OHIO DEPARTMENT OF HEALTH

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Ted Strickland/Governor

Alvin D. Jackson, M.D./Director of Health

July 14, 2008

James Luehman, Deputy Director
Division of Materials Safety and State Agreements
Federal and State Materials and Environmental Management Programs
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Luehman:

Ohio has amended rules in Ohio Administrative Code Chapters 3701:1-38 "General Radiation Protection Standards for Sources of Radiation", 3701:1-40 "Licensing Requirements for Radioactive Materials", and 3701:1-46 "General Licenses and Licenses for Manufacturing and Distribution". We are submitting the rules to the NRC for your review to ensure that they are compatible with NRC regulations. The rules were amended in accordance with RATS ID numbers 2007-2 and 2008-1.

A chart to aid you in cross referencing the Ohio rules to the applicable NRC regulations is attached. The draft Ohio rules can be found at http://www.odh.ohio.gov/rules/drafts/drafts.aspx

We believe that these Ohio rules satisfy the compatibility and health and safety categories established in the Federal and State Materials and Environmental Management Programs procedure SA-200.

If you have any questions, please feel free to contact Michael Snee of my staff at 614-644-2727 or Michael.Snee@odh.ohio.gov.

Sincerely,

Robert E. Owen, Chief
Bureau of Radiation Protection

Enclosure:
As stated

MEMORANDUM

Date: June 26, 2008

To: Interested Parties

From: Robert E. Owen, Chief
Bureau of Radiation Protection

Subject: Proposed amendments to rules in Chapters 3701:1-38, 3701:1-40 and 3701:1-46 of the Administrative Code.

The proposed amendments to rules in Chapter 3701:1-38 of the Administrative Code (rules 3701:1-38-01, -10, -12, -21) are being submitted for your review and comment. These rules contain a new definition of "Total Effective Dose Equivalent" and new requirements for reporting dose to occupational radiation workers.

Also being submitted are amendments to rules in Chapters 3701:1-40 and 3701:1-46 of the Administrative Code. The amendments were drafted due to the U.S. Nuclear Regulatory Commission's (NRC) new jurisdiction over naturally-occurring or accelerator-produced radioactive material (NARM). This new federal jurisdiction requires Ohio to amend or rescind rules dealing with exempt radioactive material. The NRC retains the sole regulatory authority over the distribution of exempt radioactive material.

The following rules will be rescinded:

3701:1-40-10
3701:1-46-13, -14, -16 through -26, Appendix to 3701:1-46-26, -27, -28, Appendix to 3701:1-46-28, -29

Please review the rules and provide any comments that you may have to the Bureau of Radiation Protection of the Ohio Department of Health at bradiation@odh.ohio.gov by August 22, 2008. Comments that are received will be forwarded to the Radioactive Materials Committee of the Radiation Advisory Council, who will consider all comments relative to further changes to the proposed rules. Following this action, the rules will then move through the formal adoption process via the Public Health Council.

NRC / ODH Crosswalk

Crosswalk		
NRC Rule	**ODH Rule**	**Title**
		RATS 2007-2
30.14	3701:1-40-08	Exempt concentrations
30.15	3701:1-40-09	Certain items containing radioactive material
30.16	3701:1-40-10	Resins containing scandium-46 and designed for sand-consolidation in oil wells **[Proposed for Rescission]**
30.18	3701:1-40-11	Exempt quantities
31.5	3701:1-46-05	Certain measuring, gauging or controlling devices
32.11	3701:1-46-13	Introduction of byproduct material, accelerator produced material, or radium in exempt concentrations into products or materials, and transfer of ownership or possession of accelerator produced material or radium in exempt concentrations: requirements for license **[To be proposed for rescission]**
32.12	3701:1-46-14	Introduction of byproduct material, accelerator produced material, or radium in exempt concentrations into products or materials, and transfer of ownership or possession of accelerator produced material or radium in exempt concentrations: records and material transfer reports **[To be proposed for rescission]**
32.13	3701:1-46-15	Introduction of radioactive material in exempt concentrations into products or materials, and transfer of ownership or possession of radioactive material in exempt concentrations: prohibition of introduction
32.14	3701:1-46-16	Certain items containing byproduct material, accelerator produced material or radium; requirements for license to apply **[To be proposed for rescission]**
32.15	3701:1-46-17	Certain items containing byproduct material, accelerator produced material or radium; quality assurance, prohibition of transfer, and labeling **[To be proposed for rescission]**
32.16	3701:1-46-18	Certain items containing byproduct material, accelerator produced material or radium: records and reports of transfer **[To be proposed for rescission]**
32.17	3701:1-46-19	Resins containing scandium-46 and designed for sand-consolidation in oil wells: requirements for license to manufacture, or initially transfer for sale or distribution **[To be proposed for rescission]**

Crosswalk		
NRC Rule	**ODH Rule**	**Title**
32.18	3701:1-46-20	Manufacture of exempt quantities of byproduct material, accelerator produced material, or radium: requirements for license **[To be proposed for rescission]**
32.19	3701:1-46-21	Manufacture of exempt quantities of byproduct material, accelerator produced material, or radium: conditions of license **[To be proposed for rescission]**
32.20	3701:1-46-22	Manufacture of exempt quantities of byproduct material accelerator produced material, or radium: records and material transfer reports **[To be proposed for rescission]**
32.21	3701:1-46-23	Radioactive drug: manufacture, preparation of capsules containing carbon-14 urea each for in-vivo diagnostic use for humans to persons exempt from licensing; requirements for a license **[To be proposed for rescission]**
32.21a	3701:1-46-24	Radioactive drug: manufacture, preparation of capsules containing carbon-14 urea each for in-vivo diagnostic use for humans to persons exempt from licensing: conditions of license **[To be proposed for rescission]**
32.22	3701:1-46-25	Self-luminous products containing tritium, krypton-85, or promethium-147: requirements for license to manufacture, process, produce **[To be proposed for rescission]**
32.23	3701:1-46-26	Self-luminous products containing tritium, krypton-85, or promethium-147: safety criteria **[To be proposed for rescission]**
32.24	3701:1-46-26 Appendix	Table of Organ Doses **[To be proposed for rescission]**
32.26	3701:1-46-27	Gas and aerosol detectors containing byproduct material, accelerator produced material, or radium: requirements for license to manufacture, process, produce, or initially transfer **[To be proposed for rescission]**
32.27	3701:1-46-28	Gas and aerosol detectors containing byproduct material, accelerator produced material, or radium: safety criteria **[To be proposed for rescission]**
32.28	3701:1-46-28 Appendix	Table of Organ Doses **[To be proposed for rescission]**

Crosswalk		
NRC Rule	**ODH Rule**	**Title**
32.40	3701:1-46-29	Schedule A - prototype tests for automobile lock illuminators **[To be proposed for rescission]**
32.51	3701:1-46-30	Radioactive material contained in devices for use under rule 3701:1-46-05 of the Administrative Code; requirements for license to manufacture, or initially transfer
32.24	3701:1-46-30 Appendix	Table of Organ Doses
		RATS 2008-1
20.1003	3701:1-38-01	Definitions
19.13	3701:1-38-10	Notices, instructions, and reports to workers
20.1201 and 20.2104	3701:1-38-12	Occupational dose limits
20.2205	3701:1-38-21	Reports

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) "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.

(6) "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.

(7) "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.

(8) "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.

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

(10) "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.

(11) "Airborne radioactive material" means radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

(12) "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~~ 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.

(13) "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.

(14) "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.

(15) "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.

(16) "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.

(17) "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.

(18) "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.

(19) "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.

(20) "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.

(21) "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.

(22) "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.

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

(24) "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.

(25) "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.

(26) "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.

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

(28) "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.

(29) "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.

(30) "Commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the natural environment of a site but does not include changes desirable for the temporary use of the land for public recreational uses, necessary borings to determine site characteristics or other preconstruction monitoring to establish background information related to the suitability of a site or to the protection of environmental values.

(31) "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.

(32) "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 ($H_{E,50} = \text{Sigma} W_T H_{T,50}$).

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

(34) "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.

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

(36) "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.

(37) "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.

(38) "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.

(39) "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.

(40) "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.

(41) "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.

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

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

(44) "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.

(45) "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.

(46) "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).

(47) "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.

~~(47)~~(48) "Director" means the director of health or a designee or authorized representative of the director.

~~(48)~~(49) "Discipline" means a branch of knowledge or of teaching.

~~(49)~~(50) "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.

~~(50)~~(51) "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.

~~(51)~~(52) "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.

~~(52)~~(53) "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.

~~(53)~~(54) "Dosimetry processor" means a person that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

~~(54)~~(55) "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$W_T H_T$).

~~(55)~~(56) "Embryo" or "fetus" means the developing human organism from conception until time of birth.

~~(56)~~(57) "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.

~~(57)~~(58) "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.

~~(58)~~(59) "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.

~~(59)~~(60) "Exposure" means being exposed to sources of ionizing radiation.

~~(60)~~(61) "External dose" means that portion of the dose equivalent received from radiation sources outside the body.

~~(61)~~(62) "Extremity" means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

~~(62)~~(63) "Eye dose equivalent" means the same as lens dose equivalent.

~~(63)~~(64) "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.

~~(64)~~(65) "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.

~~(65)~~(66) "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.

~~(66)~~(67) "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.

~~(67)~~(68) "Fit test" means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

~~(68)~~(69) "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.

~~(69)~~(70) "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).

~~(70)~~(71) "Handler" means a facility that handles sources of radiation unless possession is solely for the purpose of transportation.

~~(71)~~(72) "Hazardous waste" means those wastes designated as hazardous by rule 3745-51-03 of the Administrative Code.

~~(72)~~(73) "Helmet" means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

~~(73)~~(74) "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.

~~(74)~~(75) "Hood" means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

~~(75)~~(76) "Individual" means any human being.

~~(76)~~(77) "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.

~~(77)~~(78) "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.

~~(78)~~(79) "Industrial radiography" means the examination of the structure of materials by nondestructive methods, utilizing sealed sources of radioactive material or radiation-generating equipment.

~~(79)~~(80) "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

~~(80)~~(81) "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.

~~(81)~~(82) "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.

~~(82)~~(83) "License" means a license issued by the nuclear regulatory commission, the director, or another agreement state in accordance with rules adopted by those organizations.

~~(83)~~(84) "Licensee" means a person to whom a license is issued.

~~(84)~~(85) "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.

~~(85)~~(86) "Licensed material" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license.

~~(86)~~(87) "Loose-fitting facepiece" means a respiratory inlet covering that is designed to form a partial seal with the face.

~~(87)~~(88) "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.

~~(88)~~(89) "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.

~~(89)~~(90) "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 x A_2) per gram for solids and gases, and (0.00001 x 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 x A_2); and

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

~~(90)~~(91) "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.

~~(91)~~(92) "Medical institution" means an organization in which more than one medical discipline is practiced.

~~(92)~~(93) "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.

~~(93)~~(94) "Member of the public" means any individual except when that individual is receiving an occupational dose.

~~(94)~~(95) "Minor" means an individual less than eighteen years of age.

~~(95)~~(96) "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.

~~(96)~~(97) "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.

~~(97)~~(98) "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.

~~(98)~~(99) "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.

~~(99)~~(100) "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.

~~(100)~~(101) "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.

~~(101)~~(102) "Normal form radioactive material" means radioactive material that has not been demonstrated to qualify as special form radioactive material.

~~(102)~~(103) "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.

~~(103)~~(104) "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.

~~(104)~~(105) "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).

~~(105)~~(106) "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.

~~(106)~~(107) "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.

(108) "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.

~~(107)~~(109) "Pharmacist" means a person who is licensed by the state of Ohio to practice pharmacy pursuant to Chapter 4731. of the Revised Code.

~~(108)~~(110) "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.

~~(109)~~(111) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual dose limits.

~~(110)~~(112) "Podiatrist" means an individual licensed by the state of Ohio to practice podiatry pursuant to Chapter 4731. of the Revised Code.

~~(111)~~(113) "Positive pressure respirator" means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

~~(112)~~(114) "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.

~~(113)~~(115) "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.

~~(114)~~(116) "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.

~~(115)~~(117) "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.

~~(116)~~(118) "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.

~~(117)~~(119) "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.

~~(118)~~(120) "Quantitative fit test" or "QNFT" means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

~~(119)~~(121) "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.

~~(120)~~(122) "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.

~~(121)~~(123) "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.

~~(122)~~(124) "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.

~~(123)~~(125) "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.

~~(124)~~(126) "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.

~~(125)~~(127) "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.

~~(126)~~(128) "Radioactive waste" means waste containing regulated radioactive material.

