ARTICLE 5. RADIOLOGICAL HEALTH

Rule 1. General Provisions

410 IAC 5-1-1 Scope of rule

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 1. Pursuant to the authority found in IC 13-1-2-9 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]* providing for the granting, suspending, revoking, or amending general or specific licenses for radioactive materials and the registration of radiation sources. Nothing in 410 IAC 5 shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission. *(Indiana State Department of Health; Rule HRH-2,PT A,Sec A.1; filed May 26, 1978, 3:30 pm: 1 IR 127; filed Feb 29, 1984, 10:10 am: 7 IR 829; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-1-2 Definitions

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 2. As used in 410 IAC 5, these terms have the definitions set forth below. Additional definitions used only in a certain part will be found in that part.

"Accelerator-produced material" means any material made radioactive by exposing it in a particle accelerator.

"Act" means the Radiation Control Act of Indiana, IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*, Indiana General Assembly.

"Agreement state" means any state with which the United States Nuclear Regulatory Commission has entered into an effective agreement under Section 274 b. of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

"Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, mists, vapors, or gases.

"Airborne radioactivity area" means (1) any room, enclosure, or operating area in which airborne radioactive material exists in concentrations in excess of the amounts specified in Table I, Column 1 of 410 IAC 5-4-27; or (2) any room, enclosure, or operating area in which airborne radioactive material exists in concentrations which, averaged over the number of hours in any week during which individuals are in the area, exceed 25 percent of the amounts specified in Table I, Column 1 of 410 IAC 5-4-27.

"Board" means executive board of the Indiana State Department of Health or its duly authorized representatives.

"Byproduct material" means 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 material.

"Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method observed by him of determining calendar quarters for purposes of 410 IAC 5 except at the beginning of a calendar year.

"Calibration" means the determination of (1) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument, or (2) the strength of a source of radiation relative to a standard.

"CFR" means Code of Federal Regulations (1982 Edition).

"Controlled area" see "Restricted area."

"Curie" means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7×10^{10} transformations per second (tps). Commonly used submultiples of the curie are the millicurie and the microcurie. One millicurie (mCi) = 0.001 curie = 3.7×10^{7} tps. One microcurie ($^{\mu}$Ci) = 0.000001 curie = 3.7×10^{4} tps. (See 410 IAC 5-1-10.5 for SI equivalent becquerel.)

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

"Dose" as used in 410 IAC 5 shall mean absorbed dose or dose equivalent as appropriate.

"Absorbed dose" is the energy imparted to matter by ionizing radiation per unit mass of irradiated material at the place of interest. The special unit of absorbed dose is the rad. (See rad.) (See 410 IAC 5-1-10.5 for SI equivalent gray.)

"Dose equivalent" is a quantity that expresses on a common scale for all radiation a measure of the postulated effect on a given organ. It is defined as the absorbed dose in rads times certain modifying factors. The unit of dose equivalent is the rem. (See rem.) (See 410 IAC 5-1-10.5 for SI equivalent sievert.)

"Dose commitment" means the total radiation dose to a part of the body that will result from retention in the body of radioactive material. For purposes of estimating the dose commitment, it is assumed that from the time of intake, the period of exposure to retained material will not exceed 50 years.

*"Exposure" means the quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. (The special unit of exposure is the roentgen (R).) (See 410 IAC 5-1-10.5 for SI equivalent coulomb per kilogram).

*(When not indicated as above or indicated as "exposure (X)," the term "exposure" has a more general meaning in 410 IAC 5.)

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

"Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities" means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants or critical mass experimental facilities where AEC or NRC licenses have been terminated.

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

"High radiation area" means any area, accessible to individuals, in which there exists radiation at such levels that a major portion of the body could receive in any one hour a dose in excess of 100 millirems.

"Human use" means the internal or external administration of radiation or radioactive material to human beings.

"Individual" means any human being.

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

"Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

"License" means a license issued by the board in accordance with 410 IAC 5 and IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*.

"Licensee" means any person who is licensed by the board in accordance with 410 IAC 5 and IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*.

"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.

"Major processor" means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding 4 times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in Section 71.4 of 10 CFR Part 71.

"NARM" means any naturally-occurring or accelerator-produced radioactive material. It does not include byproduct, source or special nuclear material.

"Natural radioactivity" means radioactivity of naturally-occurring nuclides.

"Occupational dose" means exposure of an individual to radiation (1) in a restricted area or (2) in the course of employment in which the individual's duties involve exposure to radiation provided that occupational dose shall not be deemed to include any exposure of an individual to radiation for the purpose of diagnosis or therapy of such individual.

"Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV.

"Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor,

representative, agent or agency of the foregoing.

"Personnel monitoring equipment" means devices (e.g. film badges, pocket dosimeters, and thermoluminescent dosimeters) designed to be worn or carried by an individual for the purpose of estimating the dose received by the individual.

"Pharmacist" means an individual licensed by the state of Indiana to compound and dispense drugs, prescriptions, and poisons.

"Physician" means an individual licensed by the state of Indiana to dispense drugs in the practice of medicine.

"Rad" means the special unit of absorbed dose. One rad equals one hundredth of a joule per kilogram of material; for example, if tissue is the material of interest, then 1 rad equals 100 ergs per gram of tissue.

"Radiation" means ionizing radiation; i.e., gamma rays and x-rays, alpha and beta particles, high speed electrons, neutrons, high speed protons, and other nuclear particles.

"Radiation area" means any area, accessible to individuals, in which there exists radiation at such levels that a major portion of the body could receive in any one hour a dose in excess of 5 millirems, or in any 5 consecutive days a dose in excess of 100 millirems.

"Radiation machine" means any device capable of producing radiation except those which produce radiation only from radioactive material.

"Radiation safety officer" means one who has the knowledge and responsibility to apply appropriate radiation protection regulations.

"Radioactive material" means any material (solid, liquid or gas) which emits radiation spontaneously.

"Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.

"Registrant" means any person who is registered with the board and is legally obligated to register with the board as required by 410 IAC 5 and IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*.

"Registration" means registration with the board in accordance with 410 IAC 5.

"Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189.

"Rem" means a special unit of dose equivalent. (One millirem (mrem) = 0.001 rem.) For the purpose of 410 IAC 5, any of the following is considered to be equal to one rem:

(1) An exposure of 1 roentgen of x or gamma radiation;

(2) An absorbed dose of 1 rad due to x, gamma or beta radiation;

(3) An absorbed dose of 0.05 rad due to particles heavier than protons and with sufficient energy to reach the lens of the eye;

(4) An absorbed dose of 0.1 rad due to neutrons or high energy protons.[1/] (See 410 IAC 5-1-10.5 for SI equivalent sievert.)

[1/] If it is more convenient to measure the neutron flux or equivalent than to determine the neutron absorbed dose in rads, one rem of neutron radiation may, for purposes of 410 IAC 5, be assumed to be equivalent to 14 million neutrons per square centimeter incident upon the body; or if there exists sufficient information to estimate with reasonable accuracy the approximate distribution in energy of the neutrons, the incident number of neutrons per square centimeter equivalent to one rem may be estimated from the following table:

Neutron Flux Dose Equivalents

Neutron energy (MeV)	Number of neutrons per square centimeter for a dose equivalent to 1 rem (neutrons/cm^2)	Average flux density to deliver 100 millirems in 40 hours (neutrons/cm^2 per second)
Thermal.	970×10^6	670
0.0001..	720×10^6	500
0.005..	820×10^6	570
0.02..	400×10^6	280
0.1..	120×10^6	80
0.5..	43×10^6	30
1.0..	26×10^6	18
2.5..	29×10^6	20
5.0..	26×10^6	18
7.5..	24×10^6	17
10.0..	24×10^6	17
10 to 30.	14×10^6	10

"Research and development" means: (1) theoretical analysis, exploration, or experimentation or (2) 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 radiation or radioactive material to human beings.

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

"Roentgen" (R) means the special unit of exposure. One roentgen equals 2.58×10^{-4} coulombs/kilogram of air (see "Exposure").

"Sealed source" means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

"Source material" means: (1) uranium or thorium, or any combination thereof, in any physical or chemical form or (2) ores which contain by weight one-twentieth of one percent (0.05 percent) or more of (i) uranium, (ii) thorium or (iii) any combination thereof. Source material does not include special nuclear material.

"Source material milling" means any activity that results in the production of byproduct material as defined by definition (2) of source material.

"Source of radiation" means any radioactive material or any device or equipment emitting or capable of producing radiation.

"Special form" means any of the following physical forms of licensed material of any transport group:

(1) The material is in solid form having no dimension less than 0.5 millimeter or at least one dimension greater than five (5) millimeters; does not melt, sublime or ignite in air at a temperature of 1000° F (538° C); will not shatter or crumble if subjected to the percussion test described in Appendix B, 410 IAC 5-1-12; and is not dissolved or converted into dispersible form to the extent of more than 0.005 percent by weight by immersion for 1 week in water at 68° F (20° C) or in air at 86° F (30° C); or

(2) The material is securely contained in a capsule having no dimension less than 0.5 millimeter or at least one dimension greater than five (5) millimeters, which will retain its contents if subjected to the tests prescribed in Appendix B, 410 IAC 5-1-12; and which is constructed of materials which do not melt, sublime or ignite in air at 1475° F (802° C), and do not dissolve or convert into dispersible form to the extent of more than 0.005 percent by weight by immersion for 1 week in water at 68° F (20° C) or in air at 86° F (30° C).

"Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235, U-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 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 "1" (i.e., unity). For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{176 \text{ (grams contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

"Survey" means an evaluation of the production, use, release, disposal, and/or presence of sources of radiation under a specific set of conditions to determine actual or potential radiation hazards. When appropriate, such evaluation includes but is not limited to tests, physical examination and measurements of levels of radiation or concentration of radioactive material present.

"Test" means the process of verifying compliance with the applicable sections of 410 IAC 5.

"Transport group" means any one of seven groups into which radionuclides in normal form are classified according to their toxicity and their relative potential hazard in transport (see Appendix A, 410 IAC 5-1-11).

(1) Any radionuclide not specifically listed in one of the groups in Appendix A, 410 IAC 5-1-11 shall be assigned to one of the groups in accordance with the following table:

	Radioactive half-life		
Radionuclide	0 to 1000 days	1000 days to 10^6 years	Over 10^6 years
Atomic number 1-81	Group III	Group II	Group III
Atomic number 82 and over	Group I	Group I	Group III

(2) For mixtures of radionuclides the following shall apply:

(i) If the identity and respective activity of each radionuclide are known, the permissible activity of each radionuclide shall be such that the sum for all groups present of the ratio between the total activity for each group to the permissible activity for each group will not be greater than unity.

(ii) If the groups of the radionuclides are known but the amount in each group cannot be reasonably determined, the mixture shall be assigned to the most restrictive group present.

(iii) If the identity of all or some of the radionuclides cannot be reasonably determined, each of those unidentified radionuclides shall be considered as belonging to the most restrictive group which cannot be positively excluded.

(iv) Mixtures consisting of a single radioactive decay chain where the radionuclides are in the naturally-occurring proportions shall be considered as consisting of a single radionuclide. The group and activity shall be that of the first member present in the chain, except that if a radionuclide "X" has a half-life longer than that of the first member and an activity greater than that of any other member, including the first, at any time during transportation, the transport group of the nuclide "X" and the activity of the mixture shall be the maximum activity of that nuclide "X" during transportation.

"U.S. Department of Energy" means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the department exercises functions formerly vested in the U.S. Atomic Energy Commission, its chairman, members, officers, and components and transferred to the U.S. 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 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977).

"Uncontrolled area" see "Unrestricted area."

"Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

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

"Waste handling licensees" means persons licensed to receive and store radioactive wastes prior to disposal and/or persons licensed to dispose of radioactive waste.

"Worker" means any individual engaged in work under a license or registration issued by the board and controlled by a licensee or registrant but does not include the licensee or registrant. *(Indiana State Department of Health; Rule HRH-2,PT A,Sec A.2; filed May 26, 1978, 3:30 pm: 1 IR 127; filed Feb 29, 1984, 10:10 am: 7 IR 829; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; errata filed Feb 3, 2010, 2:21 p.m.: 20100224-IR-410100062ACA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-1-3 Exemptions from rule

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 3. (a) General Provision. The board may, upon application therefore or upon its own initiative, grant such exemptions or exceptions from the requirements of 410 IAC 5 as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

(b) Carriers. Common and contract carriers, freight forwarders, and warehousemen, who are subject to the rules and regulations of the U.S. Department of Transportation or the U.S. Postal Service are exempt from 410 IAC 5 to the extent that they transport or store sources of radiation in the regular course of their carriage for another or storage incident thereto. Private carriers who are subject to the rules and regulations of the U.S. Department of Transportation are exempted from 410 IAC 5 to the extent that they transport sources of radiation. Common, contract, and private carriers who are not subject to the rules and regulations of the U.S. Department of Transportation or the U.S. Postal Service are subject to applicable sections of 410 IAC 5.

