the United States atomic energy commission, its chairman, members, officers and components and transferred to the United States energy research and development administration and to the administrator thereof pursuant to Sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (PL 93-438, 88 Stat. 1233 at 1237, 42 U.S.C. 5814) and retransferred to the secretary of energy pursuant to Section 301(a) of the Department of Energy Organization Act (PL 95-91, 91 Stat. 565 at 577-578, 42 U.S.C. 7151).

(173) "Unrestricted area" or "uncontrolled area" means any area, access to which is neither restricted nor controlled by the licensee or registrant.

(174) "User seal check" or "fit check" means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

(175) "Very high radiation area" means an area, accessible to individuals, in which

radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of five gray (five hundred rad) in one hour at one meter from a source of radiation or from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem.

(176) "Veterinarian" means an individual licensed by the state of Ohio to practice veterinary medicine pursuant to Chapter 4741. of the Revised Code.

(177) "Waste" means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraph (A)(26)(b) of this rule, or byproduct material as defined in section 11 E. (3) and (4) of the Atomic Energy Act of 1954, as amended.

(178) "Week" means seven consecutive days starting on Sunday.

(179) "Weighting factor - W_T" for an organ or tissue, (T), is the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of W_T are:

Organ dose weighting factors	
Organ or tissue	W_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30 [a]
Whole body	1.00 [b]

\[a\] 0.30 results from 0.06 for each of five "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

\[b\] for the purpose of weighting the external whole body dose (for adding it to the internal dose) a single weighting factor, $W_T = 1.0$, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

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

(181) "Worker" means an individual engaged in activities licensed or registered by the department and controlled by a licensee or registrant, but does not include the licensee or registrant.

(182) "Working level" or "WL" means any combination of short-lived radon decay

products (for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212) in one liter of air that will result in the ultimate emission of 1.3 x 10^5 million electron volts alpha particle energy.

(183) "Working level month" or "WLM" means a cumulative exposure to one working level for one hundred seventy hours. (Two thousand working hours per year/twelve months per year equals approximately one hundred seventy hours per month.)

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

(B) The terms set out in paragraph (A) of this rule may be redefined in other chapters as promulgated pursuant to Chapter 3748. of the Revised Code as used in that chapter only.

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3701:1-40-14 Application for specific licenses.

(A) An applicant for a license to receive and possess radioactive material shall apply in accordance with rule 3701:1-38-02 of the Administrative Code and this chapter on a form prescribed by the director. The original application shall be filed with the director. Information contained in previous applications, statements or reports filed with the director may be incorporated by reference, provided that the reference is clear, specific, and has been on file with the department for not more than two licensing periods, and provided that the item being referenced in the document is being referenced without change.

(B) The director may at any time after the filing of the original application require additional information from the applicant in order to determine whether a license should be issued or whether a current license should be modified or revoked.

(C) Each application shall be signed by the applicant or a person duly authorized to act for the applicant.

(D) An application for a license to receive and possess radioactive material for the conduct of any activity which the director has determined pursuant to rule 3701:1-40-36 of the Administrative Code could potentially affect the quality of the environment shall be filed at least nine months prior to commencement of construction of the plant or facility in which the activity will be conducted and shall be accompanied by any environmental report required pursuant to rule 3701:1-40-36 of the Administrative Code. The applicant is prohibited from the commencement of construction activities in areas covered by the environmental reporting requirements identified in rules 3701:1-40-30 to 3701:1-40-38 of the Administrative Code before the conclusion of these reviews. The terms "construction" and "commencement of construction" shall have the same meaning as identified in rule 3701:1-38-01 of the Administrative Code.

(E)

(1) Except as provided in paragraphs (E)(2), (E)(3), and (E)(4) of this rule, an application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed sources must either:

(a) Identify the source or device by manufacturer and model number as registered in the sealed source and device registry of the United States nuclear regulatory commission in accordance with sealed source and device registry requirements contained in rule 3701:1-46-49 of the Administrative Code, or with equivalent requirements from an agreement state or the United States nuclear regulatory commission; or

(b) Contain the information specified in sealed source and device registry requirements contained in paragraph (C) of rule 3701:1-46-49 of the Administrative Code so that the director is able to perform the review.