~~(127)~~(129) "Radioactivity" means the transformation of unstable atoms by the emission of radiation.

~~(128)~~(130) "Radiography" means the same as industrial radiography.

~~(129)~~(131) "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.

~~(130)~~(132) "Registrant" means a person required by Chapter 3748. of the Revised Code to register radiation-generating equipment with the director.

~~(131)~~(133) "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).

~~(132)~~(134) "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.

~~(133)~~(135) "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).

~~(134)~~(136) "Respiratory protective equipment or device" means an apparatus, such as a respirator, used to reduce the individual's intake of airborne radioactive materials.

~~(135)~~(137) "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.

~~(136)~~(138) "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.

~~(137)~~(139) "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.

~~(138)~~(140) "Sealed source" means radioactive material that is encased in a manner designed to prevent leakage or escape of the radioactive material.

~~(139)~~(141) "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.

~~(140)~~(142) "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.

~~(141)~~(143) "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.

~~(142)~~(144) "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.

~~(143)~~(145) "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.

~~(144)~~(146) "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.

~~(145)~~(147) "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

~~(146)~~(148) "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.

~~(147)~~(149) "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.

~~(148)~~(150) "Sources of radiation" means radioactive material or radiation generating equipment.

~~(149)~~(151) "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.

~~(150)~~(152) "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.

~~(151)~~(153) "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. For example, the following quantities in combination would not exceed the limitation and are within the formula:

~~(152)~~(154) "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.

~~(153)~~(155) "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.

~~(154)~~(156) "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.

~~(155)~~(157) "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.

~~(156)~~(158) "Tight-fitting facepiece" means a respiratory inlet covering that forms a complete seal with the face.

~~(157)~~(159) "Total effective dose equivalent" or "TEDE" means the sum of the ~~deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.~~effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

~~(158)~~(160) "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).

~~(159)~~(161) "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.

~~(160)~~(162) "Type B quantity" means a quantity of radioactive material greater than a type A quantity.

~~(161)~~(163) "Type B package" is defined under ~~'package'.~~"Package."

~~(162)~~(164) "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).

~~(163)~~(165) "Unrestricted area" or "uncontrolled area" means any area, access to which is neither restricted nor controlled by the licensee or registrant.

~~(164)~~(166) "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.

~~(165)~~(167) "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.

~~(166)~~(168) "Veterinarian" means an individual licensed by the state of Ohio to practice veterinary medicine pursuant to Chapter 4741. of the Revised Code.

~~(167)~~(169) "Week" means seven consecutive days starting on Sunday.

~~(168)~~(170) "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.

~~(169)~~(171) "Whole body" means for purposes of external exposure, head; trunk, including male gonads; arms above the elbow; legs above the knee.

~~(170)~~(172) "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.

~~(171)~~(173) "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.

~~(172)~~(174) "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.)

~~(173)~~(175) "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.

3701:1-38-10 **Notices, instructions, and reports to workers.**

(A) Posting of notices to workers.

(1) Each licensee or registrant shall post current copies of the following documents:

(a) All applicable rules in this chapter;

(b) The license or certificate of registration, as applicable, any conditions or documents incorporated by reference into a license and amendments thereto;

(c) The safe operating procedures applicable to activities under the license or registration; and

(d) Any notice of violation involving radiological working conditions, proposed imposition of civil or administrative monetary penalty, or order issued pursuant to rule 3701:1-38-06 of the Administrative Code and any response from the licensee or registrant. Such document shall be posted within five working days after receipt of the document. The licensee's or registrant's response, if any, shall be posted within five working days after dispatch of the document to the department. Such documents shall remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.

(e) The Ohio department of health, bureau of radiation protection issued form entitled "Notice to Employees."

(2) If posting of a document specified in paragraphs (A)(1)(a) to (A)(1)(c) of this rule is not practical, the licensee or registrant may post a notice which describes the document and states where it may be readily examined.

(3) Documents, notices, or forms posted pursuant to paragraph (A) of this rule shall appear in a sufficient number of places to permit individuals engaged in licensed or registered activity under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

(B) Instruction to workers.

(1) The licensee or registrant shall, with respect to all individuals likely to receive an annual TEDE occupational dose in excess of one millisievert (one hundred millirem):

(a) Keep such individuals informed of the storage, transfer, or use of sources of radiation in the licensee's or registrant's workplace;

(b) Instruct such individuals in the health effects associated with exposure to radiation or radioactive material to the individual and potential offspring, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

(c) Instruct such individuals in, and instruct such individuals to observe, to the extent within the individual's control, the applicable provisions of this chapter and any license conditions for the protection of personnel from exposures to radiation or radioactive material;

(d) Instruct each such individual of his or her responsibility to report promptly to the licensee or registrant any condition which may constitute, lead to, or cause a violation of Chapter 3748. of the Revised Code, the rules promulgated thereunder, any license condition, or order, and any unnecessary exposure to radiation or radioactive material;

(e) Instruct such individuals in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and

(f) Advise such individuals of any radiation exposure reports furnished pursuant to paragraph (C) of this rule.

(2) In determining those individuals subject to the requirements of paragraph (B)(1) of this rule, licensees and registrants shall take into consideration assigned activities during normal and abnormal situations involving exposure to radiation and radioactive materials which can reasonably be expected to occur during the life of the facility. The extent of these instructions shall be commensurate with potential radiological health protection problems present in the workplace.

(C) Notifications and reports to individuals.

(1) Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in this rule. The information reported shall include data and results obtained pursuant to Chapter 3748. of the Revised Code or rules adopted thereunder, an order, or license condition as shown in records maintained by the licensee or registrant pursuant to paragraph (H) of rule 3701:1-38-20 of the Administrative Code. Each notification and report shall:

(a) Be in writing;

(b) Include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's identification number, preferably social security number;

(c) Include the individual's ~~dose~~exposure information; and

(d) Contain the statement: "This report is furnished to you under the provisions of rule 3701:1-38-10 of the Administrative Code. You should preserve this report for further reference."

(2) ~~Each licensee or registrant shall furnish to each worker annually a written report of the worker's dose as shown in records maintained by the licensee or registrant pursuant to paragraph (H) of rule 3701:1-38-20 of the Administrative Code.~~Each licensee or registrant shall make dose information available to workers as shown in records maintained by the licensee under the provisions of paragraph (H) of rule 3701:1-38-20 of the Administrative Code. The licensee or registrant shall provide an annual report to each individual monitored under rule 3701:1-38-14 of the Administrative Code, of the dose received in that monitoring year if:

(a) The individual's occupational dose exceeds one millisievert (one hundred millirem) TEDE or one millisievert (one hundred millirem) to any individual organ or tissue; or

(b) The individual requests his or her annual dose report.

~~(3) Each licensee or registrant shall furnish a written report of the worker's exposure to sources of radiation at the request of a worker formerly engaged in activities controlled by the licensee or registrant. The report shall include the dose record for each year the worker was required to be monitored pursuant to paragraph (B) of rule 3701:1-38-14 of the Administrative Code. Such report shall be furnished within thirty days from the date of the request, or within thirty days after the dose of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover the period of time that the worker's activities involved exposure to sources of radiation licensed or registered by the department and shall include the dates and locations of licensed or registered activities under the license or registration in which the worker participated during this period.~~

(3)

(a) At the request of a worker formerly engaged in activities controlled by the licensee or registrant, each licensee or registrant shall furnish to the worker a report of the worker's exposure to sources of radiation:

(i) As shown in records maintained by the licensee or registrant pursuant to rule 3701:1-38-20 of the Administrative Code for each year the worker

was required to be monitored under the provisions of rule 3701:1-38-14 of the Administrative Code; and

(ii) For each year the worker was required to be monitored under the monitoring requirements in effect prior to August 31, 1999.

(b) This report must be furnished within thirty days from the time the request is made or within thirty days after the exposure of the individual has been determined by the licensee or registrant, whichever is later. This report must cover the period of time that the worker's activities involved exposure to sources of radiation licensed or registered by the department and must include the dates and locations of licensed or registered activities in which the worker participated during this period.

(4) When a licensee or registrant is required pursuant to paragraphs (A) to (C) of rule 3701:1-38-21 of the Administrative Code to report to the department any exposure of an individual to sources of radiation, the licensee or the registrant shall also provide the individual a written report on the exposure data included ~~therein. Such reports shall~~in the report to the department. This report must be transmitted ~~at a time not~~no later than the transmittal to the department.

(5) At the request of a worker who is terminating employment with the licensee or registrant ~~in work involving~~that involved exposure to sources of radiation ~~or radioactive material, the~~during the current calendar quarter or the current year, each licensee or registrant shall provide ~~the~~at termination to each worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current calendar year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose ~~shall~~must be provided together with a clear indication that this is an estimate.

3701:1-38-12 **Occupational dose limits.**

(A) Except in the case of a planned special exposure pursuant to paragraph (F) of this rule, a licensee or registrant shall limit the occupational dose received by an individual adult, as follows:

(1) An annual limit, which is the more limiting of:

(a) The total effective dose equivalent being equal to 0.05 sievert~~, or~~ (five rem); or

(b) The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.5 sievert~~, or~~ (fifty rem).

(2) ~~The~~ The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are:

(a) A lens dose equivalent of 0.15 sievert~~, or~~ (fifteen rem), and

(b) A shallow-dose equivalent of 0.5 sievert~~, or~~ (fifty rem) to the skin of the whole body or to the skin of any extremity.

(3) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current calendar year and during the individual's lifetime in accordance with paragraph (F)(5) of this rule.

(4) ~~The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure:~~ When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the director. The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure.

(a) The assigned shallow-dose equivalent must be the dose averaged over the contiguous ten square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens-dose equivalent, and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable; or

(b) When a protective apron is worn while working with radiation-generating equipment and monitoring is conducted as specified in paragraph (C)(1) of rule 3701:1-38-14 of the Administrative Code, the effective dose equivalent for external radiation shall be determined as follows:

(i) When only one individual monitoring device is used and it is located at the neck outside the protective apron, the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation; or

(ii) When two individual monitoring devices are worn, one under the protective apron at the waist and the other outside the protective apron at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04; or

(iii) Through the use of computational methods endorsed by the "American National Standards Institute", recommended by the "National Council on Radiation Protection and Measurements", or approved by the director.

(5) Derived air concentration (DAC) and annual limit on intake (ALI) values are specified in appendix C ~~of~~to this rule and may be used by the licensee to determine the individual's dose and to demonstrate compliance with the occupational dose limits. Appendices A and B are explanatory supplements to appendix C. Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to ten milligrams in a week in consideration of chemical toxicity.

(6) In accordance with paragraph (E) of this rule, the licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person.

(B) Compliance with requirements for summation of external and internal doses shall be in accordance with the following:~~.~~

(1) If the licensee is required to monitor under both paragraphs (B)(1) and (B)(2) of rule 3701:1-38-14 of the Administrative Code, the licensee shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee is required to monitor only under paragraph (B)(1) or only under paragraph (B)(2) of rule 3701:1-38-14 of the Administrative Code, then

summation is not required to demonstrate compliance with the dose limits. The licensee may demonstrate compliance with the requirements for summation of external and internal doses by meeting one of the conditions specified in paragraph (B)(2) of this rule and the conditions in paragraphs (B)(3) and (B)(4) of this rule. The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

(2) If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, plus one of the following does not exceed unity:

(a) The sum of the fractions of the inhalation ALI for each radionuclide; or

(b) The total number of derived air concentration-hours, or DAC-hours, for all radionuclides divided by two thousand; or

(c) The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, W_T, and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than ten per cent of the maximum weighted value of $H_{T,50}$, that is, $W_T H_{T,50}$, per unit intake for any organ or tissue.

(3) If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than ten percent of the applicable oral ALI, the licensee shall account for this intake and include it in demonstrating compliance with the limits set forth in paragraph (A) of this rule.

(4) The licensee shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be further evaluated or accounted for pursuant to this paragraph.

(C) Determination of external dose from airborne radioactive material shall be in accordance with the following:

(1) When determining the dose from airborne radioactive material, the licensee shall include the contribution to the deep dose equivalent, lens dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud as specified in appendix C to this rule, footnotes [A] and [B].

(2) The licensee should not use airborne radioactivity measurements or DAC values as the primary means to assess the deep dose equivalent when the airborne

radioactive material includes radionuclides other than noble gases, or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual should be based upon measurements using instruments or individual monitoring devices.

(D) Determination of internal exposure shall be in accordance with the following:

(1) For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required under paragraph (B) of rule 3701:1-38-14 of the Administrative Code, take suitable and timely measurements of:

(a) Concentrations of radioactive materials in air in work areas; or

(b) Quantities of radionuclides in the body; or

(c) Quantities of radionuclides excreted from the body; or

(d) Combinations of these measurements.