(c) U.S. Department of Energy Contractors and U.S. Nuclear Regulatory Commission Contractors. Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following

categories operating within the state of Indiana is exempt from 410 IAC 5 to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation:

(1) Prime contractors performing work for the U.S. Department of Energy at U.S. Government-owned or -controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

(2) Prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof;

(3) Prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel; and

(4) Any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the state of Indiana and the U.S. Nuclear Regulatory Commission jointly determine:

(i) that the exemption of the prime contractor or subcontractor is authorized by law; and

(ii) that under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

(Indiana State Department of Health; Rule HRH-2,PT A,Sec A.3; filed May 26, 1978, 3:30 pm: 1 IR 130; filed Feb 29, 1984, 10:10 am: 7 IR 834; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-1-4 Recordkeeping

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 4. Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation. Additional record requirements are specified elsewhere in 410 IAC 5. *(Indiana State Department of Health; Rule HRH-2,PT A,Sec A.4; filed May 26, 1978, 3:30 pm: 1 IR 131; filed Feb 29, 1984, 10:10 am: 7 IR 835; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-1-5 Inspections of facilities and records

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 5. (a) Each licensee and registrant shall afford the board at all reasonable times opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

(b) Each licensee and registrant shall make available to the board for inspection, upon reasonable notice, records maintained pursuant to 410 IAC 5. *(Indiana State Department of Health; Rule HRH-2,PT A,Sec A.5; filed May 26, 1978, 3:30 pm: 1 IR 131; filed Feb 29, 1984, 10:10 am: 7 IR 835; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-1-6 Tests

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 6. Each licensee and registrant shall perform upon instructions from the board, or shall permit the board to perform such reasonable tests as the board deems appropriate or necessary including, but not limited to, tests of:

(a) sources of radiation;

(b) facilities wherein sources of radiation are used or stored;

(c) radiation detection and monitoring instruments; and

(d) other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation. *(Indiana State Department of Health; Rule HRH-2,PT A,Sec A.6; filed May 26, 1978, 3:30 pm: 1 IR 131; filed Feb 29, 1984, 10:10 am: 7 IR 835; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-1-7 Additional requirements

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 7. The board may by rule, regulation, or order, impose upon any licensee or registrant such requirements in addition to those established in 410 IAC 5 as it deems appropriate or necessary to minimize danger to public health and safety or property. *(Indiana State Department of Health; Rule HRH-2,PT A,Sec A.7; filed May 26, 1978, 3:30 pm: 1 IR 131; filed Feb 29, 1984, 10:10 am: 7 IR 835; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-1-8 Violations

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 8. Any person who willfully violates any provision of 410 IAC 5 or order issued thereunder will be subject to controls in IC 13-1-2-20 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]* and IC 13-1-2-21 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*. *(Indiana State Department of Health; Rule HRH-2,PT A,Sec A.8; filed May 26, 1978, 3:30 pm: 1 IR 131; filed Feb 29, 1984, 10:10 am: 7 IR 835; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-1-9 Prohibited devices

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 9. (a) Hand-held fluoroscopic screens shall not be used.

(b) Shoe-fitting fluoroscopic devices shall not be used. *(Indiana State Department of Health; Rule HRH-2,PT A,Sec A.9; filed May 26, 1978, 3:30 pm: 1 IR 131; filed Feb 29, 1984, 10:10 am: 7 IR 836; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-1-10 Board address

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 10. All communications and reports concerning 410 IAC 5, and applications filed thereunder, should be addressed to the board at its office located at the Indiana State Department of Health, 2 North Meridian Street, Indianapolis, Indiana 46204. *(Indiana State Department of Health; Rule HRH-2,PT A,Sec A.10; filed May 26, 1978, 3:30 pm: 1 IR 131; filed Feb 29, 1984, 10:10 am: 7 IR 836; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; errata filed Feb 3, 2010, 2:21 p.m.: 20100224-IR-410100062ACA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-1-10.5 International system of units

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 10.5. The Metric Conversion Act of 1975 (PL 94-168) urged the increasing awareness and use of the International System of Units (SI). Where appropriate, schedules and appendices are provided with notes concerning conversion factors. The inclusion of the SI equivalent is for informational purposes only.

(a) Absorbed dose. The unit of absorbed dose is the gray (Gy), which is equal to 1 joule per kilogram. One rad is equal to 1×10^{-2} gray. Sub-multiples included in this document are the milligray (mGy) and the microgray (μGy).

(b) Dose equivalent. The unit of dose equivalent is the sievert (Sv) which is equal to 1 joule per kilogram. One rem is equal to 1×10^{-2} sievert. Sub-multiples included in this document are the millisievert (mSv) and the microsievert (μSv).

(c) Exposure. The unit of exposure is the coulomb per kilogram (C/kg). One roentgen is equal to 2.58×10^{-4} coulomb per kilogram. Submultiples of this unit are the millicoulomb per kilogram (mC/kg) and the microcoulomb per kilogram (μC/kg).

(d) Radioactivity. The unit of measurement of radioactivity is the becquerel (Bq) and is equal to one transformation per second. One curie is equal to 3.7×10^{10} becquerels. Multiples included in this document are kilobecquerel (kBq), megabecquerel (MBq), gigabecquerel (GBq), and petabecquerel (PBq). *(Indiana State Department of Health; 410 IAC 5-1-10.5; filed Feb 29, 1984, 10:10 am: 7 IR 836; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-1-11 Transport grouping of radionuclides

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 11.

APPENDIX A

TRANSPORT GROUPING OF RADIONUCLIDES

Element[1/]	Radionuclide[2/]	Group
Actinium (89)	Ac-277	I
	Ac-228	I
Americium (95)	Am-241	I
	Am-243	I
Antimony (51)	Sb-122	IV
	Sb-124	III
	Sb-125	III
Argon (18)	Ar-37	VI
	Ar-41	II
	Ar-41 (uncompressed)[3/]	V
Arsenic (33)	As-73	IV
	As-74	IV
	As-76	IV
	As-77	IV
Astatine (85)	At-211	III
Barium (56)	Ba-131	IV
	Ba-133	II

	Ba-140	III
Berkelium (97)	Bk-249	I
Beryllium (4)	Be-7	IV
Bismuth (83)	Bi-206	IV
	Bi-207	III
	Bi-210	II
	Bi-212	III
Bromine (35)	Br-82	IV
Cadmium (48)	Cd-109	IV
	Cd-115m	III
	Cd-115	IV
Calcium (20)	Ca-45	IV
	Ca-47	IV
Californium (98)	Cf-249	I
	Cf-250	I
	Cf-252	I
Carbon (6)	C-14	IV
Cerium (58)	Ce-141	IV
	Ce-143	IV
	Ce-144	III
Cesium (55)	Cs-131	IV
	Cs-134m	III
	Cs-134	III
	Cs-135	IV
	Cs-136	IV
	Cs-137	III
Chlorine (17)	Cl-36	III
	Cl-38	IV
Chromium (24)	Cr-51	IV
Cobalt (27)	Co-56	III
	Co-57	IV
	Co-58m	IV
	Co-58	IV
	Co-60	III
Copper (29)	Cu-64	IV
Curium (96)	Cm-242	I
	Cm-243	I
	Cm-244	I
	Cm-245	I

	Cm-246	I
Dysprosium (66)	Dy-154	III
	Dy-165	IV
	Dy-166	IV
Erbium (68)	Er-169	IV
	Er-171	IV
Europium (63)	Eu-150	III
	Eu-152m	IV
	Eu-152	III
	Eu-154	II
	Eu-155	IV
Fluorine (9)	F-18	IV
Gadolinium (64)	Gd-153	IV
	Gd-159	IV
Gallium (31)	Ga-67	III
	Ga-72	IV
Germanium (32)	Ge-71	IV
Gold (79)	Au-193	III
	Au-194	III
	Au-195	III
	Au-196	IV
	Au-198	IV
	Au-199	IV
Hafnium (72)	Hf-181	IV
Holmium (67)	Ho-166	IV
Hydrogen (1)	H-3 (see tritium)	
Indium (49)	In-113m	IV
	In-114m	III
	In-115m	IV
	In-115	IV
Iodine (53)	I-124	III
	I-125	III
	I-126	III
	I-129	III
	I-131	III
	I-132	IV
	I-133	III
	I-134	IV
	I-135	IV

Iridium (77)	Ir-190	IV
	Ir-192	III
	Ir-194	IV
Iron (26)	Fe-55	IV
	Fe-59	IV
Krypton (36)	Kr-85m	III
	Kr-85m (uncompressed).[3/]	V
	Kr-85	III
	Kr-85 (uncompressed).[3/]	VI
	Kr-87	II
	Kr-87 (uncompressed).[3/]	V
Lanthanum (57)	La-140	IV
Lead (82)	Pb-203	IV
	Pb-210	II
	Pb-212	II
Lutetium (71)	Lu-172	III
	Lu-177	IV
Magnesium (12)	Mg-28	III
Manganese (25)	Mn-52	IV
	Mn-54	IV
	Mn-56	IV
Mercury (80)	Hg-197m	IV
	Hg-197	IV
	Hg-203	IV
Mixed fission products (MFP)		II
Molybdenum (42)	Mo-99	IV
Neodymium (60)	Nd-147	IV
	Nd-149	IV
Neptunium (93)	Np-237	I
	Np-239	I
Nickel (28)	Ni-56	III
	Ni-59	IV
	Ni-63	IV
	Ni-65	IV
Niobium (41)	Nb-93m	IV
	Nb-95	IV
	Nb-97	IV
Osmium (76)	Os-185	IV
	Os-191m	IV

	Os-191	IV
	Os-193	IV
Palladium (46)	Pd-103	V
	Pd-109	IV
Phosphorus (15)	P-32	IV
Platinum (78)	Pt-191	IV
	Pt-193	IV
	Pt-193m	IV
	Pt-197m	IV
	Pt-197	IV
Plutonium (94)	Pu-238(F)	I
	Pu-239(F)	I
	Pu-240	I
	Pu-241(F)	I
	Pu-242	I
Polonium (84)	Po-210	I
Potassium (19)	K-42	IV
	K-43	III
Praseodymium (59)	Pr-142	IV
	Pr-143	IV
Promethium (61)	Pm-147	IV
	Pm-149	IV
Protactinium (91)	Pa-230	I
	Pa-231	I
	Pa-233	II
Radium (88)	Ra-223	II
	Ra-224	II
	Ra-226	I
	Ra-228	I
Radon (86)	Rn-220	IV
	Rn-222	II
Rhenium (75)	Re-183	IV
	Re-186	IV
	Re-187	IV
	Re-188	IV
	Re-Natural	IV
Rhodium (45)	Rh-103m	IV
	Rh-105	IV
Rubidium (37)	Rb-86	IV

	Rb-87	IV
	Rb-Natural	IV
Ruthenium (44)	Ru-97	IV
	Ru-103	IV
	Ru-105	IV
	Ru-106	III
Samarium (62)	Sm-145	III
	Sm-147	III
	Sm-151	IV
	Sm-153	IV
Scandium (21)	Sc-46	III
	Sc-47	IV
	Sc-48	IV
Selenium (34)	Se-75	IV
Silicon (14)	Si-31	IV
Silver (47)	Ag-105	IV
	Ag-110m	III
	Ag-111	IV
Sodium (11)	Na-22	III
	Na-24	IV
Strontium (38)	Sr-85m	IV
	Sr-85	IV
	Sr-89	III
	Sr-90	II
	Sr-91	III
	Sr-92	IV
Sulfur (16)	S-35	IV
Tantalum (73)	Ta-182	III
Technetium (43)	Tc-96m	IV
	Tc-96	IV
	Tc-97m	IV
	Tc-97	IV
	Tc-99m	IV
	Tc-99	IV
Tellurium (52)	Te-125m	IV
	Te-127m	IV
	Te-127	IV
	Te-129m	III
	Te-129	IV

	Te-131m	III
	Te-132	IV
Terbium (65)	Tb-160	III
Thallium (81)	Tl-200	IV
	Tl-201	IV
	Tl-202	IV
	Tl-204	III
Thorium (90)	Th-227	II
	Th-228	I
	Th-230	I
	Th-231	I
	Th-232	III
	Th-234	II
	Th-Natural	III
Thulium (69)	Tm-168	III
	Tm-170	III
	Tm-171	IV
Tin (50)	Sn-113	IV
	Sn-117m	III
	Sn-121	III
	Sn-125	IV
Tritium (1)	H-3	IV
	H-3 (as a gas, as luminous paint, or adsorbed on solid material).	VII
Tungsten (74)	W-181	IV
	W-185	IV
	W-187	IV
Uranium (92)	U-230	II
	U-232	I
	U-233 (F)	II
	U-234	II
	U-235(F)	III
	U-236	II
	U-238	III
	U-Natural	III
	U-Enriched (F)	III
	U-Depleted	III
Vandium (23)	V-48	IV
	V-49	III

Xenon (54)	Xe-125	III
	Xe-131m	III
	Xe-131m (uncompressed).[3/]	V
	Xe-133	III
	Xe-133 (uncompressed).[3/]	VI
	Xe-135	II
	Xe-135 (uncompressed).[3/]	V
Ytterbium (70)	Yb-175	IV
Yttrium (39)	Y-88	III
	Y-90	IV
	Y-91m	III
	Y-91	III
	Y-92	IV
	Y-93	IV
Zinc (30)	Zn-65	IV
	Zn-69m	IV
	Zn-69	IV
Zirconium (40)	Zr-93	IV
	Zr-95	III
	Zr-97	IV

[1/] Atomic number shown in parentheses.

[2/] Atomic mass number shown after the element symbol.

[3/] Uncompressed means at a pressure not exceeding one atmosphere.

m Metastable state.

(F) Fissile material.

For any radionuclide not specifically listed or for mixtures of radionuclides, refer to the definition of "transport group" in 410 IAC 5-1-2. *(Indiana State Department of Health; Rule HRH-2,PT A,Appendix A; filed May 26, 1978, 3:30 pm: 1 IR 131; filed Feb 29, 1984, 10:10 am: 7 IR 836; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-1-12 Tests for special form licensed material

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 12.

APPENDIX B TESTS FOR SPECIAL
FORM LICENSED MATERIAL

(1) Free Drop–A free drop through a distance of 30 feet (9.14 meters) onto a flat essentially unyielding horizontal surface, striking the surface in such a position as to suffer maximum damage.

(2) Percussion–Impact of the flat circular end of a 1 inch (2.54 centimeters) diameter steel rod weighing 3 pounds (1.36 kilograms), dropped through a distance of 40 inches (1.02 meters). The capsule or material shall be placed on a sheet of lead, of hardness number 3.5 to 4.5 on the Vickers scale, and not more than 1 inch (2.54 centimeters) thick, supported by a smooth essentially

unyielding surface.

(3) Heating–Heating in air to a temperature of 1475° F (801.67° C) and remaining at that temperature for a period of 10 minutes.

(4) Immersion–Immersion for 24 hours in water at room temperature. The water shall be at pH 6-pH 8, with a maximum conductivity of 10 micromhos per centimeter. *(Indiana State Department of Health; Rule HRH-2,PT A,Appendix B; filed May 26, 1978, 3:30 pm: 1 IR 134; filed Feb 29, 1984, 10:10 am: 7 IR 839; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

Rule 2. Registration of Radiation Machine Facilities and Services

410 IAC 5-2-1 Scope of rules; registration of materials

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 1. (a) 410 IAC 5-2 provides for the registration of radiation machine facilities.

(b) In addition to the requirements of 410 IAC 5-2, all registrants are subject to the applicable provisions of other sections of 410 IAC 5.