(2) For sources or devices manufactured before October 23, 2012 that are not registered with the director in accordance with rule 3701:1-46-49 of the Administrative Code or equivalent requirements from an agreement state or the United States nuclear regulatory commission, and for which the applicant is unable to provide all categories of information specified in rule 3701:1-46-49 of

the Administrative Code, the applicant must provide:

(a) All available information identified in rule 3701:1-46-49 of the Administrative Code concerning the source, and, if applicable, the device; and

(b) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

(3) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with rule 3701:1-46-49 of the Administrative Code, the applicant may supply only the manufacturer, model number, and radionuclide and quantity.

(4) If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed sources and device.

(F) In the case of an application for a license specified in rule 3701:1-40-16 of the Administrative Code, or an application for a specific license specified in Chapter 3701:1-46, 3701:1-48, or 3701:1-58 of the Administrative Code, the applicant shall provide a proposed decommissioning funding plan or a certification of financial assurance for decommissioning.

(G) Requirement for an emergency response plan:

(1) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities specified in the appendix to this rule shall contain either:

(a) An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 0.01 sievert (one rem) TEDE or 0.05 sievert (five rem) to the thyroid; or

(b) An emergency plan for responding to a release of radioactive material.

(2) One or more of the following factors may be used to support an evaluation of the need to submit an emergency plan under this paragraph:

(a) The radioactive material is physically separated so that only a portion of the material could be involved in an accident;

(b) All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

(c) The release fraction in the respirable size range would be lower than the release fraction specified in the appendix to this rule due to the chemical or physical form of the material;

(d) The solubility of the radioactive material would reduce the dose received;

(e) Facility design or engineered safety features in the facility would cause the release fraction to be lower than the limit specified in the appendix to this rule;

(f) Operating restrictions or procedures would prevent a release fraction as large as that shown in the appendix to this rule; or

(g) Other factors appropriate for the specific facility as determined by the director.

(3) An emergency plan for responding to a release of radioactive material submitted under paragraph (G)(1)(b) of this rule shall include the following information:

(a) A brief description of the licensee's facility and the area near the site.

(b) An identification of each type of possible radioactive material accident which may require protective action.

(c) A classification system for classifying an accident as either an alert or a site area emergency.

(d) Identification of the means of detecting each type of accident in a timely manner.

(e) A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

(f) A brief description of the methods and equipment to assess releases of byproduct and accelerator produced materials.

(g) A brief description of the responsibilities of the licensee's personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the department, and identification of personnel responsible for developing, maintaining, and updating the plan.

(h) A commitment to, and a brief description of, the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point shall be established. The notification and coordination shall be planned so that in the event that some personnel, parts of the facility, or some equipment is not available, that unavailability will not prevent such notification and coordination. The licensee shall also commit to notifying the department immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency. These reporting requirements do not supersede or release licensees from complying with the requirements of the "Emergency Planning and Community Right-to-Know Act of 1986," Title III, Pub. L. 99-499 or other state or federal reporting requirements.

(i) A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the department.

(j) A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. The training also shall thoroughly prepare site personnel for their responsibilities in the event of an accident, including training on the emergency scenarios postulated as most probable for the specific site, and the use of team training for such scenarios.

(k) A brief description of the means of restoring the facility to a safe condition after an accident.

(l) Provisions for conducting quarterly communication checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communication checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises, although recommended, is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

(m) A certification that the applicant has met all responsibilities under the "Emergency Planning and Community Right-to-Know Act of 1986," Title III, Pub. L. 99-499, if applicable to the applicant's activities at the proposed place of use of the byproduct or accelerator produced material.

(n) The licensee must have and maintain liability coverage for incidents which would activate the plan to cover bodily injury and property damage to third parties caused by incidents which would activate the plan in the amount of at least one million dollars per occurrence with an annual aggregate of at least two million dollars, exclusive of legal defense costs.

(4) The licensee shall allow the offsite response organizations expected to respond in case of an accident sixty days to comment on the licensee's emergency plan before submitting it to the department. The licensee shall provide any comments received within the sixty days to the department with the emergency plan.

(H) Information provided by a licensee or applicant for a license or license renewal that constitutes a "trade secret" as defined in section 1333.61 of the Revised Code is not subject to public disclosure in accordance with sections 1333.61 to 1333.69 of the Revised Code.

(I) An application from a medical facility, or educational institution to produce positron emission tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use in accordance with rules in

Chapter 3701:1-58 of the Administrative Code shall include:

(1) A request for authorization for the production of PET radionuclides or evidence of an existing license issued in accordance with rule 3701:1-38-02 of the Administrative Code for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

(2) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in paragraph (A)(2) of rule 3701:1-46-43 of the Administrative Code.