(2) Unless respiratory protective equipment is used, as provided in paragraph (C) of rule 3701:1-38-16 of the Administrative Code or the assessment of intake is based on bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

(3) When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee may:

(a) Use that information to calculate the committed effective dose equivalent, and, if used, the licensee shall document that information in the individual's record; and

(b) Upon prior approval of the department, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and

(c) Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent as specified in appendix A of this rule.

(4) If the licensee chooses to assess intakes of Class Y material using the measurements given in paragraph (D)(1)(b) or (D)(1)(c) of this rule in order to make additional measurements basic to the assessments, the licensee may delay the recording and reporting of the assessments for periods up to seven months,

unless otherwise required by paragraph (B)(2) or (C) of rule ~~3701:1-38-02.1~~ 3701:1-38-21 of the Administrative Code.

(5) If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be either:

(a) The sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from appendix C ~~of~~to this rule for each radionuclide in the mixture; or

(b) The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

(6) If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall by the most restrictive DAC of any radionuclide in the mixture.

(7) When a mixture of radionuclides in air exists, a licensee may disregard certain radionuclides in the mixture if all of the following occur:

(a) The licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in paragraph (A) of this rule and in complying with the monitoring requirements in paragraph (B) of rule 3701:1-38-14 of the Administrative Code;

(b) The concentration of any radionuclide disregarded is less than ten percent of its DAC; and

(c) The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed thirty percent.

(8) When determining the committed effective dose equivalent, the licensee may consider the following:

(a) In order to calculate the committed effective dose equivalent, the licensee may assume that the inhalation of one ALI, or an exposure of two thousand DAC-hours, results in a committed effective dose equivalent of 0.05 sievert~~, or~~ (five rem), for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent; or

(b) For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 0.5 sievert~~, or~~ (fifty rem), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 ~~Sv, or~~sievert - (five rem), that is, the stochastic ALI, is listed in parentheses in table I of appendix C ~~of~~to this rule. The licensee may, as a simplifying assumption,

use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee uses the stochastic ALI, the licensee shall also demonstrate that the limit in paragraph (A)(1)(b) of this rule is met.

(E) Determination of prior occupational dose shall be made in accordance with the following:

(1) For each individual who ~~may enter the licensee's or registrant's restricted area and~~ is likely to receive~~, in a year,~~ an annual occupational dose requiring monitoring pursuant to paragraph (B) of rule 3701:1-38-14 of the Administrative Code, the licensee or registrant shall determine the occupational radiation dose received during the current year.

(2) Prior to permitting an individual to participate in a planned special exposure, the licensee shall determine:

(a) The internal and external doses from all previous planned special exposures; and

(b) All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual.

(3) In complying with the requirements of paragraphs (E)(1) ~~and~~or (E)~~(2e)~~(2) of this rule, a licensee or registrant may:

(a) Accept, as a record of the occupational dose that the individual received during the current year, a written signed statements from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual may have received during the current year;

(b) Accept, as the record of lifetime cumulative radiation dose, a current department form entitled "lifetime occupational exposure history" or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant; and

(c) Obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant, by telephone, telegram, facsimile, e-mail or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

(4) The licensee or registrant shall record the exposure history, as required by paragraph (A) of this rule, on a form provided by the department or other clear and legible record, of all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing the exposure history form. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on the exposure history form indicating the periods of time for which data are not available. ~~Licensees or registrants are not required to partition historical dose between external dose equivalent and internal committed dose equivalent. Further, occupational exposure histories obtained and recorded on the exposure history form prior to the effective date of this rule, might not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.~~

(5) If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:

(a) In establishing administrative controls pursuant to paragraph (A)(6) of this rule for the current year, that the allowable dose limit for the individual is reduced by 12.5 millisievert~~, or~~ (1.25 rem), for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

(b) That the individual is not available for planned special exposures.

(6) The licensee or registrant shall retain the records on the exposure history form until the department terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing the exposure history form for three years after the record is made.

(F) A planned special exposure may be authorized by a licensee in accordance with this paragraph. A licensee may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in paragraph (A) of this rule provided that each of the following is satisfied:

(1) The licensee authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the higher exposure are unavailable or impractical;

(2) The licensee and employer, if the employer is not the licensee, specifically authorizes the planned special exposure, in writing, before the exposure occurs;

(3) Before a planned special exposure, the licensee ensures that each individual involved is:

(a) Informed of the purpose of the planned operation; and

(b) Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

(c) Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present;

(4) Prior to permitting an individual to participate in a planned special exposure, the licensee ascertains prior doses as required by paragraph (E)(2) of this rule during the lifetime of the individual for each individual involved;

(5) The licensee shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

(a) The numerical values of any of the dose limits in paragraph (A) of this rule in any calendar year; and

(b) Five times the annual dose limits specified in paragraph (A) of this rule during the individual's lifetime;

(6) The licensee maintains records of the conduct of a planned special exposure in accordance with paragraph (E) of rule 3701:1-38-20 of the Administrative Code and submits a written report in accordance with paragraph (D) of rule 3701:1-38-21 of the Administrative Code;

(7) The licensee records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within thirty days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to paragraph (A)(1) of this rule, but shall be included in evaluations required by paragraphs (F)(4) and (F)(5) of this rule.

(G) Occupational dose limits for minors shall be ten per cent of the annual occupational dose limits specified for adult workers in paragraph (A) of this rule.

(H) Dose equivalent to an embryo or fetus shall be in accordance with the following:

(1) The licensee or registrant shall ensure that the dose equivalent to an embryo or fetus during the entire pregnancy, due to occupational exposure of a declared

pregnant woman, does not exceed five millisievert~~, or~~ (0.5 rem). Records shall be maintained in accordance with paragraph (I) of rule 3701:1-38-20 of the Administrative Code.

(2) The licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in paragraph (H)(1) of this rule.

(3) The dose equivalent to the embryo or fetus is the sum of:

(a) The deep-dose equivalent to the declared pregnant woman; and

(b) The dose equivalent to the embryo or fetus resulting from radionuclides in the embryo or fetus and from radionuclides in the declared pregnant woman.

(4) If the declared pregnant woman's exposure includes exposure from radiation generating equipment and a protective apron is worn, the dose equivalent to an embryo or fetus shall be taken as the sum of:

(a) The dose equivalent to the embryo or fetus from radionuclides in the embryo or fetus and radionuclides in the declared pregnant woman; and

(b) The dose equivalent that is most representative of the dose to the embryo or fetus from external radiation, that is, in the mother's lower torso region.

(i) If multiple measurements have not been made, assignment of the highest deep dose equivalent for the declared pregnant woman shall be the dose to the embryo or fetus, in accordance with paragraph (A)(4) of this rule; or

(ii) If multiple measurements have been made, assignment of the deep dose equivalent for the declared pregnant woman from the individual monitoring device which is most representative of the dose to the embryo or fetus shall be the dose to the embryo or fetus. Assignment of the highest deep dose equivalent for the declared pregnant woman to the embryo or fetus is not required unless that dose is also the most representative deep dose equivalent for the region of the embryo or fetus.

(5) If by the time the woman declares pregnancy to the licensee or registrant, the dose equivalent to the embryo or fetus has exceeded five millisievert, or 0.5 rem, the licensee or registrant shall be deemed to be in compliance with paragraph (A) of this rule, provided that the additional dose equivalent to the embryo or fetus does not exceed 0.5 millisievert~~, or~~ (0.05 rem), during the remainder of the pregnancy.

*** DRAFT – NOT FOR FILING ***

3701:1-38-21 **Reports.**

(A) The licensee or registrant shall report stolen, lost, or missing licensed or registered sources of radiation to the department in accordance with the following:

(1) Telephone reports shall be made as follows:

(a) To the bureau of radiation protection point of contact (POC) in accordance with the form "Notice to Employees" issued by the director.

(b) In the case of a licensee, he or she shall make contact:

(i) Immediately after the licensee determines that licensed radioactive material is stolen, lost, or missing in an aggregate quantity equal to or greater than one hundred times the quantity specified in appendix A to rule 3701:1-38-18 of the Administrative Code under such circumstances that it appears to the licensee that an exposure could result to individuals in unrestricted areas;

(ii) Within thirty days after its occurrence becomes known to the licensee, lost, stolen, or missing licensed radioactive material in an aggregate quantity greater than ten times the quantity specified in appendix A to rule 3701:1-38-18 of the Administrative Code that is still missing.

(c) In the case of a registrant, he or she shall make contact immediately after a stolen, lost, or missing radiation generating equipment becomes known to the registrant.

(2) Written reports shall be made as follows:

(a) Each licensee or registrant required to make a report pursuant to paragraph (A)(1) of this rule shall, within thirty days after making the telephone report, make a written report to the department setting forth the following information, where applicable:

(i) A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form, and in the case of radiation-generating equipment, the manufacturer, model and serial number, type and maximum energy of the radiation emitted;

(ii) A description of the circumstances under which the loss or theft occurred;

(iii) A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved;

(iv) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;

(v) Actions that have been taken, or will be taken, to recover the source of radiation; and

(vi) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

(b) Subsequent to filing the written report, the licensee or registrant shall also report additional substantive information on the loss or theft within thirty days after the licensee or registrant learns of such information.

(c) The licensee or registrant shall prepare any report filed with the department pursuant to this rule so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

(B) Notification of incidents shall be made as follows:

(1) Excluding prescribed medical doses to patients, each licensee or registrant shall immediately report each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

(a) An individual receiving:

(i) A total effective dose equivalent of 0.25 sievert (twenty-five rem) or more;

(ii) A lens dose equivalent of 0.75 sievert (seventy-five rem) or more; or

(iii) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 2.5 gray (two hundred fifty rad) or more; or

(b) The release of radioactive material, inside or outside of a restricted area that, had an individual been present for twenty-four hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

(2) Each licensee or registrant shall report to the department, within twenty-four hours of discovery, each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following:

(a) An individual to receive, in a period of twenty-four hours:

(i) A total effective dose equivalent exceeding 0.05 sievert (-five rem);

(ii) An lens dose equivalent exceeding 0.15 sievert (fifteen rem); or

(iii) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 0.5 sievert (fifty rem); or

(b) The release of radioactive material, inside or outside of a restricted area that, had an individual been present for twenty-four hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

(3) Licensees or registrants shall make the reports required by paragraphs (B)(1) and (B)(2) of this rule to the POC by telephone to the department and shall confirm the initial contact by telegram, mailgram, electronic mail, or facsimile to the department.

(4) The licensee or registrant shall prepare each report filed with the department pursuant to this rule so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

(5) The provisions of paragraph (B) of this rule do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported in accordance with this paragraph.

(C) Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the limits shall be made by the licensee or registrant as follows:

(1) Reportable events that are specified in this paragraph shall, in addition to the notification requirements in paragraph (B) of this rule, be reported to the department in writing within thirty days after learning of any of the following occurrences:

(a) Incidents for which notification is required by paragraph (B) of this rule and with doses in excess of any of the following:

(i) The occupational dose limits for adults in paragraphs (A)(1) and (A)(2) of rule 3701:1-38-12 of the Administrative Code;

(ii) The occupational dose limits for a minor in paragraph (G) of rule 3701:1-38-12 of the Administrative Code;

(iii) The limits for an embryo or fetus of a declared pregnant woman in paragraph (H) of rule 3701:1-38-12 of the Administrative Code;

(iv) The limits for an individual member of the public in paragraph (A) of rule 3701:1-38-13 of the Administrative Code;

(v) Any applicable limit in the license or registration; or

(vi) The ALARA constraints for air emissions established under paragraph (D)(4) of rule 3701:1-38-11 of the Administrative Code; or

(b) Levels of radiation or concentrations of radioactive material in:

(i) A restricted area in excess of applicable limits in the license or registration; or

(ii) An unrestricted area in excess of ten times the applicable limit set forth in this chapter or in the license or registration, whether or not involving exposure of any individual in excess of the limits in paragraph (A) of rule 3701:1-38-13 of the Administrative Code; or

(c) For licensees subject to the provisions of the United States environmental protection agency generally applicable environmental radiation standards in 40 C.F.R. 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

(2) Each report required by this rule shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(a) Estimates of each individual's dose, the level of radiation and concentration of radioactive material involved, and the cause of the elevated exposure, dose rate, or concentration; and

(b) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license or registration conditions.