(c) In addition to 410 IAC 5-2-1(a) and 410 IAC 5-2-1(b) each person who receives, possesses, uses, transfers or acquires radioactive material shall register such materials with the board in accordance with the requirements of 410 IAC 5-2. This requirement is effective until the state enters into an effective agreement with the U.S. Nuclear Regulatory Commission for the transfer of regulatory authority under Sec. 274(b) of the Atomic Energy Act of 1954, as amended (73 Stat. 689) at which time 410 IAC 5-3, Licensing of Radioactive Material, becomes effective. *(Indiana State Department of Health; Rule HRH-2,PT B,Sec B.1; filed May 26, 1978, 3:30 pm: 1 IR 135; filed Feb 29, 1984, 10:10 am: 7 IR 839; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-2-2 Definitions

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 2. (a) For purposes of 410 IAC 5-2, "facility" means the location at which one or more devices or sources are installed and/or located within one building, vehicle, or under one roof and are under the same administrative control.

(b) Pursuant to 410 IAC 5-2-1(c) "radiation machine" as used throughout 410 IAC 5-2 also refers to radioactive material. *(Indiana State Department of Health; Rule HRH-2,PT B,Sec B.2; filed May 26, 1978, 3:30 pm: 1 IR 135; filed Feb 29, 1984, 10:10 am: 7 IR 840; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-2-3 Exemptions

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 3. (a) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of 410 IAC 5-2, providing dose equivalent rate averaged over an area of 10 square cm does not exceed 0.5 mrem per hour at 5 cm from any accessible surface of such equipment. The production, testing or factory servicing of such equipment shall not be exempt.

(b) Radiation machines while in transit or storage incident thereto are exempt from the requirements of 410 IAC 5-2.

(c) Domestic television receivers are exempt from the requirements of 410 IAC 5-2. *(Indiana State Department of Health; Rule HRH-2,PT B,Sec B.3; filed May 26, 1978, 3:30 pm: 1 IR 135; filed Feb 29, 1984, 10:10 am: 7 IR 840; readopted filed Jul 11,*

2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-2-4 Application for registration of facility

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 4. Each person having a radiation machine facility shall:

(a) Register such facility with the board prior to the operation of a radiation machine facility. The registration shall be completed on forms furnished by the board and shall contain all the information required by the form and accompanying instructions.

(b) Designate on the application form an individual to be responsible for radiation protection.

(Indiana State Department of Health; Rule HRH-2,PT B,Sec B.4; filed May 26, 1978, 3:30 pm: 1 IR 135; filed Feb 29, 1984, 10:10 am: 7 IR 840; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-2-5 Issuance of registration

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 5. (a) Upon a determination that an applicant meets the requirements of 410 IAC 5, the board shall issue a registration.

(b) The board may incorporate in the registration at the time of issuance or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use and transfer of radiation machines as it deems appropriate or necessary. *(Indiana State Department of Health; Rule HRH-2,PT B,Sec B.5; filed May 26, 1978, 3:30 pm: 1 IR 135; filed Feb 29, 1984, 10:10 am: 7 IR 840; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-2-6 Notice of changes

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 6. The registrant shall notify the board in writing before making any change which would render the information contained in the registration no longer accurate. *(Indiana State Department of Health; Rule HRH-2,PT B,Sec B.6; filed May 26, 1978, 3:30 pm: 1 IR 135; filed Feb 29, 1984, 10:10 am: 7 IR 841; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-2-7 Advertising prohibitions

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 7. No person, in any advertisement, shall refer to the fact that he or his facility is registered with the board pursuant to the provisions of 410 IAC 5-2 and no person shall state or imply that any activity under such registration has been approved by the board. *(Indiana State Department of Health; Rule HRH-2,PT B,Sec B.7; filed May 26, 1978, 3:30 pm: 1 IR 135; filed Feb 29, 1984, 10:10 am: 7 IR 841; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-2-8 Dealers and assemblers; duties; notice and reports to board

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 8. (a) Any person who sells, leases, transfers, lends, disposes, assembles, or installs radiation machines in this state shall notify the board within 15 days of:

(1) the name and address of persons who have received these machines;

(2) the manufacturer, model, and serial number of each radiation machine transferred; and

(3) the date of transfer of each radiation machine.

(b) In the case of diagnostic x-ray systems which contain certified components, a copy of the assembler's report prepared in compliance with requirements of the Federal Diagnostic X-Ray Standard (21 CFR 1020.30(d)) shall be submitted to the board within 15 days following completion of the assembly. Such report shall suffice in lieu of any other report by the assembler.

(c) No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment when properly placed in operation and used shall meet the requirements of 410 IAC 5. *(Indiana State Department of Health; Rule HRH-2,PT B,Sec B.8; filed May 26, 1978, 3:30 pm: 1 IR 135; filed Feb 29, 1984, 10:10 am: 7 IR 841; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-2-9 Bringing radiation machine into state; application

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 9. (a) Whenever any radiation machine is to be brought into the state, for any temporary use, the person proposing to bring such machine into the state shall give written notice to the board at least two (2) working days before such machine is to be used in the state. The notice shall include the type of radiation machine; the nature, duration, and scope of use; the exact location(s) where the radiation machine is to be used; and states in which this machine is registered. If for a specific case the two working-day period would impose an undue hardship on the person, he may, upon application to the board, obtain permission to proceed sooner.

(b) The person referred to in 410 IAC 5-2-9(a) shall:

(1) comply with all applicable requirements of the board including the certification of x-ray machine operators;

(2) supply the board with such other information as the board may reasonably request; and

(3) not operate within the state on a temporary basis in excess of 180 calendar days per year.

(Indiana State Department of Health; Rule HRH-2,PT B,Sec B.9; filed May 26, 1978, 3:30 pm: 1 IR 136; filed Feb 29, 1984, 10:10 am: 7 IR 841; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

Rule 3. Licensing of Radioactive Material

410 IAC 5-3-1 Effective dates *(Repealed)*

Sec. 1. *(Repealed by Indiana State Department of Health; filed Feb 29, 1984, 10:10 am: 7 IR 829)*

410 IAC 5-3-2 Scope of rule

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 2. (a) 410 IAC 5-3 provides for the licensing of radioactive material. No person shall receive, possess, use, transfer, own or acquire radioactive material except as authorized in a specific or general license issued pursuant to 410 IAC 5-3 or as otherwise provided in 410 IAC 5-3.

(b) Provisions for the licensing of radioactive materials as set forth in 410 IAC 5-3 shall become effective on the date of an effective agreement between the U.S. Nuclear Regulatory Commission and the state for the transfer of regulatory authority under Section 274b of the Atomic Energy Act of 1954, as amended (73 Stat 689); however, NARM materials are covered by all applicable provisions of 410 IAC 5.

(c) In addition to the requirements of 410 IAC 5-3, all licensees are subject to the requirements of 410 IAC 5-1, 410 IAC 5-4 and 410 IAC 5-10. Licensees engaged in industrial radiographic operations are subject to the requirements of 410 IAC 5-5 and licensees using sealed sources in the healing arts are subject to the requirements of 410 IAC 5-7, and licensees engaged in wireline and subsurface tracer studies are subject to the requirements of 410 IAC 5-10.1. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.1; filed May 26, 1978, 3:30 pm: 1 IR 136; filed Feb 29, 1984, 10:10 am: 7 IR 841; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-3-3 Exemption of source materials

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 3. (a) Any person is exempt from 410 IAC 5-3 to the extent that such person receives, possesses, uses, owns or transfers source material in any chemical mixture, compound, solution or alloy in which the source material is by weight less than 1/20 of 1 percent (0.05 percent) of the mixture, compound, solution or alloy.

(b) Any person is exempt from 410 IAC 5-3 to the extent that such person receives, possesses, uses or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.

(c) Any person is exempt from 410 IAC 5-3 to the extent that such person receives, possesses, uses or transfers:

(1) Any quantities of thorium contained in:

(i) incandescent gas mantles,

(ii) vacuum tubes,

(iii) welding rods,

(iv) electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium,

(v) germicidal lamps, sunlamps and lamps for outdoor or industrial lighting provided that each lamp does not contain more than 2 grams of thorium,

(vi) rare earth metals and compounds, mixtures and products containing not more than 0.25 percent by weight thorium, uranium or any combination of these, or

(vii) personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium:

(2) Source material contained in the following products:

(i) glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight source material,

(ii) glassware, glass enamel and glass enamel frit containing not more than 10 percent by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile or other glass, glass enamel or ceramic used in construction, or

(iii) piezoelectric ceramic containing not more than 2 percent by weight source material;

(3) Photographic film, negatives and prints containing uranium or thorium;

(4) Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4 percent by weight and that this exemption shall not be deemed to authorize the chemical, physical or metallurgical treatment or processing of any such product or part;

(5) Uranium contained in counterweights installed in aircraft, rockets, projectiles and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that:

(i) The counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, authorizing distribution by the licensee pursuant to 10 CFR Part 40.

(ii) Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM", [1/]

(iii) Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED",[1/] and

(iv) This exemption shall not be deemed to authorize the chemical, physical or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering;

(6) Uranium used as shielding constituting part of any shipping container which is conspicuously and legibly impressed with the legend "CAUTION–RADIOACTIVE SHIELDING–URANIUM" and which meets the specifications for containers for radioactive material prescribed in Section 173.394 or 173.395 of 49 CFR Part 173 of U.S. Department of Transportation regulations;

(7) Thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent by weight of thorium, and that this exemption shall not be deemed to authorize either:

(i) the shaping, grinding, or polishing of such lens or manufacturing processes other than the assembly of such lens into optical systems and devices without any alteration of the lens, or

(ii) the receipt, possession, use or transfer of thorium contained in contact lenses or in spectacles or in eyepieces in binoculars or other optical instruments;

(8) Uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 microcurie of uranium; or

(9) Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

(i) the thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide), and

(ii) the thorium content in the nickel-thoria alloy does not exceed 4 percent by weight.

(d) The exemptions in 410 IAC 5-3-3(c)(2), do not authorize the manufacture of any of the products described.

[1/] The requirements specified in 410 IAC 5-3-3(c)(5)(ii) and (iii) need not be met by counterweights manufactured prior to December 31, 1969; provided, that such counterweights are impressed with the legend, "CAUTION–RADIOACTIVE MATERIAL–URANIUM", as previously required by 410 IAC 5. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.3; filed May 26, 1978, 3:30 pm: 1 IR 136; filed Feb 29, 1984, 10:10 am: 7 IR 842; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-3-4 Exemption of materials other than source materials

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 4. (a) Exempt Concentrations

(1) Except as provided in 410 IAC 5-3-4(a)(2), any person is exempt from this part to the extent that such person receives, possesses, uses, transfers, owns or acquires products containing radioactive material introduced in concentrations not in excess of those listed in Schedule A, 410 IAC 5-3-26.

(2) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under 410 IAC 5-3-4(a)(1) or equivalent regulations of the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, except in accordance with a specific license issued pursuant to 410 IAC 5-3-13(a) or the general license provided in 410 IAC 5-3-24.

(b) Exempt Quantities

(1) Except as provided in 410 IAC 5-3-4(b)(3) and (4), any person is exempt from 410 IAC 5 to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in Schedule B, 410 IAC 5-3-27.

(2) 410 IAC 5-3-4(b) does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution or the incorporation of radioactive material into products intended for commercial distribution.

(3) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Schedule B, 410 IAC 5-3-27, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under 410 IAC 5-3-4(b) or equivalent regulations of the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR Part 32 or by the board pursuant to 410 IAC 5-3-13(b) which license states

that the radioactive material may be transferred by the licensee to persons exempt under 410 IAC 5-3-4(b) or the equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state or licensing state.[2/]

(c) Exempt Items

(1) Certain items containing radioactive material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, any person is exempt from 410 IAC 5 to the extent that he receives, possesses, uses, transfers, owns or acquires the following products:[2/]

(i) Timepieces or hands or dials containing not more than the following specified quantities of byproduct material and not exceeding the following specified radiation dose rate:

(A) 25 millicuries of tritium per timepiece,

(B) 5 millicuries of tritium per hand,

(C) 15 millicuries of tritium per dial (bezels when used shall be considered as part of the dial),

(D) 100 microcuries of promethium-147 per watch or 200 microcuries of promethium-147 per any other timepiece,

(E) 20 microcuries of promethium-147 per watch hand or 40 microcuries of promethium-147 per other timepiece hand,

(F) 60 microcuries of promethium-147 per watch dial or 120 microcuries of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial),

(G) The radiation dose rate from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(aa) For wrist watches, 0.1 millirad per hour at 10 centimeters from any surface,

(bb) For pocket watches, 0.1 millirad per hour at 1 centimeter from any surface,

(cc) For any other timepiece, 0.2 millirad per hour at 10 centimeters from any surface.

(H) One microcurie of radium-226 per timepiece in timepieces acquired prior to the effective date of 410 IAC 5.

(ii) Lock illuminators containing not more than 15 millicuries of tritium or not more than 2 millicuries of promethium-147 installed in automobile locks. The radiation dose rate from each lock illuminator containing promethium-147 will not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 50 milligrams per square centimeter of absorber;

(iii) Precision balances containing not more than 1 millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance part;

(iv) Automobile shift quadrants containing not more than 25 millicuries of tritium;

(v) Marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas;

(vi) Thermostat dials and pointers containing not more than 25 millicuries of tritium per thermostat;

(vii) Electron tubes; provided, that each tube does not contain more than one of the following specified quantities of radioactive material:

(A) 150 millicuries of tritium per microwave receiver protector tube or 10 millicuries of tritium per any other electron tube;

(B) 1 microcurie of cobalt-60;

(C) 5 microcuries of nickel-63;

(D) 30 microcuries of krypton-85;

(E) 5 microcuries of cesium-137;

(F) 30 microcuries of promethium-147;

And provided further, that the radiation dose rate from each electron tube containing radioactive material will not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber;[3/]

(viii) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material, provided that:

(A) Each source contains no more than one exempt quantity set forth in Schedule B, 410 IAC 5-3-27, and

(B) Each instrument contains no more than 10 exempt quantities. For purposes of this requirement, an

instrument's source(s) may contain either one 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 Schedule B, 410 IAC 5-3-27, provided that the sum of such fractions shall not exceed unity.

(ix) Spark gap irradiators containing not more than 1 microcurie of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 3 gallons (11.4 liters) per hour.