(3) Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in paragraph (B)(2) of rule 3701:1-46-43 of the Administrative Code.

(4) Information identified in paragraph (A)(3) of rule 3701:1-46-43 of the Administrative Code, on the PET drugs to be non-commercially transferred to members of its consortium.

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3701:1-40-16 Terms and conditions of licenses.

(A)

(1) A license, or any right under a license, shall not be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the director finds that the transfer is in accordance with this rule and Chapters 3701:1-46, 3701:1-48, 3701:1-49, 3701:1-52, and 3701:1-58 of the Administrative Code. A license or any right contained therein may not be transferred or conveyed without the written authorization of the director. If the director approves the transfer and receives payment of the appropriate licensing fee, a new license will be issued to the transferee.

(2) An application for transfer of license must include:

(a) The identity, technical and financial qualifications of the proposed transferee; and

(b) Financial assurance for decommissioning information required by rule 3701:1-40-17 of the Administrative Code.

(B) Each licensee shall confine possession and use of radioactive material to the locations and purposes authorized in the license. Preparation for shipment and transport of radioactive material shall be in accordance with Chapter 3701:1-50 of the Administrative Code.

(C) The director may incorporate at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements or conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material as the director deems appropriate or necessary in order to protect the environment, protect health, or minimize danger to life or property. The director may require such reports and the keeping of such records, and provide for such inspections of activities under the license as may be necessary to effectuate the purposes of Chapter 3748. of the Revised Code or rules adopted thereunder.

(D) A licensee that is required to submit an emergency plan pursuant to rule 3701:1-40-14 of the Administrative Code shall follow the emergency plan approved by the director. The licensee may amend the approved plan without approval of the director provided that the amendment does not decrease the effectiveness of the plan. Within six months after amending the emergency plan, the licensee shall furnish the amended plan to both the director and to affected offsite response organizations. Any proposed amendment to the emergency plan that decreases, or potentially decreases, the effectiveness of the approved emergency plan may not be implemented without prior approval by the director.

(E) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with rule 3701:1-58-35 of the Administrative Code. The licensee shall record the results of each test and retain each record for three years after the record is made.

(F) Each licensee must notify the director by certified mail within ten business days of the commencement of a voluntary or involuntary bankruptcy petition that has been filed by or against:

(1) The licensee;

(2) An entity, defined in this rule as person, estate, trust, governmental unit, and United States trustee, controlling the licensee or listing the license or licensee as property of the estate; or

(3) An affiliate of the licensee defined in this rule as an entity that directly or indirectly owns, controls, or holds with power to vote, twenty per cent or more of the outstanding voting securities of the debtor, other than an entity that holds such securities:

(a) In a fiduciary or agency capacity without sole discretionary power to vote such securities; or

(b) Solely to secure a debt, if such entity has not in fact exercised such power to vote.

The notification shall specify the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing petition.

(G) The director may, upon application including adequate documentation by a person or by his own initiative, grant such exemptions from the requirements of this chapter or other chapters of the Administrative Code involving radioactive materials promulgated under Chapter 3748. of the Revised Code that are authorized by law and will not result in undue hazard to life or property and are otherwise in the public interest.

(H) Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(I)

(1) Authorization under paragraph (I) of rule 3701:1-40-14 of the Administrative Code to produce positron emission tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable United States federal drug administration, other federal, and state requirements governing radioactive drugs.

(2) Each licensee authorized under paragraph (I) of rule 3701:1-40-14 of the Administrative Code to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(a) Satisfy the labeling requirements in paragraph (A)(4) of rule 3701:1-46-43 of the Administrative Code for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

(b) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in paragraph (C) of rule 3701:1-46-43 of the Administrative Code.

(3) A licensee that is a pharmacy authorized under paragraph (I) of rule 3701:1-40-14 of the Administrative Code to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(a) An authorized nuclear pharmacist that meets the requirements in paragraph (B)(2) of rule 3701:1-46-43 of the Administrative Code, or

(b) An individual under the supervision of an authorized nuclear pharmacist as specified in rule 3701:1-58-14 of the Administrative Code.

(4) A pharmacy, authorized under paragraph (I) of rule 3701:1-40-14 of the Administrative Code to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of paragraph (B)(5) of rule 3701:1-46-43 of the Administrative Code.

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