(3) Each report filed pursuant to this rule shall include, for each occupationally overexposed individual, the name, social security account number, and date of birth of the individual. In the case of the limit for an embryo or fetus in paragraph (H) of rule 3701:1-38-12 of the Administrative Code, the identifiers

should be those of the declared pregnant woman. The report shall be prepared so that information on each individual is stated in a separate and detachable portion of the report.

(4) All licensees or registrants who make reports pursuant to this rule shall submit the report in writing to the department.

(D) Reports of planned special exposures shall be submitted by the licensee in a written report to the department within thirty days following any planned special exposure conducted in accordance with paragraph (F) of rule 3701:1-38-12 of the Administrative Code, informing the department that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by paragraph (G) of rule 3701:1-38-20 of the Administrative Code.

(E) When a licensee or registrant is required pursuant to ~~paragraph~~paragraphs (C) or (D) of this rule to report to the department any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, the licensee or registrant shall also ~~notify~~ provide the individual a report on his or her exposure data included in the report to director. ~~Such notice~~This report shall be transmitted ~~at a time not~~no later than the transmittal to the department, and shall comply with the provisions of paragraph (C)(1) of rule 3701:1-38-10 of the Administrative Code.

(F) A report of a leaking or contaminated sealed source shall be filed by the licensee with the department within five days of the test results, if the test reveals the presence of one hundred eighty-five becquerels (0.005 microcurie) or more of removable contamination. The report shall include the equipment involved, the test results and the corrective action taken.

3701:1-40-08 **Exempt concentrations.**

(A) Except as may be required in paragraphs (C) and (D) of this rule, ~~a~~any person is exempt from the ~~license~~ requirements for a license set forth in this chapter ~~or~~ and Chapters 3701:1-46, 3701:1-48, 3701:1-49, 3701:1-52, and 3701:1-58 of the Administrative Code to the extent that such person receives, possesses, uses, transfers, owns, or acquires products or materials containing ~~byproduct or accelerator produced~~radioactive material in concentrations that do not exceed those listed in the appendix to this rule.

(B) This rule shall not be deemed to authorize the import of ~~byproduct~~radioactive material or products containing ~~byproduct~~radioactive material. ~~Import of NARM or products containing NARM shall be able to meet requirements of Chapter 3748. of the Revised Code or any rules adopted thereunder, as applicable, and transportation regulations in Title 49 of the Code of Federal Regulations.~~

(C) A manufacturer, processor, or producer of a product or material ~~in an agreement state, a state regulated by the United States nuclear regulatory commission, or a NARM licensing state~~ is exempt from the requirements for a license set forth in this chapter and from the rules in this chapter and Chapters 3701:1-46, 3701:1-48, 3701:1-49, 3701:1-52, and 3701:1-58 of the Administrative Code to the extent that the ~~manufacturer, processor, or producer of a product or material~~person transfers ~~byproduct or accelerator produced~~radioactive material contained in a product or material in concentrations not in excess of those specified in the appendix to this rule and introduced into the product or material by a licensee holding a specific license issued by an agreement state, the United States nuclear regulatory commission, ~~a NARM licensing state,~~ or the director, ~~or the atomic energy commission~~ expressly authorizing such introduction. This exemption does not apply to the transfer of ~~byproduct or accelerator produced~~ radioactive material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(D) No person may introduce ~~byproduct~~radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under this rule, except in accordance with a license issued ~~pursuant to rule 3701:1-46-13 of the Administrative Code or the general license provided in rule 3701:1-40-28 of the Administrative Code~~by the United States nuclear regulatory commission.

3701:1-40-09 **Certain items containing ~~byproduct or accelerator produced~~ radioactive material.**

(A) Except for ~~a person~~persons who ~~applies byproduct or accelerator produced~~apply radioactive material to, or ~~a person~~persons who ~~incorporates~~incorporate ~~byproduct or accelerator produced~~radioactive material into, the following products, or persons who initially transfer for sale or distribution the following products containing ~~byproduct or accelerator produced~~radioactive material, ~~a~~any person is exempt from the ~~license~~ requirements for a license set forth in this chapter and ~~Chapters~~ 3701:11-38, 3701:1-46, 3701:1-48, 3701:1-49, 3701:1-52, and 3701:1-58 of the Administrative Code to the extent that such person receives, possesses, uses, transfers, owns, or acquires the following products:

(1) Timepieces or hands or dials containing not more than the following specified quantities of ~~byproduct or accelerator produced~~radioactive material and not exceeding the following specified levels of radiation:

(a) Nine hundred twenty-five megabecquerels (twenty-five millicuries) of tritium per timepiece,

(b) One hundred eighty-five megabecquerels (five millicuries) of tritium per hand,

(c) Five hundred fifty-five megabecquerels (fifteen millicuries) of tritium per dial (bezels when used shall be considered as part of the dial),

(d) 3.7 megabecquerels (one hundred microcuries) of promethium-147 per watch or 7.4 megabecquerels (two hundred microcuries) of promethium-147 per any other timepiece,

(e) Seven hundred forty kilobecquerels (twenty microcuries) of promethium-147 per watch hand or one thousand four hundred eighty kilobecquerels (forty microcuries) of promethium-147 per other timepiece hand,

(f) Two thousand two hundred twenty kilobecquerels (sixty microcuries) of promethium-147 per watch dial or 4.44 megabecquerels (one hundred twenty microcuries) of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial), and

(g) The levels of radiation from hands and dials containing promethium-147 will not exceed, when measured through fifty milligrams per square centimeter of absorber:

(i) For wrist watches, one nanogray (0.1 millirad) per hour ~~(0.1 millirad per hour)~~ at ten centimeters from any surface,

(ii) For pocket watches, one nanogray (0.1 millirad) per hour ~~(0.1 millirad per hour)~~ at one centimeter from any surface, and

(iii) For any other timepiece, two nanogray (0.2 millirad) per hour ~~(0.2 millirad per hour)~~ at ten centimeters from any surface.

(h) ~~For timepieces containing radium, thirty seven~~ Thirty-seven kilobecquerels (one microcurie) of radium-226 per timepiece in intact timepieces - manufactured ~~acquired~~ prior to July 22, 2001.

~~(2) Lock illuminators containing not more than five hundred fifty five megabecquerels (fifteen millicuries) of tritium or not more than seventy four megabecquerels (two millicuries) of promethium 147 installed in automobile locks. The levels of radiation from each lock illuminator containing promethium 147 will not exceed ten nanogray per hour (one millirad per hour) at one centimeter from any surface when measured through fifty milligrams per square centimeter of absorber.~~

~~(3)~~(2) Balances of precision containing not more than thirty-seven megabecquerels (one millicurie) of tritium per balance or not more than 18.5 megabecquerels (0.5 millicurie) of tritium per balance part manufactured before December 17, 2007.

~~(4) Automobile shift quadrants containing not more than nine hundred twenty five megabecquerels (twenty five millicuries) of tritium.~~

~~(5)~~(3) Marine compasses containing not more than 27.75 gigabecquerels (seven hundred fifty millicuries) of tritium gas and other marine navigational instruments containing not more than 9.25 gigabecquerels (two hundred fifty millicuries) of tritium gas manufactured before December 17, 2007.

~~(6) Thermostat dials and pointers containing not more than nine hundred twenty five megabecquerels (twenty five millicuries) of tritium per thermostat.~~

(4) Ionization chamber smoke detectors containing not more than thirty-seven kilobecquerels (one microcurie) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

~~(7)~~(5) Electron tubes: provided, that each tube does not contain more than one of the following specified quantities of byproduct material:

(a) 5.55 gigabecquerels (one hundred fifty millicuries) of tritium per microwave receiver protector tube or three hundred seventy megabecquerels (ten millicuries) of tritium per any other electron tube;

(b) Thirty-seven kilobecquerels (one microcurie) of cobalt-60;

(c) One hundred eighty-five kilobecquerels (five microcuries) of nickel-63;

(d) –One thousand one hundred ten kilobecquerels (thirty microcuries) of krypton-85;

(e) One hundred eighty-five kilobecquerels (five microcuries) of cesium-137; ~~and~~or

(f) –One thousand one hundred ten kilobecquerels (thirty microcuries) of promethium-147;

And provided further, that the levels of radiation from each electron tube containing ~~byproduct or accelerator produced~~radioactive material do not exceed ten nanogray (one millirad) per hour ~~(one millirad per hour)~~ at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber. For purposes of this paragraph, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

~~(8)~~(6) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of ~~byproduct or accelerator produced~~radioactive material, provided that:

(a) Each source contains no more than one exempt quantity as set forth in the appendix to rule 3701:1-40-11 of the Administrative Code; and

(b) Each instrument contains no more than ten exempt quantities. For the purposes of this paragraph ~~(A)(8)(a) of this rule~~, an instrument's source may contain either one type or different types of radionuclides, and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in the appendix to rule 3701:1-40-11 of ~~this chapter~~the Administrative Code, –provided that the sum of such fractions shall not exceed unity.

(c) For purposes of this paragraph, 1.85 kilobecquerels (0.05 microcurie) of americium-241 is considered an exempt quantity under the appendix to rule 3701:1-40-11 of the Administrative Code.

~~(9) Spark gap irradiators containing not more than thirty-seven kilobecquerels (one microcurie) of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 11.4 liters per hour (three gallons per hour).~~

~~(10) The following materials are exempt from licensure if they meet the criteria for free release:~~

~~(a) A component of a particle accelerator that becomes radioactive as part of the particle accelerator operation unless the radioactive component is removed from the immediate proximity of the particle accelerator, or is altered in physical or chemical form.~~

~~(b) Products or materials containing quantities of NARM that are exempt from licensure and that are distributed in accordance with a specific license or an equivalent license issued by a NARM licensing state, agreement state, or the United States nuclear regulatory commission.~~

(B) Any person who desires to apply ~~byproduct or accelerator produced~~radioactive material to, or to incorporate ~~byproduct or accelerator produced~~radioactive material into, the products exempted in paragraph (A) of this rule, or who desires to initially transfer for sale or distribution such products containing ~~byproduct or accelerator produced~~radioactive material, shall apply for a specific license issued by the United States nuclear regulatory commission. ~~pursuant to rule 3701:1-46-16 of the Administrative Code. A license to distribute exempt quantities of atomic energy act material must be obtained from the United States nuclear regulatory commission.~~

3701:1-40-10 **Resins containing scandium-46 and designed for sand-consolidation in oil wells.**

A person is exempt from the license requirements set forth in this chapter, and Chapters 3701:1-38, 3701:1-46, 3701:1-48, 3701:1-49, 3701:1-52, and 3701:1-58 of the Administrative Code to the extent that such person receives, possesses, uses, transfers, owns, or acquires synthetic plastic resins containing scandium-46 which are designed for sand-consolidation in oil wells, and which have been manufactured or initially transferred for sale or distribution, in accordance with a specific license issued for manufacturing and distribution under Chapter 3701:1-46 of the Administrative Code or equivalent regulations of an agreement state, or the United States nuclear regulatory commission. The exemption in this section does not authorize the manufacture or initial transfer for sale or distribution of any resins containing scandium-46.

3701:1-40-11 **Exempt quantities.**

(A) Except as ~~may be required in paragraph (B) or (C)~~provided in paragraphs (C) to (E) of this rule, ~~a~~any person is exempt from the requirements for a license ~~requirements~~ set forth in this chapter and from the rules in Chapters 3701:1-46, 3701:1-48, 3701:1-49, and 3701:1-52 of the Administrative Code, to the extent that such person receives, possesses, uses, transfers, owns, or acquires ~~byproduct or accelerator produced~~radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in the appendix to this rule.

(B) Any person who possesses radioactive material received or acquired before September 25, 1971, under the general license then provided in 10 C.F.R. section 31.4 or similar general license of a state, is exempt from the requirements for a license set forth in this chapter and from the rules in Chapters 3701:1-46, 3701:1-48, 3701:1-49, and 3701:1-52 of the Administrative Code, to the extent that this person possesses, uses, transfers, or owns radioactive material.

~~(B)~~(C) This rule does not ~~exempt from licensure the~~authorize for purposes of commercial distribution~~,~~ the production, packaging, repackaging, or transfer of ~~byproduct or accelerator produced~~radioactive material or the incorporation of ~~byproduct or accelerator produced~~radioactive material into products intended for commercial distribution.

~~(C)~~(D) No person ~~shall~~may, for purposes of commercial distribution, transfer ~~byproduct or accelerator produced~~radioactive material in the individual quantities set forth in the appendix to this rule, knowing or having reason to believe that such quantities of ~~byproduct or accelerator produced~~radioactive material will be transferred to persons exempt under this chapter or equivalent regulations of an agreement state~~, NARM licensing state,~~ or the United States nuclear regulatory commission, except in accordance with a license, issued by the United States nuclear regulatory commission ~~under rule 3701:1-46-20 of the Administrative Code~~, which states that the ~~byproduct or accelerator produced~~radioactive material may be transferred by the licensee to persons exempt under this rule or the equivalent regulations of an agreement state~~, NARM licensing state,~~ or the United States nuclear regulatory commission.