(2) Self-Luminous Products Containing Radioactive Material.

(i) Tritium, Krypton-85 or Promethium-147. Except for persons who manufacture, process or produce self-luminous products containing tritium, krypton-85 or promethium-147, any person is exempt from 410 IAC 5 to the extent that such person receives, possesses, uses, transfers, owns or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR Part 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in 410 IAC 5-3-4(c)(2) does not apply to tritium, krypton-85 or promethium-147 used in products for frivolous purposes or in toys or adornments.

(ii) Radium-226. Any person is exempt from 410 IAC 5 to the extent that such person receives, possesses, uses, transfers or owns articles containing less than 0.1 microcurie of radium-226 which were acquired prior to the effective date of 410 IAC 5.

(3) Gas and aerosol detectors containing radioactive material.

(i) Except for persons who manufacture, process or produce gas and aerosol detectors containing radioactive material, any person is exempt from 410 IAC 5 to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material shall have been manufactured, imported or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission[2]/ pursuant to Section 32.26 of 10 CFR Part 32; or a licensing state pursuant to 410 IAC 5-3-13(c) which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.

(ii) Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an agreement state shall be considered exempt under 410 IAC 5-3-4(c)(3)(i), provided that the device is labeled in accordance with the specific license authorizing distribution of the general licensed device, and provided further that they meet the requirements of 410 IAC 5-3-13(c).

(iii) Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific license issued by a licensing state shall be considered exempt under 410 IAC 5-3-4(c)(3)(i), provided that the device is labeled in accordance with the specific license authorizing distribution, and provided further that they meet the requirements of 410 IAC 5-3-13(c).

(4) Resins containing scandium-46 and designed for sand consolidation in oil wells. Any person is exempt from 410 IAC 5 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. Such resins shall have been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or shall have been manufactured in accordance with the specifications contained in a specific license issued by the board or any agreement state to the manufacturer of such resins pursuant to licensing requirements equivalent to those in Sections 32.16 and 32.17 of 10 CFR Part 32 of the regulations of the Nuclear Regulatory Commission. This exemption does not authorize the manufacture of any resins containing scandium-46.

[2]/ Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity or other product containing byproduct material whose subsequent possession, use, transfer and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

[3]/ For purposes of 410 IAC 5-3-4(c)(1)(vii) "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes and any other completely sealed tube that is designed to conduct or control electrical currents. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.4; filed May 26, 1978, 3:30 pm: 1 IR 137; filed Feb 29, 1984, 10:10 am: 7 IR 843; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-*

410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-3-5 Types of licenses

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 5. Licenses for radioactive materials are of two types: general and specific.

(a) General licenses provided in 410 IAC 5-3 are effective without the filing of applications with the board or the issuance of licensing documents to the particular persons, although the filing of a certificate with the board may be required by the particular general license. The general licensee is subject to all other applicable portions of 410 IAC 5 and any limitations of the general license.

(b) Specific licenses require the submission of an application to the board and the issuance of a licensing document by the board. The licensee is subject to all applicable portions of 410 IAC 5 as well as any limitations specified in the licensing document. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.20; filed May 26, 1978, 3:30 pm: 1 IR 139; filed Feb 29, 1984, 10:10 am: 7 IR 845; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-3-6 General licenses for source materials

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 6. (a) A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and state and local government agencies to use and transfer not more than 15 pounds (6.82 kg) of source material at any one time for research, development, educational, commercial, or operational purposes. A person authorized to use or transfer source material, pursuant to this general license, may not receive more than a total of 150 pounds (68.2 kg) of source material in any one calendar year.

(b) Persons who receive, possess, use or transfer source material pursuant to the general license issued in 410 IAC 5-3-6(a) are exempt from the provisions of 410 IAC 5-4 and 410 IAC 5-10 of 410 IAC 5 to the extent that such receipt, possession, use or transfer is within the terms of such general license; provided, however, that this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to 410 IAC 5-3-6.

(c) A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use or transfer source material.

(d) Depleted Uranium in Industrial Products and Devices.

(1) A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of 410 IAC 5-3-6(d)(2), (3), (4) and (5) depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

(2) The general license in 410 IAC 5-3-6(d)(1) applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to 410 IAC 5-3-13(m) or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an agreement state which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an agreement state.

(3)(i) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by 410 IAC 5-3-6(d)(1) shall file board form "W" "Registration Certificate–Use of Depleted Uranium Under General License," with the board. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The registrant shall furnish on board form "W" the following information and such other information as may be required by that form:

(A) Name and address of the registrant;

(B) A statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 410 IAC 5-3-6(d)(1) and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(C) Name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in 410 IAC 5-3-6(d)(3)(i)(B).

(ii) The registrant possessing or using depleted uranium under the general license established by 410 IAC 5-3-6(d)(1) shall report in writing to the board any changes in information furnished by him in board form W "Registration Certificate–Use of Depleted Uranium Under General License." The report shall be submitted within 30 days after the effective date of such change.

(4) A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by 410 IAC 5-3-6(d)(1):

(i) Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

(ii) Shall not abandon such depleted uranium;

(iii) Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 410 IAC 5-3-22. In the case where the transferee receives the depleted uranium pursuant to the general license established by 410 IAC 5-3-6(d)(1), the transferor shall furnish the transferee a copy of 410 IAC 5 and a copy of board form "W", 410 IAC 5-3-32. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission or agreement state's rule equivalent to 410 IAC 5-3-6(d)(1), the transferor shall furnish the transferee a copy of 410 IAC 5 and a copy of board form "W" accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or agreement state under requirements substantially the same as those in 410 IAC 5;

(iv) Within 30 days of any transfer, shall report in writing to the board the name and address of the person receiving the depleted uranium pursuant to such transfer; and

(v) Shall not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.

(5) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by 410 IAC 5-3-6(d)(1)is exempt from the requirements of 410 IAC 5-4 and 410 IAC 5-10 with respect to the depleted uranium covered by that general license.

(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.21; filed May 26, 1978, 3:30 pm: 1 IR 140; filed Feb 29, 1984, 10:10 am: 7 IR 846; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-3-7 General licenses for materials other than source materials

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 7. General Licenses*–Radioactive Material Other Than Source Material. (a) Certain Devices and Equipment. A general license is hereby issued to transfer, receive, acquire, own, possess and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested, and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission for use pursuant to Section 31.3 of 10 CFR Part 31. This general license is subject to the provisions of 410 IAC 5-1-4 through 410 IAC 5-1-9, 410 IAC 5-3-4(a)(2), 410 IAC 5-3-15, 410 IAC 5-3-22, 410 IAC 5-3-23, 410 IAC 5-3-25, 410 IAC 5-4,[4/] and 410 IAC 5-10.

*Different general licenses are issued in this section, each of which has its own specific conditions and requirements.

[4/] Attention is directed particularly to the provisions of 410 IAC 5-4 which relates to the labeling of containers.

(1) Static Elimination Device. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of polonium-210 per device or a total of not more than 50 millicuries of hydrogen-3 (tritium) per device.

(2) Ion Generating Tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of polonium-210 per device or a total of not more than 50 millicuries of hydrogen-3 (tritium) per device.

(b) Reserved

(c) Reserved

(d) Certain Measuring, Gauging or Controlling Devices.

(1) A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of 410 IAC 5-3-7(d)(2), (3), and (4), radioactive material, excluding special nuclear 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.

(2) The general license in 410 IAC 5-3-7(d)(1) applies only to radioactive material contained in devices which have been manufactured and labeled in accordance with the specifications contained in a specific license issued by the board pursuant to 410 IAC 5-3-13(d) or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state, which authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state.[5/]

[5/] Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in 21 CFR 179.21.

(3) Any person who owns, receives, acquires, possesses, uses or transfers radioactive material in a device pursuant to the general license in 410 IAC 5-3-7(d)(1):

(i) 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;

(ii) 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 on 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 100 microcuries of other beta and/or gamma emitting material or 10 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;

(iii) Shall assure that other testing, installation, servicing and removal from installation involving the radioactive material, its shielding or containment, are performed:

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

(B) By a person holding an applicable specific license from the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to perform such activities;

(iv) Shall maintain records showing compliance with the requirements of 410 IAC 5-3-7(d)(3)(ii) and (iii). The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by 410 IAC 5-3-7(d)(3)(ii) shall be maintained for 1 year after the next required leak test is performed or until the sealed source is transferred or disposed of. Records of tests of the on/off mechanism and indicator required by 410 IAC 5-3-7(d)(3)(ii) shall be maintained for 1 year after the next required test of the on/off mechanism and indicator is performed or until the sealed source is transferred or disposed of. Records which are required by 410 IAC 5-3-7(d)(3)(iii) shall be maintained for a period of 2 years from the date of the recorded event or until the device is transferred or disposed of;

(v) Upon the occurrence of 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 0.005 microcurie or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to repair such devices, or disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device and, within 30 days, furnish to the board a report containing a brief description of the event and the remedial action taken;

(vi) Shall not abandon the device containing radioactive material;

(vii) Except as provided in 410 IAC 5-3-7(d)(3)(viii), shall transfer or dispose of the device containing radioactive

material only by transfer to a specific licensee of the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state whose specific license authorizes him to receive the device and within 30 days after transfer of a device to a specific licensee shall furnish to the board a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device;

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

(A) Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of 410 IAC 5 and any safety documents identified in the label on the device and within 30 days of the transfer, report to the board the manufacturer's name and model number of device transferred, the name and address of the transferee, and the name and/or position of an individual who may constitute a point of contact between the board and the transferee; or

(B) Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee; and

(ix) Shall comply with the provisions of 410 IAC 5-4-22 and 410 IAC 5-4-23 for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of 410 IAC 5-4 and 410 IAC 5-10.

(4) The general license in 410 IAC 5-3-7(d)(1) does not authorize the manufacture of devices containing radioactive material.

(5) The general license provided in 410 IAC 5-3-7(d)(1) is subject to the provisions of 410 IAC 5-1-4 through 410 IAC 5-1-9, 410 IAC 5-3-15, 410 IAC 5-3-22, 410 IAC 5-3-23, and 410 IAC 5-3-25.

(e) Luminous Safety Devices for Aircraft.

(1) A general license is hereby issued to own, receive, acquire, possess and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:

(i) Each device contains not more than 10 curies of tritium or 300 millicuries of promethium-147; and

(ii) Each device has been manufactured, assembled or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the board or any agreement state to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in Section 32.53 of 10 CFR Part 32.

(2) Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in 410 IAC 5-3-7(e)(1) are exempt from the requirements of 410 IAC 5-4 and 410 IAC 5-10 except that they shall comply with the provisions of 410 IAC 5-4-22 and 410 IAC 5-4-23.

(3) This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.

(4) This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.

(5) This general license is subject to the provisions of 410 IAC 5-1-4 through 410 IAC 5-1-9, 410 IAC 5-3-15, 410 IAC 5-3-22, 410 IAC 5-3-23, and 410 IAC 5-3-25.

(f) Ownership of Radioactive Material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of 410 IAC 5-3, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

(g) Calibration and Reference Sources.

(1) A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use and transfer, in accordance with the provisions of 410 IAC 5-3-7(g)(4) and (5), americium-241 in the form of calibration or reference sources:

(i) Any person who holds a specific license issued by the board which authorizes him to receive, possess, use and transfer radioactive material; and

(ii) Any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes him to receive, possess, use and transfer special nuclear material.

(2) A general license is hereby issued to own, receive, possess, use and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of 410 IAC 5-3-7(g)(4) and (5) to any person who holds a specific license issued by the board which authorizes him to receive, possess, use and transfer radioactive material.

(3) A general license is hereby issued to own, receive, possess, use and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of 410 IAC 5-3-7(g)(4) and (5) to any person who holds a specific license

issued by the board which authorizes him to receive, possess, use and transfer radioactive material.

(4) The general licenses in 410 IAC 5-3-7(g)(1), (2), and (3) apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the board, any agreement state or licensing state pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70.

(5) The general licenses provided in 410 IAC 5-3-7(g)(1), (2) and (3) are subject to the provisions of 410 IAC 5-1-4 through 410 IAC 5-1-9, 410 IAC 5-3-15, 410 IAC 5-3-22, 410 IAC 5-3-23, and 410 IAC 5-3-25 and 410 IAC 5-4, and 410 IAC 5-10. In addition, persons who own, receive, acquire, possess, use or transfer one or more calibration or reference sources pursuant to these general licenses:

(i) Shall not possess at any one time, at any one location of storage or use, more than 5 microcuries of americium-241, 5 microcuries of plutonium or 5 microcuries of radium-226 in such sources;

(ii) Shall not receive, possess, use or transfer such source unless the source, or the storage container, bears a label which includes the following statements as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, as appropriate:

(A) The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION–RADIOACTIVE MATERIAL–THIS SOURCE CONTAINS (AMERICIUM-241). (PLUTONIUM)[6/] DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____
Name of manufacturer or importer

[6/] Showing only the name of the appropriate material.

(B) The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of a licensing state. Do not remove this label.

CAUTION–RADIOACTIVE MATERIAL–THIS SOURCE CONTAINS RADIUM-226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____
Name of manufacturer or importer

(iii) Shall not transfer, abandon or dispose of such source except by transfer to a person authorized by a license from the board, the U.S. Nuclear Regulatory Commission, an agreement state, or licensing state to receive the source;

(iv) Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 which might otherwise escape during storage; and

(v) Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(6) These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.

(h) Medical Diagnostic Uses[7/8/]

[7/] 410 IAC 5-3-13 requires manufacturers of radiopharmaceuticals which are under the general license in this paragraph to affix a certain identifying label to the container or in the leaflet or brochure which accompanies the radiopharmaceutical.

[8/] The New Drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

(1) A general license is hereby issued to any physician to receive, possess, transfer or use radioactive material set forth below for the stated diagnostic uses, provided, however, that the use is in accordance with the provision of 410 IAC 5-3-7(h)(2), (3), and (4), the radioactive material is in the form of capsules, disposable syringes or other prepackaged individual doses; and the radioactive material has been manufactured in accordance with a specific license issued by the board pursuant to 410 IAC 5-3-13(g), or by the U.S. Nuclear Regulatory Commission, any agreement state or a licensing state pursuant to equivalent rules authorizing distribution to persons generally licensed pursuant to 410 IAC 5-3-7(h) or its equivalent.