~~(D) This rule does not authorize:~~

~~(1) The bundling of exempt quantities of byproduct or accelerator produced material;~~

~~(2) Any program advising persons to combine exempt quantity sources; or~~

~~(3) The possession and use of bundled, exempt sources, in unregistered devices, by persons exempt from licensing.~~

(E) No person may, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits set forth in the appendix to this rule, except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the rules in this chapter.

APPENDIX

EXEMPT QUANTITIES

RADIONUCLIDE	BECQUERELS (kBq)	MICROCURIES (μCi)
Antimony 122 (Sb 122)	3700	100
Antimony 124 (Sb 124)	370	10
Antimony 125 (Sb 125)	370	10
Arsenic 73 (As 73)	3700	100
Arsenic 74 (As 74)	370	10
Arsenic 76 (As 76)	370	10
Arsenic 77 (As 77)	3700	100
Barium 131 (Ba 131)	370	10
Barium 133 (Ba 133)	370	10
Barium 140 (Ba 140)	370	10
Bismuth 210 (Bi 210)	37	1
Bromine 82 (Br 82)	370	10
Cadmium 109 (Cd 109)	370	10
Cadmium 115m (Cd 115M)	370	10
Cadmium 115 (Cd 115)	3700	100
Calcium 45 (Ca 45)	370	10
Calcium 47 (Ca 47)	370	10
Carbon 14 (C 14)	3700	100
Cerium 141 (Ce 141)	3700	100
Cerium 143 (Ce 143)	3700	100
Cerium 144 (Ce 144)	37	1
*Cesium 129 (Cs 129)	3700	100

Cesium 131 (Cs 131)	37000	1,000
Cesium 134m (Cs 134m)	3700	100
Cesium 134 (Cs 134)	37	1
Cesium 135 (Cs 135)	370	10
Cesium 136 (Cs 136)	370	10
Cesium 137 (Cs 137)	370	10
Chlorine 36 (Cl 36)	370	10
Chlorine 38 (Cl 38)	370	10
Chromium 51 (Cr 51)	37000	1,000
*Cobalt 57 (Co 57)	3700	100
Cobalt 58m (Co 58m)	370	10
Cobalt 58 (Co 58)	370	10
Cobalt 60 (Co 60)	37	1
Copper 64 (Cu 64)	3700	100
Dysprosium 165 (Dy 165)	370	10
Dysprosium 166 (Dy 166)	3700	100
Erbium 169 (Er 169)	3700	100
Erbium 171 (Er 171)	3700	100
Europium 152 (Eu 152) 9.2 h	3700	100
Europium 152 (Eu 152) 13 yr	37	1
Europium 154 (Eu 154)	37	1
Europium 155 (Eu 155)	370	10
Fluorine 18 (F 18)	37000	1,000
Gadolinium 153 (Gd 153)	370	10
Gadolinium 159 (Gd 159)	3700	100
*Gallium 67 (Ga 67)	3700	100
Gallium 72 (Ga 72)	370	10
*Germanium 68 (Ge 68)	370	10

Germanium 71 (Ge71)	3700	100
*Gold 195 (Au 195)	370	10
Gold 198 (Au 198)	3700	100
Gold 199 (Au 199)	3700	100
Hafnium 181 (Hf 181)	370	10
Holmium 166 (Ho 166)	3700	100
Hydrogen 3 (H 3)	37000	1,000
*Indium 111 (In 111)	3700	100
Indium 113M (In 113M)	3700	100
Indium 114M (In 114M)	370	10
Indium 115M (In 115M)	3700	100
Indium 115 (In 115)	370	10
*Iodine 123 (I 123)	3700	100
Iodine 125 (I 125)	37	1
Iodine 126 (I 126)	37	1
Iodine 129 (I 129)	3.7	0.1
Iodine 131 (I 131)	37	1
Iodine 132 (I 132)	370	10
Iodine 133 (I 133)	37	1
Iodine 134 (I 134)	370	10
Iodine 135 (I 135)	370	10
Iridium 192 (Ir 192)	370	10
Iridium 194 (Ir 194)	3700	100
*Iron 52 (Fe 52)	370	10
Iron 55 (Fe 55)	3700	100
Iron 59 (Fe 59)	370	10
Krypton 85 (Kr 85)	3700	100
Krypton 87 (Kr 87)	370	10

Lanthanum 140 (La 140)	370	10
Lutetium 177 (Lu 177)	3700	100
Manganese 52 (Mn 52)	370	10
Manganese 54 (Mn 54)	370	10
Manganese 56 (Mn 56)	370	10
Mercury 197m (Hg 197m)	3700	100
Mercury 197 (Hg 197)	3700	100
Mercury 203 (Hg 203)	370	10
Molybdenum 99 (Mo 99)	3700	100
Neodymium 147 (Nd 147)	3700	100
Neodymium 149 (Nd 149)	3700	100
Nickel 59 (Ni 59)	3700	100
Nickel 63 (Ni 63)	370	10
Nickel 65 (Ni 65)	3700	100
Niobium 93m (Nb 93m)	370	10
Niobium 95 (Nb 95)	370	10
Niobium 97 (Nb 97)	370	10
Osmium 185 (Os 185)	370	10
Osmium 191m (Os 191m)	3700	100
Osmium 191 (Os 191)	3700	100
Osmium 193 (Os 193)	3700	100
Palladium 103 (Pd 103)	3700	100
Palladium 109 (Pd 109)	3700	100
Phosphorus 32 (P 32)	370	10
Platinum 191 (Pt 191)	3700	100
Platinum 193m (Pt 193m)	3700	100
Platinum 193 (Pt 193)	3700	100
Platinum 197m (Pt 197m)	3700	100

Platinum 197 (Pt 197)	3700	100
Polonium 210 (Po 210)	3.7	0.1
Potassium 42 (K 42)	370	10
*Potassium 43 (K 43)	370	10
Praseodymium 142 (Pr 142)	3700	100
Praseodymium 143 (Pr 143)	3700	100
Promethium 147 (Pm 147)	370	10
Promethium 149 (Pm 149)	370	10
*Radium 224, 226, 228 (Ra 224, 226, 228)	3.7	0.1
Rhenium 186 (Re 186)	3700	100
Rhenium 188 (Re 188)	3700	100
Rhodium 103m (Rh 103m)	3700	100
Rhodium 105 (Rh 105)	3700	100
*Rubidium 81 (Rb 81)	370	10
Rubidium 86 (Rb 86)	370	10
Rubidium 87 (Rb 87)	370	10
Ruthenium 97 (Ru 97)	3700	100
Ruthenium 103 (Ru 103)	370	10
Ruthenium 105 (Ru 105)	370	10
Ruthenium 106 (Ru 106)	37	1
Samarium 151 (Sm 151)	370	10
Samarium 153 (Sm 153)	3700	100
Scandium 46 (Sc 46)	370	10
Scandium 47 (Sc 47)	3700	100
Scandium 48 (Sc 48)	370	10
Selenium 75 (Se 75)	370	10
Silicon 31 (Si 31)	3700	100
Silver 105 (Ag 105)	370	10

Silver 110m (Ag 110m)	37	1
Silver 111 (Ag 111)	3700	100
*Sodium 22 (Na 22)	370	10
Sodium 24 (Na 24)	370	10
Strontium 85 (Sr 85)	370	10
Strontium 89 (Sr 89)	37	1
Strontium 90 (Sr 90)	3.7	0.1
Strontium 91 (Sr 91)	370	10
Strontium 92 (Sr 92)	370	10
Sulphur 35 (S 35)	3700	100
Tantalum 182 (Ta 182)	370	10
Technetium 96 (Tc 96)	370	10
Technetium 97m (Tc 97m)	3700	100
Technetium 97 (Tc 97)	3700	100
Technetium 99m (Tc 99m)	3700	100
Technetium 99 (Tc 99)	370	10
Tellurium 125m (Te 125m)	370	10
Tellurium 127m (Te 127m)	370	10
Tellurium 127 (Te 127)	3700	100
Tellurium 129m (Te 129m)	370	10
Tellurium 129 (Te 129)	3700	100
Tellurium 131m (Te 131m)	370	10
Tellurium 132 (Te 132)	370	10
Terbium 160 (Tb 160)	370	10
Thallium 200 (Ti 200)	3700	100
Thallium 201 (Tl 201)	3700	100
Thallium 202 (Tl 202)	3700	100
Thallium 204 (Tl 204)	370	10

Thulium 170 (Tm 170)	370	10
Thulium 171 (Tm 171)	370	10
Tin 113 (Sn 113)	370	10
Tin 125 (Sn 125)	370	10
Tungsten 181 (W 181)	370	10
Tungsten 185 (W 185)	370	10
Tungsten 187 (W 187)	3700	100
Vanadium 48 (V 48)	370	10
Xenon 131m (Xe 131m)	37000	1,000
Xenon 133 (Xe 133)	3700	100
Xenon 135 (Xe 135)	3700	100
Ytterbium 175 (Yb 175)	3700	100
*Yttrium 87 (Y 87)	370	10
*Yttrium 88 (Y 88)	370	10
Yttrium 90 (Y 90)	370	10
Yttrium 91 (Y 91)	370	10
Yttrium 92 (Y 92)	3700	100
Yttrium 93 (Y 93)	3700	100
Zinc 65 (Zn 65)	370	10
Zinc 69m (Zn 69m)	3700	100
Zinc 69 (Zn 69)	37000	1,000
Zirconium 93 (Zr 93)	370	10
Zirconium 95 (Zr 95)	370	10
Zirconium 97 (Zr 97)	370	10
Any radioactive material not listed above other than alpha emitting radioactive material.	3.7	0.1

* NARM exempt quantities refer to possession, storage, use, transportation and commercial distribution when not intended for medical use.

3701:1-46-05 **Certain measuring, gauging or controlling devices.**

(A) A general license is hereby issued to commercial and industrial firms; ~~and~~ research, educational, and medical institutions~~;~~; individuals in the conduct of their business~~;~~; and state or local government agencies to acquire, receive, possess, use or transfer, in accordance with the provisions of paragraphs (B) to (D) of this rule, ~~byproduct material, accelerator-produced material, or radium~~radioactive material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere. ~~Persons possessing byproduct material, accelerator-produced material, or radium in devices under the general license issued before January 15, 1975, may continue to possess, use or transfer that material in accordance with the requirements of regulations in effect on January 14, 1975.~~

(B)

(1) The general license in paragraph (A) of this rule applies only to ~~byproduct material, accelerator-produced material, or radium~~radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in ~~rule 3701:1-46-30 of the Administrative Code in accordance with~~:

(a) A specific license issued under rule 3701:1-46-30 of the Administrative Code;

(b) An equivalent specific license issued by an agreement state; or

(c) An equivalent specific license issued by the United States nuclear regulatory commission.

(2) The devices must have been received from one of the specific licensees described in paragraph (B)(1) of this rule or through a transfer made under paragraph (C)(9) of this rule.

(C) Any person who acquires, receives, possesses, uses or transfers ~~byproduct material, accelerator-produced material, or radium~~radioactive material in a device pursuant to the general license in paragraph (A) of this rule:

(1) Shall assure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels;

(2) Shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than

six-month intervals or at such other intervals as are specified in the label; however:

(a) Devices containing only krypton need not be tested for leakage of radioactive material, and

(b) Devices containing only tritium or not more than 3.7 megabecquerels (one hundred microcuries) of other beta and/or gamma emitting material or three hundred seventy kilobecquerels (ten microcuries) of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

(3) Shall assure that the tests required by paragraph (C)(2) of this rule and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

(a) In accordance with the instructions provided by the labels; or

(b) By a person holding a specific license pursuant to this chapter and Chapter 3701:1-40 of the Administrative Code or from an agreement state or the United States nuclear regulatory commission to perform such activities;

(4) Shall maintain records showing compliance with the requirements of paragraphs (C)(2) and (C)(3) of this rule. The records must show the results of tests. The records also must show the dates of performance of, and the names of persons performing, testing, installing, servicing, and removing from the installation radioactive material and its shielding or containment. The licensee shall retain these records as follows:

(a) Each record of a test for leakage or radioactive material required by paragraph (C)(2) of this rule must be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of.

(b) Each record of a test of the on-off mechanism and indicator required by paragraph (C)(2) of this rule must be retained for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of.