(i) Chromium-51 as sodium radiochromate for determination of red blood cell volumes and studies of red blood cell

survival time;

(ii) Cobalt-57 for the measurement of intestinal absorption of cyanocobalamin;

(iii) Cobalt-58 for the measurement of intestinal absorption of cyanocobalamin;

(iv) Cobalt-60 for the measurement of intestinal absorption of cyanocobalamin;

(v) Iodine-125 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;

(vi) Iodine-131 as sodium iodide for measurement of thyroid uptake; and

(vii) Iodine-131 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;

(2) No physician shall receive, possess, use or transfer radioactive material pursuant to the general license established by 410 IAC 5-3-7(h)(1) until he has filed board form "U," 410 IAC 5-3-30, "Certificate–Medical Use of Radioactive Material Under General License" with the board and received from the board a validated copy of the board form "U," 410 IAC 5-3-30, with certification number assigned. The generally licensed physician shall furnish on board form "U," 410 IAC 5-3-30, the following information and such other information as may be required by that form:

(i) name and address of the generally licensed physician;

(ii) a statement that the generally licensed physician is a duly licensed physician (authorized to dispense drugs) in the practice of medicine in Indiana; and

(iii) a statement that the generally licensed physician has appropriate radiation measuring instruments to carry out the diagnostic procedures for which he proposes to use radioactive material under the general license of 410 IAC 5-3-7(h) and that he is competent in the use of such instruments.

(3) A physician who receives, possesses, or uses a pharmaceutical containing radioactive material pursuant to the general license established by 410 IAC 5-3-7(h)(1) shall comply with the following:

(i) he shall not possess at any one time, pursuant to the general license in 410 IAC 5-3-7(h)(1) more than:

(A) 200 microcuries of iodine-131,

(B) 200 microcuries of iodine-125,

(C) 5 microcuries of cobalt-57,

(D) 5 microcuries of cobalt-58,

(E) 5 microcuries of cobalt-60, and

(F) 200 microcuries of chromium-51;

(ii) he shall store the pharmaceutical until administered in the original shipping container, or a container providing equivalent radiation protection;

(iii) he shall use the pharmaceutical only for the uses authorized by 410 IAC 5-3-7(h)(1);

(iv) he shall not administer the pharmaceutical to a woman with confirmed pregnancy or to a person under 18 years of age; and

(v) he shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the board, the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, or in any manner other than in the unopened, labeled shipping container as received from the supplier, except by administering it to a patient.

(4) The generally licensed physician possessing or using radioactive material under the general license of 410 IAC 5-3-7(h)(1) shall report in duplicate to the board, any changes in the information furnished by him in the "Certificate–Medical Use of Radioactive Material Under General License," board form "U." The report shall be submitted within 30 days after the effective date of such change.

(5) Any person using radioactive material pursuant to the general license of 410 IAC 5-3-7(h)(1) is exempt from the requirements of 410 IAC 5-4 and 410 IAC 5-10 with respect to the radioactive material covered by the general license.

(i) General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing.[8/]

[8/] The New Drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

(1) A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of 410 IAC 5-3-7(i)(2), (3), (4), (5), and (6), the following radioactive materials in prepackaged units for use in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

(i) Carbon-14, in units not exceeding 10 microcuries each;

(ii) Cobalt-57, in units not exceeding 10 microcuries each;
(iii) Hydrogen-3 (tritium), in units not exceeding 50 microcuries each;
(iv) Iodine-125, in units not exceeding 10 microcuries each;
(v) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie iodine-129 and 0.005 microcurie of americium-241 each;
(vi) Iodine-131, in units not exceeding 10 microcuries each;
(vii) Iron-59, in units not exceeding 20 microcuries each;
(viii) Selenium-75, in units not exceeding 10 microcuries each;

(2) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by 410 IAC 5-3-7(i)(1) until he has filed board form "V," 410 IAC 5-3-31, "Certificate–In Vitro Testing with Radioactive Material Under General License," with the board and received from the board a validated copy of board form "V" with certification number assigned, or until he has been authorized pursuant to 410 IAC 5-3-11(c)(3) to use radioactive material under the general license in 410 IAC 5-3-7(i). The physician, veterinarian, clinical laboratory or hospital shall furnish on board form "V" the following information and such other information as may be required by that form:

(i) name and address of the physician, veterinarian, clinical laboratory or hospital;
(ii) the location of use; and
(iii) a statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in 410 IAC 5-3-7(i)(1) and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

(3) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by 410 IAC 5-3-7(i)(1) shall comply with the following:

(i) the general licensee shall not possess at any one time, pursuant to the general license in 410 IAC 5-3-7(i)(1) at any one location of storage or use, a total amount of iodine-125, iodine-131, iron-59, selenium-75, and/or cobalt-57 in excess of 200 microcuries;
(ii) the general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection;
(iii) the general licensee shall use the radioactive material only for the uses authorized by 410 IAC 5-3-7(i)(1);
(iv) the general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the board, the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier;
(v) the general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in 410 IAC 5-3-7(i)(1)(viii) as required by 410 IAC 5-4-16.

(4) The general licensee shall not receive, acquire, possess or use radioactive material pursuant to 410 IAC 5-3-7(i)(1):

(i) Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 410 IAC 5-3-13(h), or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, any agreement state or licensing state which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under 410 IAC 5-3-7(i) or its equivalent; and
(ii) Unless one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

(A) This radioactive material may be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority.

_____

Name of manufacturer

(B) This radioactive material shall be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a licensing state.

_____

Name of manufacturer

(5) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of 410 IAC 5-3-7(i)(1) shall report in writing to the board, any changes in the information furnished by him in the "Certificate–In Vitro Testing with Radioactive Material Under General License," board form "V," 410 IAC 5-3-31. The report shall be furnished within 30 days after the effective date of such change.

(6) Any person using radioactive material pursuant to the general license of 410 IAC 5-3-7(i)(1) is exempt from the requirements of 410 IAC 5-4 and 410 IAC 5-10 with respect to radioactive material covered by that general license, except, that such persons using the Mock Iodine-125 described in 410 IAC 5-3-7(i)(1)(viii) shall comply with the provisions of 410 IAC 5-4-16, 410 IAC 5-4-22, and 410 IAC 5-4-23.

(j) Ice Detection Devices.

(1) A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 microcuries of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the board or an agreement state to the manufacturer of such device pursuant to licensing requirements equivalent to those in Section 32.61 of 10 CFR Part 32.

(2) Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in 410 IAC 5-3-7(j)(1),

(i) Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an agreement state to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of 410 IAC 5-4-16;

(ii) Shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and

(iii) Are exempt from the requirements of 410 IAC 5-4 and 410 IAC 5-10 except that such persons shall comply with the provisions of 410 IAC 5-4-16, 410 IAC 5-4-22, and 410 IAC 5-4-23.

(3) This general license does not authorize the manufacture, assembly, disassembly or repair of strontium-90 in ice detection devices.

(4) This general license is subject to the provisions of 410 IAC 5-1-4 through 410 IAC 5-1-9, 410 IAC 5-3-15, 410 IAC 5-3-22, 410 IAC 5-3-23, and 410 IAC 5-3-25.

(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.22; filed May 26, 1978, 3:30 pm: 1 IR 141; filed Feb 29, 1984, 10:10 am: 7 IR 847; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-3-8 Intrastate transportation of radioactive material; general license *(Repealed)*

Sec. 8. *(Repealed by Indiana State Department of Health; filed Feb 29, 1984, 10:10 am: 7 IR 829)*

410 IAC 5-3-9 Applications for specific licenses

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 9. (a) Applications for specific licenses shall be filed (in triplicate) on a form prescribed by the board.

(b) The board may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the board to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(c) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

(d) An application for a license may include a request for a license authorizing one or more activities.

(e) In his application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the board provided such references are clear and specific. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.24; filed May 26, 1978, 3:30 pm: 1 IR 148; filed Feb 29, 1984, 10:10 am: 7 IR 855; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-3-10 Approval of specific licenses; environmental reports; surety for site reclamation; long-term care fund

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 10. A license application will be approved if the board determines that:

(a) The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with 410 IAC 5 in such a manner as to minimize danger to public health and safety or property;

(b) The applicant's proposed equipment, facilities and procedures are adequate to minimize danger to public health and safety or property;

(c) The issuance of the license will not be inimical to the health and safety of the public; and

(d) The applicant satisfies any applicable special requirements in 410 IAC 5-3-11, 410 IAC 5-3-12, 410 IAC 5-3-13.

(e) Environmental Report, Commencement of Construction. In the case of an application for a license to receive and possess radioactive material for commercial waste disposal by land burial, source material milling, or for the conduct of any other activity which the board determines will significantly affect the quality of the environment, the board, before commencement of construction of the plant or facility in which the activity will be conducted, shall make a determination, after weighing the environmental, economic, technical and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such determination shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility. As used in this paragraph, the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

(f) Financial Surety Arrangements for Site Reclamation.

(1) Pursuant to applicable state statutes, and as otherwise provided, financial surety arrangements for site reclamation which may consist of surety bonds, cash deposits, certificates of deposit, deposits of government securities, letters or lines of credit, or any combination of the above for the categories of licensees listed in 410 IAC 5-3-10(f)(4) shall be established to ensure the protection of the public health and safety in the event of abandonment, default, or other inability of the licensee to meet the requirements of IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]* and 410 IAC 5.

(i) The amount of funds to be ensured by such surety arrangements shall be based on board-approved cost estimates.

(ii) Self insurance, or any arrangement which essentially constitutes self insurance, will not satisfy the surety requirement since this provides no additional assurance other than that which already exists through license requirements.

(2) The arrangements required in 410 IAC 5-3-10(f)(1) shall be established prior to issuance of the license to assure that sufficient funds will be available to carry out the decontamination and decommissioning of the facility.

(3) Amendments to licenses in effect on the effective date of 410 IAC 5 may be issued providing that the required surety arrangements are established within 90 days after the effective date of 410 IAC 5-3-10(f).

(4) The following specific licensees are required to make financial surety arrangements:

(i) major processors;

(ii) waste handling licensees;

(iii) former U.S. Atomic Energy Commission or U.S. Nuclear Regulatory Commission licensed facilities;
(iv) source material milling operations; and
(v) all others except persons exempt pursuant to 410 IAC 5-3-10(f)(5).

(5) The following persons are exempt from the requirements of 410 IAC 5-3-10(f)(1):
(i) all state, local, or other government agencies, unless they are subject to 410 IAC 5-3-10(f)(4)(ii) or (iv);
(ii) persons authorized to possess no more than 1,000 times the quantity specified in Schedule B, 410 IAC 5-3-27 or combination of radioactive material listed therein as given in Schedule B, 410 IAC 5-3-27, Note 1;
(iii) persons authorized to possess hydrogen-3 contained as hydrogen gas in a sealed source; or
(iv) persons authorized to possess radioactive noble gases in sealed sources with no radioactive daughter product with half-life greater than 30 days.

(g) Long-Term Care Requirements. Pursuant to the appropriate state statutes, and as otherwise provided, a long-term care fund shall be established by the following specific licensees prior to the issuance of the license or prior to the termination of the license if the applicant chooses at the time of the licensure to provide a surety in lieu of a long-term care fund:[9/]

(1) Waste handling licensees; and
(2) Source material milling licensees.

[9/] Long-term care funding may also be required for former U.S. Atomic Energy Commission or U.S. Nuclear Regulatory Commission licensed facilities. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.25; filed May 26, 1978, 3:30 pm: 1 IR 148; filed Feb 29, 1984, 10:10 am: 7 IR 855; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-3-11 Specific licenses for human, medical and industrial uses

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 11. (a) Human Use of Radioactive Material in Institutions. In addition to the requirements set forth in 410 IAC 5-3-10, a specific license for human use of radioactive material in institutions will be issued if:

(1) The applicant has appointed a medical isotopes committee of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of radioactive material within that institution. Membership of the committee should include physicians expert in internal medicine, hematology, therapeutic radiology, and a person experienced, in assay of radioactive material and protection against radiation;
(2) The applicant possesses adequate facilities for the clinical care of patients;
(3) The physician designated on the application as the individual user has substantial experience in the handling and administration of radioactive material and, where applicable, the clinical management of radioactive patients; and
(4) The application is for a license to use unspecified quantities or multiple types of radioactive material, the applicant's staff has substantial experience in the use of a variety of radioactive materials for a variety of human uses.

(b) Licensing of Individual Physicians for Human Use of Radioactive Material.

(1) An application by an individual physician or group of physicians for a specific license for human use of radioactive material will be approved if:
(i) The applicant satisfies the general requirements specified in 410 IAC 5-3-10;
(ii) The application is for use in the applicant's practice in an office outside a medical institution;
(iii) The applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable; and
(iv) The applicant has extensive experience in the proposed use, the handling and administration of radionuclides, and where applicable, the clinical management of radioactive patients.

(2) The board will not approve an application by an individual physician or group of physicians for a specific license to receive, possess, or use radioactive material on the premises of a medical institution unless:
(i) The use of radioactive material is limited to:
(A) The administration of radiopharmaceuticals for diagnostic or therapeutic purposes,
(B) The performance of diagnostic studies on patients to whom a radiopharmaceutical has been administered,

(C) The performance of in vitro diagnostic studies, or

(D) The calibration and quality control checks of radioactive assay instrumentation, radiation safety instrumentation, and diagnostic instrumentation;

(ii) The physician brings the radioactive material with him and removes the radioactive material when he departs (the institution cannot receive, possess, or store radioactive material other than the amount of material remaining in the patient); and

(iii) The medical institution does not hold a radioactive material license under 410 IAC 5-3-11(a).

(c) Specific Licenses for Certain Groups of Medical Uses of Radioactive Material.

(1) Subject to the provisions of 410 IAC 5-3-11(c)(2), (3), and (4) an application for a specific license pursuant to 410 IAC 5-3-11(a), (b) or (d) for any medical use or uses of radioactive material specified in one or more of Groups I to VI, inclusive, of Schedule C, 410 IAC 5-3-28, will be approved for all of the uses within the group or groups which include the use or uses specified in the application if:

(i) The applicant satisfies the requirements of 410 IAC 5-3-11(a), (b) and (d);

(ii) The applicant, or the physician designated in the application as the individual user, has adequate clinical experience in the types of uses included in the group or groups;

(iii) The applicant, or the physicians and all other personnel who will be involved in the preparation and use of the radioactive material, have adequate training and experience in the handling of radioactive material appropriate to their participation in the uses included in the group or groups;

(iv) The applicant's radiation detection and measuring instrumentation is adequate for conducting the procedures involved in the uses included in the group or groups; and

(v) The applicant's radiation safety operating procedures are adequate for handling and disposal of the radioactive material involved in the uses included in the group or groups.