(c) Each record that is required by paragraph (C)(3) of this rule must be retained for three years from the date of the recorded event or until the device is transferred or disposed of.

(5) Shall immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the

detection of one hundred eighty-five becquerels (0.005 microcurie) or more removable radioactive material. The device may not be operated until it has been repaired ~~using requirements in the instruction manual,~~ by the manufacturer or other person holding a specific license to repair such devices that was issued under Chapters 3701:1-40 and 3701:1-46 of the Administrative Code or by an agreement state or the United States nuclear regulatory commission. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material ~~contained~~ in the device or as otherwise approved by the director. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of one hundred eighty-five becquerels (0.005 microcurie) or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be furnished to the director within thirty days.

(6) Shall not abandon the device containing ~~byproduct material, accelerator produced material or radium~~radioactive material;

(7) Shall not export the device containing ~~byproduct material, accelerator produced material, or radium~~radioactive material except in accordance with applicable United States nuclear regulatory commission regulations;

(8)

(a) Shall transfer or dispose of the device containing radioactive material only by export as provided by paragraph (C)(7) of this rule, by transfer to another general licensee as authorized in paragraph (C)(9) of this rule, or to a person authorized to receive the device by a specific license issued under this chapter and Chapter 3701:1-40 of the Administrative Code, utilizing a licensed broker or other authorized waste collector, or equivalent regulations of an agreement state, United States nuclear regulatory commission, or as approved under paragraph (C)(8)(c) of this rule.

(b) Shall within thirty days after the transfer of a device to a specific licensee or export, furnish a report to the director ~~within thirty days after the transfer of a device to a specific licensee or export.~~by an appropriate method listed in rule 3701:1-40-04 of the Administrative Code, The report must contain:

(i) The identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number;

(ii) The name, address, and license number of the person receiving the device; and

(iii) The date of the transfer.

(c) Shall obtain written director approval before transferring the device to any other specific licensee not specifically identified in paragraph (C)(8)(a) of this rule.; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if the holder:

(i) Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

(ii) Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by paragraph (C)(1) of this rule) so that the device is labeled in compliance with rule 3701:1-38-18 of the Administrative Code; however the manufacturer, model number, and serial number must be retained;

(iii) Obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and

(iv) Reports the transfer under paragraph (C)(8)(b) of this rule.

(9) Shall transfer the device to another general licensee only if:

(a) The device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of this rule and any safety documents identified in the label of the device. Within thirty days of the transfer, the transferor shall report to the department:

(i) The manufacturer's (or initial transferor's) name;

(ii) The model number and the serial number of the device transferred;

(iii) The transferee's name and mailing address for the location of use; and

(iv) The name, title, and phone number of the responsible individual identified by the transferee in accordance with paragraph (C)(12) of this rule to have knowledge of and authority to take actions to ensure compliance with the appropriate rules and requirements; or

(b) The device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee.

(10) Shall comply with the provisions of paragraphs (A) and (B) of rule 3701:1-38-21 of the Administrative Code for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of Chapter 3701:1-38 of the Administrative Code.

(11) Shall respond to written requests from the director to provide information relating to the general license within thirty calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the director, by an appropriate method listed in rule 3701:1-40-04 of the Administrative Code, a written justification for the request.

(12) Shall appoint an individual responsible for having knowledge of the appropriate rules and requirements and the authority for taking required actions to comply with appropriate rules and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate rules and requirements. This appointment does not relieve the general licensee of responsibility in this regard.

(13)

(a) Shall report, in accordance with paragraphs (C)(13)(b) and (C)(13)(c) of this rule, devices containing at least three hundred seventy megabecquerels (ten millicuries) of cesium-137, 3.7 megabecquerels (0.1 millicurie) of strontium-90, thirty-seven megabecquerels (one millicurie) of cobalt-60, 3.7 kilobecquerels (0.1 microcurie) of radium, or thirty-seven megabecquerels (one millicurie) of americium-241 or any other transuranic, i.e., element with atomic number greater than uranium (92), based on the activity indicated on the label. Each address for a location of use, as described under paragraph (C)(13)(c)(iv) of this rule, represents a separate general license and requires a separate registration and fee.

(b) If in possession of a device meeting the criteria of paragraph (C)(13)(a) of this rule, shall report these devices annually to the director and ~~is subject to~~ shall pay the ~~fees in~~fee required by paragraph (U) of rule 3701:1-38-02 of the Administrative Code. Reporting must be done by verifying, correcting, and/or adding to the information ~~contained~~provided in a request ~~provided by~~received from the director. The information must be submitted to the director within thirty days of the date of the request for information or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of paragraph (C)(13)(a) of this rule is subject to the bankruptcy notification requirement in Chapter 3701:1-40 of the Administrative Code.

(c) In reporting the devices, the general licensee shall furnish the following information and any other information specifically requested by the director:

(i) Name and mailing address of the general licensee.

(ii) Information about each device: the manufacturer (or initial transferor), model number, serial number, the radionuclide and activity (as indicated on the label).

(iii) Name, title, and telephone number of the responsible person designated as a representative of the general licensee under paragraph (C)(12) of this rule.

(iv) Address or location at which the device(s) are used and/or stored.

(v) Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information.

(vi) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

(14) Shall report changes ~~of~~to the mailing address for the location of use (including change in name of general licensee) to the director within thirty days of the effective date of the change.

(15) May not hold devices that are not in use for longer than two years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by paragraph (C)(2) of this rule need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

(D) The director may order the inspection of any facility licensed under this rule if the director determines that an appropriate reason for the inspection exists. These inspections shall be considered as full cost inspections as defined in rule 3701:1-38-02 of the Administrative Code. The reasons the director may conduct for cause inspections include, but are not limited to,

(1) Failure to respond to official correspondence,

(2) Release of radioactive material to the environment,

(3) Investigations of alleged violations of department rules, or

(4) Failure to comply with the license application process.

(E) All portable devices containing radioactive material, used within the state of Ohio, shall be licensed in accordance with rule 3701:1-38-02 and paragraph (I) of rule 3701:1-40-14 of the Administrative Code.

(F) The general license in paragraph (A) of this rule does not authorize the manufacture or import of devices containing ~~byproduct material, accelerator produced material or radium~~radioactive material.

3701:1-46-13 **Introduction of byproduct material, accelerator produced material, or radium in exempt concentrations into products or materials, and transfer of ownership or possession of accelerator produced material or radium in exempt concentrations: requirements for license.**

(A) An application for a specific license on forms provided by the director authorizing the introduction of byproduct material, accelerator produced material, or radium into a product or material owned by or in the possession of the licensee or another and the transfer of ownership or possession of the product or material containing accelerator produced material or radium will be approved if the applicant:

(1) Satisfies the general requirements specified in rule 3701:1-40-15 of the Administrative Code;

(2) Provides a description of the:

(a) Product or material into which the byproduct material, accelerator produced material, or radium will be introduced;

(b) Intended use of the byproduct material, accelerator produced material, or radium and the product or material into which it is introduced;

(c) Method of introduction;

(d) Initial concentration of the byproduct material, accelerator produced material, or radium in the product or material;

(e) Control methods to assure that no more than the specified concentration is introduced into the product or material;

(f) Estimated time interval between introduction and transfer of the product or material; and

(g) Estimated concentration of the radionuclides in the product or material at the time of transfer; and

(3) Provides reasonable assurance:

(a) That the concentrations of byproduct material, accelerator produced material, or radium at the time of transfer will not exceed the concentrations in rule 3701:1-40-08 of the Administrative Code;

(b) That reconcentration of the byproduct material, accelerator produced material, or radium in concentrations exceeding those in rule 3701:1-40-08 of the Administrative Code is not likely;

(c) That use of lower concentrations is not feasible; and

(d) That the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(B) Manufacture of the product or material will be through a specific license issued by the department.

(C) Transfer of byproduct material to persons exempt from licensing in accordance with rule 3701:1-40-08 of the Administrative Code will be in accordance with a license issued by the United States nuclear regulatory commission.

(D) Transfer of accelerator produced material to persons exempt from licensing in accordance with rule 3701:1-40-08 of the Administrative Code will require a distribution license.

3701:1-46-14 **Introduction of byproduct material, accelerator produced material, or radium in exempt concentrations into products or materials, and transfer of ownership or possession of accelerator produced material or radium in exempt concentrations: records and material transfer reports.**

(A) Each person licensed under rule 3701:1-46-13 of the Administrative Code shall maintain records of transfer of material and file a report with the

"Ohio Department of Health

Bureau of Radiation Protection

246 North High Street

Columbus, Ohio 43215"

(B) The report must identify the:

(1) Type and quantity of each product or material into which byproduct material, accelerator produced material, or radium has been introduced during the reporting period;

(2) Name and address of the person who owned or possessed the product or material, into which byproduct material, accelerator produced material, or radium has been introduced, at the time of introduction;

(3) The type and quantity of radionuclide introduced into each product or material; and

(4) The initial concentrations of the radionuclide in the byproduct material, accelerator produced material, or radium at time of transfer of the byproduct material, accelerator produced material, or radium by the licensee.

(C) The licensee shall file the report within thirty days following:

(1) Five years after filing the preceding report; or

(2) Filing an application for renewal of the license pursuant to rule 3701:1-38-02 of the Administrative Code; or

(3) Notifying the director, under rule 3701:1-40-16 of the Administrative Code, of the licensee's decision to permanently discontinue activities authorized under the license issued under rule 3701:1-46-13 of the Administrative Code.

(D) The report must cover the period between the filing of the preceding report and the occurrence specified in paragraph (C)(1), (C)(2), or (C)(3) of this rule. If no transfers of byproduct material, accelerator produced materials, or radium have been made under rule 3701:1-46-13 of this chapter during the reporting period, the report shall so indicate.

(E) The licensee shall maintain the record of a transfer for a period of one year after the event is included in a report to the director.

3701:1-46-15 **Introduction of ~~byproduct material, accelerator produced material, or radium~~radioactive material in exempt concentrations into products or materials, and transfer of ownership or possession of ~~accelerator produced material or radium~~radioactive material in exempt concentrations: prohibition of introduction.**

No person may introduce ~~byproduct material, accelerator produced material, or radium~~ radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under rule 3701:1-40-08 of the Administrative Code or equivalent regulations of the United States nuclear regulatory commission or an agreement state, except in accordance with a license issued by the United States nuclear regulatory commission. ~~pursuant to rule 3701:1-46-13 of the Administrative Code or the general license provided in rule 3701:1-40-28 of the Administrative Code~~.

3701:1-46-16 **Certain items containing byproduct material, accelerator produced material or radium; requirements for license to apply.**

An application for a specific license to apply byproduct material, accelerator produced material, or radium to or to incorporate byproduct material, accelerator produced material, or radium into the products specified in rule 3701:1-40-09 of the Administrative Code will be approved if:

(A) The applicant satisfies the general requirements specified in rule 3701:1-40-15 of the Administrative Code;

(B) The applicant submits sufficient information regarding the product pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of byproduct material, accelerator produced material, or radium in each product;

(2) Details of construction and design of each product;

(3) The method of containment or binding of the byproduct material, accelerator produced material, or radium in the product;

(4) Procedures for and results of prototype testing to demonstrate that the material will not become detached from the product and that the byproduct material, accelerator produced material, or radium will not be released to the environment under the most severe conditions likely to be encountered in normal use of the product;

(5) Quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet;

(6) The proposed method of labeling or marking each unit, except timepieces or hands or dials containing tritium or promethium-147, and its container with the identification of the manufacturer or initial transferor of the product and the byproduct material, accelerator produced material, or radium in the product;

(7) For products for which limits on levels of radiation are specified in rule 3701:1-40-09 of the Administrative Code, the radiation level and the method of measurement;

(8) Any additional information, including experimental studies and tests, required by the director to facilitate a determination of the safety of the product.

(C) Each product will contain no more than the quantity of byproduct material, accelerator produced material, or radium specified for that product in rule 3701:1-40-09 of the Administrative Code. The levels of radiation from each product containing byproduct material, accelerator produced material, or radium will not exceed the limits specified for that product in rule 3701:1-40-09 of the Administrative Code.

(D) The director determines that:

(1) The byproduct material, accelerator produced material, or radium is properly contained in the product under the most severe conditions that are likely to be encountered in normal use and handling.

(2) For automobile lock illuminators, the product has been subjected to and meets the requirements of the prototype tests prescribed by rule 3701:1-46-29 of the Administrative Code.