(2) Any licensee or registrant who is authorized to use radioactive material pursuant to one or more groups in 410 IAC 5-3-11(c)(1) and Schedule C, 410 IAC 5-3-28, is subject to the following conditions:

(i) For Groups I, II, IV, and V, no licensee or registrant shall receive, possess or use radioactive material except as a radiopharmaceutical manufactured in the form to be administered to the patient, labeled, packaged and distributed in accordance with a specific license issued by the board pursuant to 410 IAC 5-3-13(j), a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.72 of 10 CFR Part 32, or a specific license issued by an agreement state or a licensing state pursuant to equivalent regulations.

(ii) For Group III, no licensee or registrant shall receive, possess or use generators or reagent kits containing radioactive material or shall use reagent kits that do not contain radioactive material to prepare radiopharmaceuticals containing radioactive material, except:

(A) Reagent kits not containing radioactive material that are approved by the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state for use by persons licensed pursuant to 410 IAC 5-3-11(c) and Schedule C, 410 IAC 5-3-28, or equivalent regulations; or

(B) Generators or reagent kits containing radioactive material that are manufactured, labeled, packaged and distributed in accordance with a specific license issued by the board pursuant to 410 IAC 5-3-13(k) a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.73 of 10 CFR Part 32, or a specific license issued by an agreement state or a licensing state pursuant to equivalent regulations.

(iii) For Group VI, no licensee or registrant shall receive, possess, or use radioactive material except as contained in a source or device that has been manufactured, labeled, packaged and distributed in accordance with a specific license issued by the board pursuant to 410 IAC 5-3-13(l), a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.74 of 10 CFR Part 32, or a specific license issued to the manufacturer by an agreement state or a licensing state pursuant to equivalent regulations.

(iv) For Group III, any licensee or registrant who uses generators or reagent kits shall:

(A) Elute the generator, or process radioactive material with the reagent kit, in accordance with instructions approved by the U.S. Nuclear Regulatory Commission, an agreement state or licensing state and furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit;

(B) Before administration to patients, cause each elution or extraction of technetium-99m from a molybdenum-

99/technetium-99m generator to be tested to determine either the total molybdenum-99 activity or the concentration of molybdenum-99. This testing shall be conducted according to written procedures and by personnel who have been specifically trained to perform the test;

(C) Prohibit the administration to patients of technetium-99m containing more than 1 microcurie of molybdenum-99 per millicurie of technetium-99m, or more than 5 microcuries of molybdenum-99 per administered dose, at the time of administration; and

(D) Maintain for 3 years for board inspection records of the molybdenum-99 test conducted on each elution from the generator.

(v) For Groups I, II, and III, any licensee using radioactive material for clinical procedures other than those specified in the product labeling (package insert) shall comply with the product labeling regarding:

(A) Chemical and physical form;

(B) Route of administration; and

(C) Dosage range.

(3) Any licensee who is licensed pursuant to 410 IAC 5-3-11 for one or more of the medical use groups in Schedule C, 410 IAC 5-3-28, also is authorized to use radioactive material under the general license in 410 IAC 5-3-7(i) for the specified in vitro uses without filing board form "V" as required by 410 IAC 5-3-7(i)(2); provided, that the licensee is subject to the other provisions of 410 IAC 5-3-7(i).

(4) Any licensee who is licensed pursuant to 410 IAC 5-3-11(c)(1) for one or more of the medical use groups in Schedule C, 410 IAC 5-3-28, also is authorized, subject to the provisions of 410 IAC 5-3-11(c)(4) and (5), to receive, possess and use for calibration and reference standards:

(i) Any radioactive material listed in Group I, Group II, or Group III of Schedule C, 410 IAC 5-3-28, with a half-life not longer than 100 days, in amounts not to exceed 15 millicuries total;

(ii) Any radioactive material listed in Group I, Group II, or Group III of Schedule C, 410 IAC 5-3-28, with half-life greater than 100 days in amounts not to exceed 200 microcuries total;

(iii) Technetium-99m in amounts not to exceed 30 millicuries; and

(iv) Any radioactive material, in amounts not to exceed 3 millicuries per source, contained in calibration or reference sources that have been manufactured, labeled, packaged and distributed in accordance with a specific license issued by the board pursuant to 410 IAC 5-3-13(l), a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.74 of 10 CFR Part 32, or a specific license issued to the manufacturer by an agreement state or a licensing state pursuant to equivalent regulations.

(5)(i) Any licensee or registrant who possesses sealed sources as calibration or reference sources pursuant to 410 IAC 5-3-11(c)(4) shall cause each sealed source containing radioactive material, other than hydrogen-3, with a half-life greater than 30 days in any form other than gas to be tested for leakage and/or contamination at intervals not to exceed 6 months. In the absence of a certificate from a transferor indicating that a test has been made within 6 months prior to the transfer, the sealed sources should not be used until tested, provided, however, that no leak tests are required when:

(A) The source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material, or

(B) The sealed source is stored and is not being used; such sources shall, however, be tested for leakage prior to any use or transfer unless they have been leak tested within 6 months prior to the date of use or transfer.

(ii) The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which contamination might be expected to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the board;

(iii) If the leak test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee or registrant shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with 410 IAC 5-3 and 410 IAC 5-4. A report shall be filed within 5 days of the test with the board describing the equipment involved, the test results, and the corrective action taken.

(6) Any licensee or registrant who possesses and uses calibration and reference sources pursuant to 410 IAC 5-3-11(c)(4)(iv) shall:

(i) Follow the radiation safety and handling instructions approved by the board, the U.S. Nuclear Regulatory

Commission, an agreement state or a licensing state and furnished by the manufacturer on the label attached to the source, or permanent container thereof, or in the leaflet or brochure that accompanies the source, and maintain such instruction in a legible and conveniently available form; and

(ii) Conduct a quarterly physical inventory to account for all sources received and possessed. Records of the inventories shall be maintained for inspection by the board and shall include the quantities and kinds of radioactive material, location of sources, and the date of the inventory.

(d) Human Use of Sealed Sources. In addition to the requirements set forth in 410 IAC 5-3-10, a specific license for human use of sealed sources will be issued only if the applicant or, if the application is made by an institution, the individual user:

(1) Has specialized training in the diagnostic or therapeutic use of the sealed source considered, or has experience equivalent to such training, and

(2) Is a physician.

(e) Use of Sealed Sources in Industrial Radiography. In addition to the requirements set forth in 410 IAC 5-3-10, a specific license for use of sealed sources in industrial radiography will be issued if:

(1) The applicant will have an adequate program for training radiographers and radiographer's assistants and submits to the board a schedule or description of such program which specifies the:

(i) Initial training,

(ii) Periodic training,

(iii) On-the-job training,

(iv) Means to be used by the licensee to determine the radiographer's knowledge and understanding of and ability to comply with board rules and licensing requirements, and the operating and emergency procedures of the applicant, and

(v) Means to be used by the licensee to determine the radiographer's assistant's knowledge and understanding of and ability to comply with the operating and emergency procedures of the applicant;

(2) The applicant has established and submits to the board satisfactory written operating and emergency procedures described in 410 IAC 5-5-13;

(3) The applicant will have an internal inspection system adequate to assure that these rules, license provisions, and the applicant's operating and emergency procedures are followed by radiographers and radiographer's assistants; the inspection system shall include the performance of internal inspections at intervals not to exceed 3 months and the retention of records of such inspections for 2 years;

(4) The applicant submits to the board a description of the overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and responsibility for operation of the program;

(5) The applicant who desires to conduct his own leak tests has established adequate procedures to be followed in testing sealed sources for possible leakage and contamination and submits to the board a description of such procedures including:

(i) instrumentation to be used,

(ii) method of performing tests, and

(iii) pertinent experience of the individual who will perform the test; and

(6) The licensee shall conduct a program for inspection and maintenance of radiographic exposure devices and storage containers to assure proper functioning of components important to safety.

(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.26; filed May 26, 1978, 3:30 pm: 1 IR 148; filed Feb 29, 1984, 10:10 am: 7 IR 856; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-3-12 Specific licenses of broad scope

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 12. This section prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain regulations governing holders of such licenses.[10/]

[10/] Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity or other product containing byproduct material whose subsequent possession, use, transfer and disposal by all other persons are

exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(a) The different types of broad licenses are set forth below:

(1) A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.

(2) A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Schedule D, 410 IAC 5-3-29, for any authorized purpose. The possession limit for a Type B license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Schedule D, 410 IAC 5-3-29, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Schedule D, 410 IAC 5-3-29, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

(3) A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Schedule D, 410 IAC 5-3-29, for any authorized purpose. The possession limit for a Type C license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Schedule D, 410 IAC 5-3-29, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide determine the ratio of the quantity possessed to the applicable quantity specified in Schedule D, 410 IAC 5-3-29, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

(b) An application for a Type A specific license of broad scope will be approved if:

(1) The applicant satisfies the general requirements specified in 410 IAC 5-3-10;

(2) The applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

(3) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(i) The establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management and persons trained and experienced in the safe use of radioactive material;

(ii) The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

(iii) The establishment of appropriate administrative procedures to assure:

(A) Control of procurement and use of radioactive material;

(B) Completion of safety evaluations of proposed uses of radiactive *[sic.]* material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

(C) Review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with 410 IAC 5-3-12(b)(3)(iii)(B) prior to use of the radioactive material.

(c) An application for a Type B specific license of broad scope will be approved if:

(1) The applicant satisfies the general requirements specified in 410 IAC 5-3-10; and

(2) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(i) The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters, and

(ii) The establishment of appropriate administrative procedures to assure:

(A) Control of procurement and use of radioactive material,

(B) Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

(C) Review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses

prepared in accordance with 410 IAC 5-3-12(c)(2)(ii)(B) prior to use of the radioactive material.

(d) An application for a Type C specific license of broad scope will be approved if:

(1) The applicant satisfies the general requirements specified in 410 IAC 5-3-10;

(2) The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

(i) A college degree at the bachelor level, or equivalent training experience, in the physical or biological sciences or in engineering, and

(ii) At least 40 hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and

(3) The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting, and management review necessary to assure safe operations.

(e) Specific licenses of broad scope are subject to the following conditions:

(1) Unless specifically authorized, persons licensed pursuant to 410 IAC 5-3-12 shall not:

(i) Conduct tracer studies in the environment involving direct release of radioactive material;

(ii) Receive, acquire, own, possess, use, or transfer devices containing 100,000 curies or more of radioactive material in sealed sources used for irradiation of materials;

(iii) Conduct activities for which a specific license issued by the board under 410 IAC 5-3-11, 410 IAC 5-3-13 or 410 IAC 5-3-12.5 is required; or

(iv) Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

(2) Each Type A specific license of broad scope issued under 410 IAC 5-3-12 shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

(3) Each Type B specific license of broad scope issued under 410 IAC 5-3-12 shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

(4) Each Type C specific license of broad scope issued under 410 IAC 5-3-12 shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of 410 IAC 5-3-12(d).

(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.27; filed May 26, 1978, 3:30 pm: 1 IR 152; filed Feb 29, 1984, 10:10 am: 7 IR 861; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-3-12.5 Specific licenses for source material milling

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 12.5. In addition to the requirements set forth in 410 IAC 5-3-9, a specific license for source material milling will be issued if the applicant submits to the board a satisfactory application as described herein and meets the other conditions specified below: (a) An application for a license to receive title to, receive, possess, and use source material for milling or byproduct material as defined in 410 IAC 5-1-2 shall address the following:

(1) Description of the proposed project or action;

(2) Area/site characteristics including geology, topography, hydrology, and meteorology;

(3) Radiological and nonradiological impacts of the proposed project or action, including waterway and groundwater impacts;

(4) Environmental effects of accidents;

(5) Long-term impacts including decommissioning, decontamination, and reclamation; and

(6) Site and project alternatives.

(b) Pursuant to 410 IAC 5-3-10(e), the applicant shall not commence construction of the project until the board has weighed

the environmental, economic, technical, and other benefits against the environmental costs and has concluded that the issuance of the license is appropriate.

(c) At least 1 full year prior to any major site construction, a preoperational monitoring program shall be conducted to provide complete baseline data on a milling site and its environs. Throughout the construction and operating phases of the mill, an operational monitoring program shall be conducted to measure or evaluate compliance with applicable standards and regulations; to evaluate performance of control systems and procedures; to evaluate environmental impacts of operation; and to detect potential long-term effects.

(d) Prior to issuance of the license, the applicant shall establish financial surety arrangements consistent with the requirements of 410 IAC 5-3-10(f).

(1) The amount of funds to be ensured by financial surety arrangements shall be based on board-approved cost estimates in an approved plan for decontamination and decommissioning of mill buildings and the milling site to levels which would allow unrestricted use of these areas upon decommissioning, and the reclamation of tailings and/or waste disposal areas. The licensee shall submit this plan in conjunction with an environmental report that addresses the expected environmental impacts of the milling operation, decommissioning and tailings reclamation, and that evaluates alternatives for mitigating these impacts. In establishing specific surety arrangements, the licensee's cost estimates shall take into account total costs that would be incurred if an independent contractor were hired to perform the decommissioning and reclamation work. In order to avoid unnecessary duplication and expense, the board may accept financial sureties that have been consolidated with financial surety arrangements established to meet requirements of other federal or state agencies and/or local governing bodies for such decommissioning, decontamination, reclamation, and long-term site surveillance, provided such arrangements are considered adequate to satisfy these requirements and that portion of the surety which covers the decommissioning and reclamation of the mill, mill tailings site and associated areas, and the long-term funding charge are clearly identified. The licensee's surety mechanism will be reviewed annually by the board to assure that sufficient funds will be available for completion of the reclamation plan if the work had to be performed by an independent contractor. The amount of surety liability should be adjusted to recognize any increases or decreases resulting from inflation, changes in engineering plans, activities performed, and any other conditions affecting costs. Regardless of whether reclamation is phased through the life of the operation or takes place at the end of operations, an appropriate portion of surety liability shall be retained until final compliance with the reclamation plan is determined. This will yield a surety that is at least sufficient at all times to cover the costs of decommissioning, decontamination, and reclamation of the areas that are expected to be disturbed before the next license renewal. The term of the surety mechanism must be open ended, unless it can be demonstrated that another arrangement would provide an equivalent level of assurance. This assurance could be provided with a surety instrument which is written for a specified period of time (e.g., 5 years) which must be automatically renewed unless the surety agent notifies the beneficiary (the state regulatory agency) and the principal (the licensee) some reasonable time (e.g., 90 days) prior to the renewal date of their intention not to renew. In such a situation, the surety requirement still exists and the licensee would be required to submit an acceptable replacement surety within a brief period of time to allow at least 60 days for the regulatory agency to collect.

(2) The total amount of funds for reclamation or long-term surveillance and control shall be transferred to the United States if title and custody of such material and its disposal site is transferred to the United States upon termination of a license. Such funds include, but are not limited to, sums collected for long-term surveillance and control. Such funds do not, however, include monies held as surety where no default has occurred, and the reclamation or other bonded activity has been performed.

(e) The applicant shall provide procedures describing the means employed to meet the following requirements during the operational phase of any project.

(1) Milling operations shall be conducted so that all effluent releases are below the limits of 410 IAC 5-4 and are as low as is reasonably achievable.

(2) The mill operator shall conduct daily inspection of any tailings or waste retention systems. Such inspections shall be conducted by a qualified engineer or scientist. Records of such inspections shall be maintained for review by the board.

(3) The mill operator shall immediately notify the board of the following:

(i) Any failure in a tailings or waste retention system which results in a release of tailings or waste into unrestricted areas, and

(ii) Any unusual conditions or conditions not contemplated in the design of the retention system which, if not corrected, could lead to failure of the system and result in a release of tailings or waste into unrestricted areas.

(f) Continued Surveillance Requirements for Source Material Mills Having Reclaimed Residues.

(1) The final disposition of tailings or wastes at source material milling sites should be such that the need for ongoing active maintenance is not necessary to preserve isolation. As a minimum, annual site inspections shall be conducted by the government agency retaining ultimate custody of the site where tailings or wastes are stored to confirm the integrity of the stabilized tailings or waste systems and to determine the need, if any, for maintenance and/or monitoring. Results of the inspection shall be reported to the U.S. Nuclear Regulatory Commission within 60 days following each inspection. The U.S. Nuclear Regulatory Commission may require more frequent site inspections, if, on the basis of a site-specific evaluation, such a need appears necessary due to the features of a particular tailings or waste disposal system.

(2) A minimum charge of $250,000 in 1978 dollars to cover the costs of long-term surveillance shall be paid by each mill operator to the board prior to the termination of a uranium or thorium mill license. If site surveillance or control requirements at a particular site are determined, on the basis of a site-specific evaluation, to be significantly greater than those specified in 410 IAC 5-3-13(f)(1), additional funding requirements may be specified by the board. The total charge to cover the costs of long-term surveillance shall be such that, with an assumed 1 percent annual real interest rate, the collected funds will yield interest in the amount sufficient to cover the annual costs of site surveillance. The charge will be reviewed annually to recognize or adjust for inflation.

(Indiana State Department of Health; 410 IAC 5-3-12.5; filed Feb 29, 1984, 10:10 am: 7 IR 863; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-3-13 Specific licenses to manufacture, repair, or distribute products containing radioactive materials

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 13. (a) Licensing the Introduction of Radioactive Material into Products in Exempt Concentrations. (1) In addition to the requirements set forth in 410 IAC 5-3-10, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under 410 IAC 5-3-4(a)(1) will be issued if:

(i) The applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer; and

(ii) The applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Schedule A, 410 IAC 5-3-26, that reconcentration of the radioactive material in concentrations exceeding those in Schedule A is not likely, that use of lower concentrations is not feasible, and 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.

(2) Each person licensed under 410 IAC 5-3-13(a) shall file an annual report with the board which shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into each such product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made pursuant to 410 IAC 5-3-13(a) during the reporting period, the report shall so indicate. The report shall cover the year ending June 30, and shall be filed within 30 days thereafter.

(b) Licensing the Distribution of Radioactive Material in Exempt Quantities.[10/]

(1) An application for a specific license to distribute NARM to persons exempted from 410 IAC 5 pursuant to 410 IAC 5-3-4(b) will be approved if:

(i) The radioactive 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;

(ii) The radioactive material 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

(iii) The applicant submits copies of prototype labels and brochures and the board approves such labels and brochures.

(2) The license issued under 410 IAC 5-3-13(b)(1) is subject to the following conditions:

(i) No more than 10 exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions shall not exceed unity.

(ii) Each exempt quantity shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to 410 IAC 5-3-4(b). The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour.

(iii) The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:

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

(B) Bears the words "Radioactive Material."

(iv) In addition to the labeling information required by 410 IAC 5-3-13(b)(2)(iii), the label affixed to the immediate container, or an accompanying brochure, shall:

(A) State that the contents are exempt from licensing state requirements;

(B) 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

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

(3) Each person licensed under 410 IAC 5-3-13(b) shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under 410 IAC 5-3-4 or the equivalent regulations of a licensing state, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the board. Each report shall cover the year ending June 30, and shall be filed within thirty (30) days thereafter. If no transfers of radioactive material have been made pursuant to 410 IAC 5-3-13(b) during the reporting period, the report shall so indicate.

[10/] Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(c) Licensing the Incorporation of Naturally-Occurring and Accelerator-Produced Radioactive Material into Gas and Aerosol Detectors. An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under 410 IAC 5-3-4(c)(3) will be approved if the application satisfies requirements equivalent to those contained in Section 32.26 of 10 CFR Part 32. The maximum quantity of radium-226 in each device shall not exceed 0.1 microcurie.

(d) Licensing the Manufacture and Distribution of Devices to Persons Generally Licensed Under 410 IAC 5-3-7(d).

(1) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under 410 IAC 5-3-7(d) or equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state will be approved if:

(i) The applicant satisfies the general requirements of 410 IAC 5-3-10;

(ii) 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 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 any period of one calendar quarter a dose in excess of 10 percent of the limits specified in the table in 410 IAC 5-4-2(a); 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 following organ doses:

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	15 rems
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	200 rems
Other organs	50 rems; and

(iii) Each device bears a durable, legible, clearly visible label or labels approved by the board, 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 requirement, 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 isotope, quantity of radioactivity, and date of determination of the quantity; and

(C) The information called for in one of the following statements, as appropriate, in the same or substantially similar form:

(aa) The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____[11/], are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or a state with which the U.S. 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.

CAUTION-RADIOACTIVE MATERIAL

_____

Name of manufacturer or distributor

(bb) The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____[11/], are subject to a general license or the equivalent, and the regulations of a licensing state. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION-RADIOACTIVE MATERIAL

_____

Name of manufacturer or distributor

(2) 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 the 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 board will consider information which includes, but is not limited to:

(i) Primary containment or source capsule;
(ii) Protection of primary containment;
(iii) Method of sealing containment;
(iv) Containment construction materials;
(v) Form of contained radioactive material;
(vi) Maximum temperature withstood during prototype test;
(vii) Maximum pressure withstood during prototype tests;
(viii) Maximum quantity of contained radioactive material;
(ix) Radiotoxicity of contained radioactive material; and
(x) Operating experience with identical devices or similarly designed and constructed devices.

(3) In the event the applicant desires that the general licensee under 410 IAC 5-3-7(d), or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state or a licensing 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 basis for such estimates. The submitted information shall demonstrate that performance of such 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 calendar quarter dose in excess of 10 percent of the limits specified in the table in 410 IAC 5-4-2(a).

(4) Each person licensed under 410 IAC 5-3-13(d) to distribute devices to generally licensed persons shall:

(i) Furnish a copy of the general license contained in 410 IAC 5-3-7(d) to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in 410 IAC 5-3-7(d);

(ii) Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's, agreement state's or licensing state's regulation equivalent to 410 IAC 5-3-7(d), or alternatively, furnish a copy of the general license contained in 410 IAC 5-3-7(d) to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission, the agreement state or the licensing state. If a copy of the general license in 410 IAC 5-3-7(d) is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the U.S. Nuclear Regulatory Commission, agreement state or licensing state under requirements substantially the same as those in 410 IAC 5-3-7(d);

(iii) Report to the board all transfers of such devices to persons for use under the general license in 410 IAC 5-3-7(d). Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the board and the general licensee, the type and model number of device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to the persons generally licensed under 410 IAC 5-3-7(d) during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter;

(iv) Furnish reports to other agencies:

(A) Report to the U.S. Nuclear Regulatory Commission all transfers of such devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 31.5 of 10 CFR Part 31;

(B) Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to 410 IAC 5-3-13(d) for use under a general license in that state's regulations equivalent to 410 IAC 5-3-7(d);

(C) Such reports shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the board and the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. The report shall be submitted within 30 days after the end of each calendar quarter in which such a device is transferred to the generally licensed person;

(D) If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission;

(E) If no transfers have been made to general licensees within a particular state during the reporting period, this information shall be reported to the responsible state agency upon request of that agency.

(v) Keep records showing the name, address, and the point of contact for each general licensee to whom he directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in 410 IAC 5-3-7(d), or equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state. The records should show the date of each transfer, the radionuclide and the quantity of radioactivity in each device transferred, the identity of any intermediate person and compliance with the report requirements of 410 IAC 5-3-13(d)(4).

[11/] The model, serial number, and name of manufacturer or distributor may be omitted from this label provided the information is elsewhere specified and labeling affixed to the device.

(e) Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for Use in Aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under 410 IAC 5-3-7(e) will be approved if:

(1) The applicant satisfies the general requirements specified in 410 IAC 5-3-10, and

(2) The applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, 32.56, and 32.101 of 10 CFR Part 32 or their equivalent.

(f) Special Requirements for License to Manufacture Calibration Sources Containing Americium-241, Plutonium, or Radium-226 for Distribution to Persons Generally Licensed Under 410 IAC 5-3-7(g). An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under 410 IAC 5-3-7(g) will be approved if:

(1) The applicant satisfies the general requirement of 410 IAC 5-3-10, and

(2) The applicant satisfies the requirements of Sections 32.57, 32.58, 32.59, and 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 or their equivalent.

(g) Manufacture and Distribution of Radioactive Material for Medical Use Under General License. In addition to requirements set forth in 410 IAC 5-3-10, a specific license authorizing the distribution of radioactive material for use by physicians under the general license in 410 IAC 5-3-7(h) will be issued if:

(1) The applicant submits evidence that the radioactive material is to be manufactured, labeled and packaged in accordance with a new drug application which the Commissioner of Food and Drugs, Food and Drug Administration, has approved, or in accordance with a license for a biologic product issued by the Secretary, U.S. Department of Health and Human Services; and

(2) One of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on the label affixed to the container or appears in the leaflet or brochure which accompanies the package:

(i) This radioactive drug may be received, possessed, and used only by physicians licensed (to dispense drugs) in the practice of medicine. Its receipt, possession, use, and transfer are subject to the regulations and a general license or its equivalent of the U.S. Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority,

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Name of manufacturer

(ii) This radioactive drug may be received, possessed, and used only by physicians licensed (to dispense drugs) in the practice of medicine. Its receipt, possession, use, and transfer are subject to the regulations and a general license or its equivalent of a licensing state.

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Name of manufacturer

(h) Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under General License. An application for a specific license to manufacture or distribute radioactive material for use under the general license of 410 IAC 5-3-7(i) will be approved if:

(1) The applicant satisfies the general requirements specified in 410 IAC 5-3-10;

(2) The radioactive material is to be prepared for distribution in prepackaged units of:

(i) Carbon-14 in units not exceeding 10 microcuries each;

(ii) Cobalt-57 in units not exceeding 10 microcuries each;

(iii) Hydrogen-3 (tritium) in units not exceeding 50 microcuries each;

(iv) Iodine-125 in units not exceeding 10 microcuries each;

(v) Mock Iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcuries of americium-241 each;

(vi) Iodine-131 in units not exceeding 10 microcuries each;

(vii) Iron-59 in units not exceeding 20 microcuries each;

(viii) Selenium-75 in units not exceeding 10 microcuries each;

(3) Each prepackaged unit bears a durable, clearly visible label:

(i) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries of iodine-125, iodine-131, selenium-75, cobalt-57, or carbon-14; 50 microcuries of hydrogen-3 (tritium); 20 microcuries of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each; and

(ii) Displaying the radiation caution symbol described in 410 IAC 5-4-11(a)(1) and the words, "CAUTION, RADIOACTIVE MATERIAL," and "Not for Internal or External Use in Humans or Animals."

(4) One of the following statements, or a substantially similar statement which contains the information called for in the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

(i) This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority.

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Name of manufacturer

(ii) This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only in in vitro clinical or laboratory tests not involving internal or external administration of the material or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of a licensing state.

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Name of manufacturer

(5) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source, must also contain directions to the licensee regarding the waste disposal requirements set out in 410 IAC 5-4-16.

(i) Licensing the Manufacture and Distribution of Ice Detection Devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under 410 IAC 5-3-10 will be approved if:

(1) The applicant satisfies the general requirements of 410 IAC 5-3-10, and

(2) The criteria of Sections 32.61, 32.62, and 32.103 of 10 CFR Part 32 are met.

(j) Manufacture and Distribution of Radiopharmaceuticials *[sic.]* Containing Radioactive Material for Medical Use Under Group Licenses. An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to 410 IAC 5-3-11(c) for the uses listed in Group I, Group II, IV, or V of Schedule C, 410 IAC 5-3-28, will be approved if:

(1) The applicant satisfies the general requirements specified in 410 IAC 5-3-10;

(2) The applicant submits evidence that:

(i) The radiopharmaceutical containing radioactive material will be manufactured, labeled, and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA, or

(ii) The manufacture and distribution of the radiopharmaceutical containing radioactive material is not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

(3) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material which is appropriate for safe handling and storage of radiopharmaceuticals by group licensees; and

(4)(i) The label affixed to each package of the radiopharmaceutical contains information on the radionuclide, quantity, and date of assay and the label affixed to each package, or the leaflet or brochure which accompanies each package, contains a statement that the radiopharmaceutical is licensed by the board for distribution to persons licensed pursuant to 410 IAC 5-3-11(c) and Schedule C, 410 IAC 5-3-28, Group I, Group II, Group IV, and Group V, as appropriate, or under equivalent

licenses of the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state.