3701:1-46-17 **Certain items containing byproduct material, accelerator produced material or radium; quality assurance, prohibition of transfer, and labeling.**

(A) Each person licensed under rule 3701:1-46-16 of the Administrative Code shall:

(1) Maintain quality assurance practices in the manufacture of the part or product, or the installation of the part into the product;

(2) Subject inspection lots to such testing as may be required as a condition of the license issued under rule 3701:1-46-16 of the Administrative Code taking a random sample of the size required by the tables in rule 3701:1-46-48 of the Administrative Code, and for lot tolerance per cent defective of five per cent, accept or reject inspection lots in accordance with the directions of rule 3701:1-46-48 of the Administrative Code; and

(3) Visually inspect each unit, except electron tubes containing byproduct or accelerator produced material, in inspection lots. Any unit which has an observable physical defect that could affect containment of the byproduct or accelerator produced material shall be considered as a defective unit.

(B) An application for a license or for amendment of a license may include a description of procedures proposed as alternatives to those prescribed by paragraph (A)(2) of this rule, and proposed criteria for acceptance under those procedures. The director will approve the proposed alternative procedures if the applicant demonstrates that the operating characteristic curve or confidence interval estimate for the alternative procedures provides a lot tolerance per cent defective of five per cent at the consumer's risk of 0.10.

(C) No person licensed under rule 3701:1-46-16 of the Administrative Code shall transfer to other persons for use under rule 3701:1-40-09 of the Administrative Code, or equivalent regulations of the United States nuclear regulatory commission or an agreement state:

(1) Any part or product which has been tested and found defective under the criteria and procedures specified in the license issued under rule 3701:1-46-16 of the Administrative Code, unless the defective units have been repaired or reworked and have then met such criteria as may be required as a condition of the license issued under rule 3701:1-46-16 of the Administrative Code; or

(2) Any inspection lot which has been rejected as a result of the procedures in rule 3701:1-46-48 of the Administrative Code or alternative procedures in paragraph (B) of this rule, unless the defective units have been sorted and removed or have been repaired or reworked and have then met such criteria as may be required as

a condition of the license issued under rule 3701:1-46-16 of the Administrative Code.

(D) Each person licensed under rule 3701:1-46-16 of the Administrative Code shall label or mark each unit, except timepieces or hands or dials containing tritium or promethium-147, and its container so that the manufacturer or initial transferor of the product and the byproduct material, accelerator produced material, or radium in the product can be identified.

3701:1-46-18 **Certain items containing byproduct material, accelerator produced material or radium: records and reports of transfer.**

(A) Each person licensed under rule 3701:1-46-16 or rule 3701:1-46-19 of the Administrative Code shall maintain records of transfer of material and submit a report to the director.

(B) The report must include the following information on items transferred to other persons for use under rules 3701:1-40-09 or 3701:1-40-19 of the Administrative Code, or equivalent regulations of the United States nuclear regulatory commission or an agreement state:

(1) A description or identification of the type of each product;

(2) For each radionuclide in each type of product, the total quantity of the radionuclide; and

(3) The number of units of each type of product transferred during the reporting period.

(C) The licensee shall file the report within thirty days after:

(1) Five years after filing the preceding report; or

(2) Filing an application for renewal of the license under rule 3701:1-38-02 of the Administrative Code; or

(3) Notifying the director under rule 3701:1-40-16 of the Administrative Code, of the licensee's decision to permanently discontinue activities authorized under the license issued under rule 3701:1-46-16 or 3701:1-46-19 of the Administrative Code.

(D) The report must cover the period between the filing of the preceding report and the occurrence specified in paragraph (C)(1), (C)(2), or (C)(3) of this rule. If no transfers of byproduct material, accelerator produced material, or radium have been made under rule 3701:1-46-16 or 3701:1-46-19 of the Administrative Code during the reporting period, the report must so indicate.

(E) The licensee shall maintain the record of a transfer for a period of one year after the event is included in a report to the director.

3701:1-46-19 **Resins containing scandium-46 and designed for sand-consolidation in oil wells: requirements for license to manufacture, or initially transfer for sale or distribution.**

An application for a specific license to manufacture, or initially transfer for sale or distribution, synthetic plastic resins containing scandium-46 for use pursuant to rule 3701:1-40-10 of the Administrative Code will be approved if:

(A) The applicant satisfies the general requirements specified in rule 3701:1-40-15 of the Administrative Code;

(B) The product is designed to be used only for sand-consolidation in oil wells;

(C) The applicant submits the following information:

(1) The general description of the product to be manufactured or initially transferred.

(2) A description of control procedures to be used to assure that the concentration of scandium-46 in the final product at the time of distribution will not exceed 51.8 becquerels (1.4 nanocuries) per milliliter.

(D) Each container of such product will bear a durable, legible label approved by the director, which contains the following information:

(1) The product name;

(2) A statement that the product contains radioactive scandium and is designed and manufactured only for sand-consolidation in oil wells;

(3) Instructions necessary for proper use; and

(4) The manufacturer's name.

3701:1-46-20 **Manufacture of exempt quantities of byproduct material, accelerator produced material, or radium: requirements for license.**

(A) An application for a specific license to manufacture, process, or produce quantities of byproduct material, accelerator produced material, or radium for commercial distribution to persons exempt pursuant to rule 3701:1-40-11 of the Administrative Code or the equivalent regulations of the United States nuclear regulatory commission or an agreement state will be approved if:

(1) The applicant satisfies the general requirements specified in rule 3701:1-40-15 of the Administrative Code, provided, however, that the requirements of paragraphs (A)(2) and (A)(3) of rule 3701:1-40-15 of the Administrative Code do not apply to an application for a license to transfer byproduct material, accelerator produced material, or radium manufactured, processed, produced, packaged, or repackaged pursuant to a license issued by the United States nuclear regulatory commission or an agreement state;

(2) The byproduct material or accelerator produced material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

(3) The byproduct material, accelerator produced material, or radium is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

(4) The applicant submits copies of prototype labels and brochures and the director approves such labels and brochures.

(B) Distribution of exempt quantities of byproduct material shall satisfy the criteria in paragraph (D) of rule 3701:1-40-08 of the Administrative Code.

3701:1-46-21 **Manufacture of exempt quantities of byproduct material, accelerator produced material, or radium: conditions of licenses.**

Each license issued under rule 3701:1-46-20 of the Administrative Code is subject to the following conditions:

(A) No more than ten exempt quantities of byproduct material, accelerator produced material, or radium set forth in rule 3701:1-40-11 of the Administrative Code, shall be sold or transferred in any single transaction. For purposes of this requirement, an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in rule 3701:1-40-11 of the Administrative Code, provided that the sum of such fractions shall not exceed unity.

(B) Each quantity of byproduct material, accelerator produced material, or radium set forth in rule 3701:1-40-11 of the Administrative Code shall be separately and individually packaged. No more than ten such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to rule 3701:1-40-11 of the Administrative Code. The outer package shall be such that the dose rate at the external surface of the package does not exceed five microsieverts (0.5 millirem) per hour.

(C) The immediate container of each quantity or separately packaged fractional quantity of byproduct material, accelerator produced material, or radium shall bear a durable, legible label which

(1) Identifies the radionuclide and the quantity of radioactivity, and

(2) Bears the words "Radioactive Material."

(D) In addition to the labeling information required by paragraph (C) of this rule, the label affixed to the immediate container, or an accompanying brochure, shall also

(1) State that the contents are exempt from Ohio, United States nuclear regulatory commission or agreement state licensing requirements;

(2) Bear the words "Radioactive Material-Not for Human Use-Introduction Into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or Into Products Manufactured for Commercial Distribution is Prohibited-Exempt Quantities Should Not be Combined"; and

(3) Set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

3701:1-46-22 **Manufacture of exempt quantities of byproduct material, accelerator produced material, or radium: records and material transfer reports.**

(A) Each person licensed under rule 3701:1-46-20 of the Administrative Code shall maintain records of transfer of material identifying, by name and address, each person to whom byproduct material, accelerator produced material, or radium is transferred for use under rule 3701:1-40-11 of the Administrative Code or the equivalent regulations of the United States nuclear regulatory commission or an agreement state and stating the kinds and quantities of byproduct, accelerator produced material, or radium transferred. The licensee shall maintain the record of a transfer for a period of one year after the event is included in a summary report to the director.

(B) The licensee shall file a summary report stating the total quantity of each radionuclide transferred under the specific license with the director.

(C) The licensee shall file the summary report within thirty days following:

(1) Five years after filing the preceding report; or

(2) Filing an application for renewal of the license under rule 3701:1-38-02 of the Administrative Code; or

(3) Notifying the director under rule 3701:1-40-16 of the Administrative Code, of the licensee's decision to permanently discontinue activities authorized under the license issued under rule 3701:1-46-20 of the Administrative Code.

(D) The report must cover the period between the filing of the preceding report and the occurrences specified in paragraph (C)(1), (C)(2), or (C)(3) of this rule. If no transfers of byproduct material, accelerator produced material, or radium have been made under rule 3701:1-46-20 of the Administrative Code during the reporting period, the report must so indicate.

3701:1-46-23 **Radioactive drug: manufacture, preparation of capsules containing carbon-14 urea each for in-vivo diagnostic use for humans to persons exempt from licensing; requirements for a license.**

(A) An application for a specific license to manufacture, prepare, process, or produce capsules containing thirty-seven kilobecquerels (one microcurie) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each for in-vivo diagnostic use, to persons exempt from licensing under rule 3701:1-40-03 of the Administrative Code or the equivalent regulations of the United States nuclear regulatory commission or an agreement state will be approved if:

(1) The applicant satisfies the general requirements specified in rule 3701:1-40-15 of the Administrative Code, provided that the requirements of paragraphs (A)(2) and (A)(3) of rule 3701:1-40-15 of the Administrative Code do not apply to an application for a license to transfer byproduct material manufactured, prepared, processed, produced, packaged, or repackaged pursuant to a license issued by the United States nuclear regulatory commission or an agreement state;

(2) The applicant meets the requirements under paragraph (A)(2) of rule 3701:1-46-43 of the Administrative Code;

(3) The applicant provides evidence that each capsule contains thirty-seven kilobecquerels (one microcurie) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process);

(4) The carbon-14 urea is not contained in any food, beverage, cosmetic, drug (except as described in this rule) or other commodity designed for ingestion or inhalation by, or topical application to a human being;

(5) The carbon-14 urea is in the form of a capsule, identified as radioactive, and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

(6) The applicant submits copies of prototype labels and brochures and the United States nuclear regulatory commission approves these labels and brochures.

(B) Nothing in this rule relieves the licensee from complying with applicable United States food and drug administration, other federal, and state requirements governing drugs.

3701:1-46-24 **Radioactive drug: manufacture, preparation of capsules containing carbon-14 urea each for in-vivo diagnostic use for humans to persons exempt from licensing: conditions of license.**

Each license issued under rule 3701:1-46-23 of the Administrative Code is subject to the following conditions:

(A) The immediate container of the capsule(s) must bear a durable, legible label which:

(1) Identifies the radionuclide, the physical and chemical form, the quantity of radioactivity of each capsule at a specific date; and

(2) Bears the words "Radioactive Material."

(B) In addition to the labeling information required by paragraph (A) of this rule, the label affixed to the immediate container, or an accompanying brochure also must:

(1) State that the contents are exempt from Ohio, United States nuclear regulatory commission or agreement state licensing requirements; and

(2) Bear the words "Radioactive Material. For in-vivo diagnostic use only. This material is not to be used for research involving human subjects and must not be introduced into foods, beverages, cosmetics, or other drugs or medicinals, or into products manufactured for commercial distribution. This material may be disposed of in ordinary trash."

3701:1-46-25 **Self-luminous products containing tritium, krypton-85, or promethium-147: requirements for license to manufacture, process, produce.**

(A) An application for a specific license to manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, or to initially transfer such products for use pursuant to rule 3701:1-40-12 of the Administrative Code or equivalent regulations of the United States nuclear regulatory commission or an agreement state, will be approved if:

(1) The applicant satisfies the general requirements specified in rule 3701:1-40-15 of the Administrative Code: provided, however, that the requirements of paragraphs (A)(2) and (A)(3) of rule 3701:1-40-15 of the Administrative Code, do not apply to an application for a license to transfer tritium, krypton-85, or promethium-147 in self-luminous products manufactured, processed, or produced pursuant to a license issued by the United States nuclear regulatory commission or an agreement state.

(2) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the self-luminous product to demonstrate that the product will meet the safety criteria set forth in rule 3701:1-46-26 of the Administrative Code. The information should include:

(a) A description of the product and its intended use or uses.

(b) The type and quantity of byproduct material in each unit.

(c) Chemical and physical form of the byproduct material in the product and changes in chemical and physical form that may occur during the useful life of the product.

(d) Solubility in water and body fluids of the forms of the byproduct material identified in paragraphs (A)(2)(c) and (A)(2)(l) of this rule.

(e) Details of construction and design of the product as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product.

(f) Maximum external radiation levels at five and twenty-five centimeters from any external surface of the product, averaged over an area not to exceed ten square centimeters, and the method of measurement.

(g) Degree of access of human beings to the product during normal handling and use.

(h) Total quantity of byproduct material expected to be distributed in the product annually.

(i) The expected useful life of the product.

(j) The proposed method of labeling or marking each unit with identification of the manufacturer or initial transferor of the product and the byproduct material in the product.

(k) Procedures for prototype testing of the product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the product.

(l) Results of the prototype testing of the product, including any change in the form of the byproduct material contained in the product, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features.

(m) The estimated external radiation doses and dose commitments relevant to the safety criteria in rule 3701:1-46-26 of the Administrative Code and the basis for such estimates.

(n) A determination that the probabilities with respect to the doses referred to in paragraph (D) of rule 3701:1-46-26 of the Administrative Code meet the criteria of that paragraph.

(o) Quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet.

(p) Any additional information, including experimental studies and tests, required by the director.

(B) Notwithstanding the provisions of paragraph (A) of this rule, the director may deny an application for a specific license under this section if the end uses of the product cannot be reasonably foreseen.

3701:1-46-26 **Self-luminous products containing tritium, krypton-85, or promethium-147: safety criteria.**

An applicant for a license under rule 3701:1-46-25 of the Administrative Code shall demonstrate that the product is designed and will be manufactured so that:

(A) In normal use and disposal of a single exempt unit, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the dose to the appropriate organ as specified in column I of the table in appendix A to this rule.

(B) In normal handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the dose to the appropriate organ as specified in column II of the table in appendix A to this rule.

(C) It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product from wear and abuse likely to occur in normal handling and use of the product during its useful life.

(D) In use and disposal of a single exempt unit, or in handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in column III of the table in appendix A to this rule, and the probability is negligible that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in column IV of the table in appendix A to this rule.

It is the intent of this paragraph that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such a dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates which are to be made. The following values may be used as guides in estimating compliance with the criteria:

(1) Low-not more than one such failure per year for each ten thousand exempt units distributed.

(2) Negligible-not more than one such failure per year for each one million exempt units distributed.

Appendix A - Table of Organ Doses

Part of body	Column I μSv (rem)	Column II μSv (rem)	Column III μSv (rem)
Whole body; head and trunk; active bloodforming organs; gonads; or lens of eye.	50 (0.005)	5000 (0.5)	1.5×10^5 (15)
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter.	750 (0.075)	75000 (7.5)	2.0×10^6 (200)
Other organs	150 (0.015)	15000 (1.5)	5.0×10^5 (50)

3701:1-46-27 **Gas and aerosol detectors containing byproduct material, accelerator produced material, or radium: requirements for license to manufacture, process, produce, or initially transfer.**

An application for a specific license to manufacture, process, or produce gas and aerosol detectors containing byproduct material, accelerator produced material, or radium and designed to protect life or property from fires and airborne hazards, or to initially transfer such products for use pursuant to rule 3701:1-40-13 of the Administrative Code or equivalent regulations of the United States nuclear regulatory commission or an agreement state, will be approved if:

(A) The applicant satisfies the general requirements specified in rule 3701:1-40-15 of the Administrative Code: provided, however, that the requirements of paragraphs (A)(2) and (A)(3) of rule 3701:1-40-15 of the Administrative Code do not apply to an application for a license to transfer byproduct material in gas and aerosol detectors manufactured, processed or produced pursuant to a license issued by the United States nuclear regulatory commission or an agreement state.

(B) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the gas and aerosol detector to demonstrate that the product will meet the safety criteria set forth in rule 3701:1-46-28 of the Administrative Code. The information should include:

(1) A description of the product and its intended use or uses;

(2) The type and quantity of byproduct material, accelerator produced material, or radium in each unit;

(3) Chemical and physical form of the byproduct material, accelerator produced material, or radium in the product and changes in chemical and physical form that may occur during the useful life of the product;

(4) Solubility in water and body fluids of the forms of the byproduct material, accelerator produced material, or radium identified in paragraphs (B)(3) and (B)(12) of this rule;

(5) Details of construction and design of the product as related to containment and shielding of the byproduct material, accelerator produced material or radium and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product;

(6) Maximum external radiation levels at five and twenty-five centimeters from any external surface of the product, averaged over an area not to exceed ten square centimeters, and the method of measurement;

(7) Degree of access of human beings to the product during normal handling and use;

(8) Total quantity of byproduct material, accelerator produced material, or radium expected to be distributed in the product annually;

(9) The expected useful life of the product;

(10) The proposed methods of labeling or marking the detector and its point-of-sale package;

(11) Procedures for prototype testing of the product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the product;

(12) Results of the prototype testing of the product, including any change in the form of the byproduct material, accelerator produced material, or radium contained in the product, the extent to which the byproduct material, accelerator produced material, or radium may be released to the environment, any increase in external radiation levels, and any other changes in safety features;

(13) The estimated external radiation doses and dose commitments relevant to the safety criteria in rule 3701:1-46-28 of the Administrative Code and the basis for such estimates;

(14) A determination that the probabilities with respect to the doses referred to in paragraph (C) rule 3701:1-46-28 of the Administrative Code meet the criteria of that paragraph;

(15) Quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet; and

(16) Any additional information, including experimental studies and tests, required by the director.

3701:1-46-28 **Gas and aerosol detectors containing byproduct material, accelerator produced material, or radium: safety criteria.**

An applicant for a license under rule 3701:1-46-27 of the Administrative Code shall demonstrate that the product is designed and will be manufactured so that:

(A) In normal use and disposal of a single exempt unit, and in normal handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the dose to the appropriate organ as specified in column I of appendix A to this chapter.

(B) It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product from wear and abuse likely to occur in normal handling and use of the product during its useful life.

(C) In use and disposal of a single exempt unit and in handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in column II of appendix A to this rule, and the probability is negligible that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in column III of appendix A to this rule.

It is the intent of this paragraph that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such a dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates which are to be made. The following values may be used as guides in estimating compliance with the criteria:

(1) Low-not more than one such failure per year for each ten thousand exempt units distributed, and

(2) Negligible-not more than one such failure per year for each one million exempt units distributed.

Appendix A - Table of Organ Doses

Part of body	Column I μSv (rem)	Column II μSv (rem)	Column III μSv (rem)
Whole body; head and trunk; active bloodforming organs; gonads; or lens of eye.	50 (0.005)	5000 (0.5)	1.5×10^5 (15)
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter.	750 (0.075)	75000 (7.5)	2.0×10^6 (200)
Other organs	150 (0.015)	15000 (1.5)	5.0×10^5 (50)

3701:1-46-29 **Schedule A - prototype tests for automobile lock illuminators.**

An applicant for a license pursuant to rule 3701:1-46-16 of the Administrative Code to install lock illuminators into automobile locks, or to initially transfer lock illuminators in automobile locks for use pursuant to rule 3701:1-40-09 of the Administrative Code shall conduct the following prototype tests on each of five prototype devices, consisting of the automobile lock with the installed illuminator in the following order:

(A) The device shall be subjected to one hundred hours of accelerated weathering in a suitable weathering machine which simulates the most severe conditions of normal use;

(B) The device shall be dropped upon a concrete or iron surface in a three-foot free gravitational fall, or shall be subjected to an equivalent treatment in a test device simulating such a fall. The drop test shall be repeated one hundred times from random orientations;

(C) The device shall be attached to a vibratory fixture and vibrated at a rate of not less than twenty-six cycles per second and a vibration acceleration of not less than two G for a period of not less than one hour;

(D) On completion of the foregoing tests, the device shall be immersed in thirty inches of water for twenty-four hours and shall show no visible evidence of water entry into the lock illuminator. Absolute pressure of the air above the water shall then be reduced to one inch of mercury. Lowered pressure shall be maintained for one minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any evidence of bubbles emanating from within the lock illuminator, or water entering the lock illuminator, shall be considered leakage;

(E) After each of the tests prescribed by this rule, each device shall be examined for evidence of physical damage and for loss of tritium or promethium-147. Any evidence of damage to or failure of any device which could affect the containment of the tritium or promethium-147 in such devices shall be cause for rejection of the design on which such prototype devices were constructed or manufactured if the damage or failure is attributable to design defect. Loss of tritium or promethium-147 from each tested device shall be measured both by sampling the immersion test water used in paragraph (D) of this rule and by wiping with filter paper the entire accessible area of the lock illuminator. Measurements of tritium or promethium-147 shall be made in an apparatus calibrated to measure tritium or promethium-147, as appropriate. If more than 0.1 per cent of the original amount of tritium or promethium-147 in the device is found in the immersion test water of the test in paragraph (D) of this rule, or if more than two thousand two hundred disintegrations per minute of tritium or promethium-147 on the filter paper is measured after any of the tests in paragraphs (A) to (D) of this rule the device shall be rejected.

3701:1-46-30 ~~Byproduct material, accelerator produced material, or radium~~ Radioactive material **contained in devices for use under rule 3701:1-46-05 of the Administrative Code; requirements for license to manufacture, or initially transfer.**

(A) An application for a specific license to manufacture, or initially transfer devices containing ~~byproduct material, accelerator produced material, or radium~~radioactive material to persons generally licensed under rule 3701:1-46-05 of the Administrative Code or equivalent regulations of the United States nuclear regulatory commission or an agreement state will be approved if:

(1) The applicant satisfies the general requirements of rule 3701:1-40-15 of the Administrative Code;

(2) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(a) The device can be safely operated by persons not having training in radiological protection;

(b) Under ordinary conditions of handling, storage, and use of the device, the ~~byproduct material, accelerator produced material, or radium~~radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in one year a dose in excess of ten per cent of the annual limits specified in paragraph (A) of rule 3701:1-38-12 of the Administrative Code; and

(c) Under accident conditions (such as fire and explosion) associated with handling, storage and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in ~~column IV of~~ appendix A to this rule. ~~3701:1-46-26 of the Administrative Code.~~

(3) Each device bears a durable, legible, clearly visible label or labels approved by the director which contain in a clearly identified and separate statement:

(a) Instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);

(b) The requirements, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for

such testing, and the identification of radioactive material by radionuclide, quantity of radioactivity, and date of determination of the quantity; and

(c) The information called for in the following statement in the same or substantially similar form. Devices licensed by the United States nuclear regulatory commission prior to January 19, 1975, may bear labels authorized by the regulations in effect on January 1, 1975. The receipt, possession, use, and transfer of this device model, serial no., are subject to a general license or the equivalent and the regulations of the United States nuclear regulatory commission or a state with which the United States nuclear regulatory commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited. The model, serial number, and the name of the manufacturer, or initial transferor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.

"CAUTION-RADIOACTIVE MATERIAL"

(Name of manufacturer, or initial transferor)

(4) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the radionuclide and quantity, the words, "Caution: Radioactive Material," the radiation symbol described in paragraph (A) of rule 3701:1-38-18 of the Administrative Code, and the name of the manufacturer or initial distributor.

(5) Each device meeting the criteria of paragraph (C)(13)(a) of rule 3701:1-46-05 of the Administrative Code, bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution: Radioactive Material," and, if practicable, the radiation symbol described in paragraph (A) of rule 3701:1-38-18 of the Administrative Code.

(B) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in this application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices, and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the director will consider information which includes, but is not limited to:

(1) Primary containment (source capsule);

(2) Protection of primary containment;

(3) Method of sealing containment;

(4) Containment construction materials;

(5) Form of contained radioactive material;

(6) Maximum temperature withstood during prototype tests;

(7) Maximum pressure withstood during prototype tests;

(8) Maximum quantity of contained radioactive material;

(9) Radiotoxicity of contained radioactive material; and

(10) Operating experience with identical devices or similarly designed and constructed devices.

(C) In the event the applicant desires that the general licensee under rule 3701:1-46-05 of the Administrative Code, or under equivalent regulations of the United States nuclear regulatory commission or an agreement state be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and the bases for these estimates. The submitted information must demonstrate that performance of this activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of ten per cent of the annual limits specified in paragraph (A) of rule 3701:1-38-12 of the Administrative Code.

Appendix A – Table of Organ Doses

Part of Body	μSv (rem)
Whole body; head and trunk; active bloodforming organs; gonads; or lens of eye.	1.5×10^5 (15)
Hands and forearms; feet and ankles; localized areas of skin averaged over area no larger than one square centimeter.	2.0×10^6 (200)
Other organs	5.0×10^5 (50)