(ii) The labels, leaflets, or brochures required by 410 IAC 5-3-13(j)(4)(i) are in addition to the labeling required by the Food and Drug Administration and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

(k) Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material.[12/] An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to 410 IAC 5-3-11(c) for the uses listed in Group III of Schedule C, 410 IAC 5-3-28, will be approved if:

(1) The applicant satisfies the general requirements specified in 410 IAC 5-3-10;

(2) The applicant submits evidence that:

(i) The generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application approved by the Food and Drug Administration or a "Notice of Claimed Investigational Exemption for a New Drug" that has been accepted by the FDA, or

(ii) The manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

(3) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;

(4) The label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and

(5) The label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:

(i) Adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit, and

(ii) A statement that this generator or reagent kit, as appropriate, is approved for use by persons licensed by the board pursuant to 410 IAC 5-3-11(c) and Schedule C, 410 IAC 5-3-28, Group III or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state. The labels, leaflets or brochures required by 410 IAC 5-3-13(k) are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

[12/] Although the board does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have his reagent kits approved by the board for use by persons licensed pursuant to 410 IAC 5-3-11(c) and Group III of Schedule C, 410 IAC 5-3-28, may submit the pertinent information specified in 410 IAC 5-3-13(k).

(l) Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to 410 IAC 5-3-11(c) for use as a calibration or reference source or for the uses listed in Group VI of Schedule C, 410 IAC 5-3-28, will be approved if:

(1) The applicant satisfies the general requirements in 410 IAC 5-3-10;

(2) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(i) The radioactive material contained, its chemical and physical form, and amount,

(ii) Details of design and construction of the source or device,

(iii) Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,

(iv) For devices containing radioactive material, the radiation profile of a prototype device,

(v) Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,

(vi) Procedures and standards for calibrating sources and devices,

(vii) Legend and methods for labeling sources and devices as to their radioactive content, and

(viii) Instruction for handling and storing the source or device from the radiation safety standpoint; these instructions

are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label; and

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the name of source or device is licensed by the board for distribution to persons licensed pursuant to 410 IAC 5-3-11(c) and Schedule C, 410 IAC 5-3-28, Group VI or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state, provided, that such labeling for sources which do not require long term storage may be on a leaflet or brochure which accompanies the source.

(4) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and

(5) In determining the acceptable interval for test of leakage of radioactive material, the board will consider information that includes, but is not limited to:

(i) Primary containment or source capsule;

(ii) Protection of primary containment;

(iii) Method of sealing containment;

(iv) Containment construction materials;

(v) Form of contained radioactive material;

(vi) Maximum temperature withstood during prototype tests;

(vii) Maximum pressure withstood during prototype tests;

(viii) Maximum quantity of contained radioactive material;

(ix) Radiotoxicity of contained radioactive material; and

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

(m) Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications.

(1) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to 410 IAC 5-3-6(d) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state will be approved if:

(i) The applicant satisfies the general requirements specified in 410 IAC 5-3-10;

(ii) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one calendar quarter a radiation dose in excess of 10 percent of the limits specified in 410 IAC 5-4-2(a); and

(iii) The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(2) In the case of an industrial product or device whose unique benefits are questionable, the board will approve an application for a specific license under 410 IAC 5-3-13(m) only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(3) The board may deny any application for a specific license under 410 IAC 5-3-13(m) if the end use(s) of the industrial product or device cannot be reasonably foreseen.

(4) Each person licensed pursuant to 410 IAC 5-3-13(m)(1) shall:

(i) Maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

(ii) Label or mark each unit to:

(A) Identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of

depleted uranium in each product or device; and

(B) State that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or an agreement state;

(iii) Assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";

(iv)(A) Furnish a copy of the general license contained in 410 IAC 5-3-6(d) and a copy of board form "W," 410 IAC 5-3-32, to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license contained in 410 IAC 5-3-6(d); or

(B) Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or agreement state's regulation equivalent to 410 IAC 5-3-6(d) and a copy of the U.S. Nuclear Regulatory Commission's or agreement state's certificate; or alternatively, furnish a copy of the general license contained in 410 IAC 5-3-6(d) and a copy of board form "W," 410 IAC 5-3-32, to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an agreement state, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an agreement state under requirements substantially the same as those in 410 IAC 5-3-6(d).

(v) Report to the board all transfers of industrial products or devices to persons for use under the general license in 410 IAC 5-3-6(d). Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the board and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under 410 IAC 5-3-6(d) during the reporting period, the report shall so indicate;

(vi)(A) Report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 40.25 of 10 CFR Part 40.

(B) Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to 410 IAC 5-3-13(m) for use under a general license in that state's regulations equivalent to 410 IAC 5-3-6(d).

(C) Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person.

(D) If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission.

(E) If no transfers have been made to general licensees within a particular agreement state during the reporting period, this information shall be reported to the responsible agreement state agency upon the request of that agency.

(vii) Keep records showing the name, address, and point of contact for each general licensee to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in 410 IAC 5-3-6(d) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state. The records shall be maintained for a period of 2 years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this section.

(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.28; filed May 26, 1978, 3:30 pm: 1 IR 154; filed Feb 29, 1984, 10:10 am: 7 IR 865; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-3-14 Issuance of specific licenses; incorporation of additional requirements

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 14. (a) Upon a determination that an application meets the requirements of IC 13-1-2 *[IC 13-1 was repealed by P.L.1-*

1996, SECTION 99, effective July 1, 1996.] and 410 IAC 5, the board will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(b) The board may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to 410 IAC 5-3-14 as it deems appropriate or necessary in order to:

(1) Minimize danger to public health and safety or property;

(2) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

(3) Prevent loss or theft of material subject to 410 IAC 5-3.

(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.30; filed May 26, 1978, 3:30 pm: 1 IR 162; filed Feb 29, 1984, 10:10 am: 7 IR 874; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-3-15 Terms and conditions of licenses; transfer

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 15. (a) Each license issued pursuant to 410 IAC 5-3 shall be subject to all the provisions of IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*, now or hereafter in effect, and to all rules, regulations, and orders of the board.

(b) No license issued or granted under 410 IAC 5-3 and no right to possess or utilize radioactive material granted by any license issued pursuant to 410 IAC 5-3 shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the board shall, after securing full information find that the transfer is in accordance with the provisions of IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*, and shall give its consent in writing.

(c) Each person licensed by the board pursuant to 410 IAC 5-3 shall confine his use and possession of the material licensed to the locations and purposes authorized in the license. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.31; filed May 26, 1978, 3:30 pm: 1 IR 162; filed Feb 29, 1984, 10:10 am: 7 IR 875; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-3-16 Expiration of licenses

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 16. Except as provided in 410 IAC 5-3-17(b), each specific license shall expire at the end of the specified day in the month and year stated therein. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.32; filed May 26, 1978, 3:30 pm: 1 IR 163; filed Feb 29, 1984, 10:10 am: 7 IR 875; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-3-17 Renewal of licenses

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 17. (a) Applications for renewal of specific licenses shall be filed in accordance with 410 IAC 5-3-9.

(b) In any case in which a licensee, not less than 30 days prior to expiration of his existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until final action by the board. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.33; filed May 26, 1978, 3:30 pm: 1 IR 163; filed Feb*

29, 1984, 10:10 am: 7 IR 875; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-3-18 Amendment of licenses

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 18. Applications for amendment of a license shall be filed in accordance with 410 IAC 5-3-9 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.34; filed May 26, 1978, 3:30 pm: 1 IR 163; filed Feb 29, 1984, 10:10 am: 7 IR 875; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-3-19 Criteria for renewal or amendment of licenses

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 19. In considering an application by a licensee to renew or amend his license, the board will apply the criteria set forth in 410 IAC 5-3-10, 410 IAC 5-3-11, 410 IAC 5-3-12, or 410 IAC 5-3-13, as applicable. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.35; filed May 26, 1978, 3:30 pm: 1 IR 163; filed Feb 29, 1984, 10:10 am: 7 IR 875; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-3-20 United States nuclear regulatory commission license; expiration

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 20. Persons Possessing a License for Source, Byproduct or Special Nuclear Material in Quantities Not Sufficient to Form A Critical Mass on Effective Date of 410 IAC 5. Any person who, on the effective date of 410 IAC 5, possesses a general or specific license for source, byproduct, or special nuclear material in quantities not sufficient to form a critical mass, issued by the U.S. Nuclear Regulatory Commission, shall be deemed to possess a like license issued under 410 IAC 5-3 and IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*, such license to expire either 90 days after receipt from the board of a notice of expiration of such license, or on the date of expiration specified in the U.S. Nuclear Regulatory Commission license, whichever is earlier. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.36; filed May 26, 1978, 3:30 pm: 1 IR 163; filed Feb 29, 1984, 10:10 am: 7 IR 875; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-3-21 Naturally-occurring and accelerator-produced radioactive material; expiration of license

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 21. Persons Possessing Naturally-Occurring and Accelerator-Produced Radioactive Material (NARM) on Effective Date of 410 IAC 5. Any person who, on the effective date of 410 IAC 5, possesses NARM for which a specific license is required by IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]* or 410 IAC 5-3 shall be deemed to possess such a license issued under IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]* and 410 IAC 5-3. Such license shall expire 90 days after the effective date of 410 IAC 5; provided, however, that if within the 90 days the person possessing such material files an application in proper form for a license, such existing license shall not expire until the application has been finally determined by the board. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.37; filed May 26, 1978,*

3:30 pm: 1 IR 163; filed Feb 29, 1984, 10:10 am: 7 IR 875; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-3-22 Transfer of material

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 22. (a) No licensee shall transfer radioactive material except as authorized pursuant to 410 IAC 5-3-22(c).

(b) Except as otherwise provided in his license and subject to the provisions of 410 IAC 5-3-22(c) and (d), any licensee may transfer radioactive material:

(1) To the board;[13/]

(2) To the U.S. Department of Energy;

(3) To any person exempt from 410 IAC 5-3 to the extent permitted under such exemption;

(4) To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the board, the U.S. Nuclear Regulatory Commission, any agreement state or any licensing state or to any person otherwise authorized to receive such material by the federal government or any agency thereof, the board, an agreement state or a licensing state; or

(5) As otherwise authorized by the board in writing.

[13/] A licensee may transfer material to the board only after receiving prior approval from the board.

(c) Before transferring radioactive material to a specific licensee of the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state, or to a general licensee who is required to register with the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferree's *[sic.]* license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

(d) Any of the following methods for the verification required by 410 IAC 5-3-22(c) is acceptable:

(1) The transferor may possess and read a current copy of the transferee's specific license or registration certificate;

(2) The transferor may possess a written certification that the transferee is authorized by license or registration certificate to receive the type, form and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;

(3) For emergency shipments the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date; provided, that the oral certification is confirmed in writing within 10 days;

(4) The transferor may obtain other information compiled by a reporting service from official records of the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state regarding the identity of licensees and the scope and expiration dates of licenses and registration; or

(5) When none of the methods of verification described in 410 IAC 5-3-22(d)(1) to (4) are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the board, the U.S. Nuclear Regulatory Commission, or an agreement state or a licensing state that the transferee is licensed to receive the radioactive material.

(e) Shipment and transport of radioactive material shall be in accordance with the provisions of 410 IAC 5-3-25. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.40; filed May 26, 1978, 3:30 pm: 1 IR 163; filed Feb 29, 1984, 10:10 am: 7 IR 876; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-3-23 Modification of license terms and condition; suspension or revocation of license

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 23. (a) The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*, or by reason of rules, regulations, and orders issued by the board.

(b) Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the board to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*, or of the license, or of any rule, regulation, or order of the board.

(c) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefore, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

(d) The board may terminate a specific license upon request submitted by the licensee to the board in writing. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.50; filed May 26, 1978, 3:30 pm: 1 IR 164; filed Feb 29, 1984, 10:10 am: 7 IR 877; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-3-24 Reciprocal licensure

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 24. (a) Licenses of Byproduct, Source, and Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass.

(1) Subject to 410 IAC 5, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or any agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 days in any calendar year provided that:

(i) The licensing document does not limit the activity authorized by such document to specified installations or locations;

(ii) The out-of-state licensee notifies the board in writing at least 3 days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the *[sic.]* day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the board, obtain permission to proceed sooner. The board may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in 410 IAC 5-3-24(a)(1);

(iii) The out-of-state licensee complies with all applicable rules of the board and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable rules of the board;

(iv) The out-of-state licensee supplies such other information as the board may request; and

(v) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in 410 IAC 5-3-24(a)(1) except by transfer to a person:

(A) Specifically licensed by the board or by the U.S. Nuclear Regulatory Commission to receive such material, or

(B) Exempt from the requirements for a license for such material under 410 IAC 5-3-4(a).

(2) Notwithstanding the provisions of 410 IAC 5-3-24(a)(1), any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission or an agreement state authorizing the holder to manufacture, transfer, install, or service a device described in 410 IAC 5-3-7(d)(1) within areas subject to the jurisdiction of the licensing body is hereby granted a

general license to install, transfer, demonstrate, or service such a device in Indiana provided that:

(i) Such person shall file a report with the board within 30 days after the end of each calendar quarter in which any device is transferred to or installed in Indiana. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

(ii) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an agreement state;

(iii) Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and

(iv) The holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in 410 IAC 5-3-7(d).

(3) The board may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission or an agreement state, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

(b) Licenses of Naturally-Occurring and Accelerator-Produced Radioactive Material.

(1) Subject to 410 IAC 5, any person who holds a specific license from a licensing state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within Indiana for a period not in excess of 180 days in any calendar year provided that:

(i) The licensing document does not limit the activity authorized by such document to specified installations or locations;

(ii) The out-of-state licensee notifies the board in writing at least 3 days prior to engaging in such activity. Such notification shall indicate the location, period and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the 3 day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the board, obtain permission to proceed sooner. The board may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in 410 IAC 5-3-24(b)(1);

(iii) The out-of-state licensee complies with all applicable rules of the board and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable rules of the board;

(iv) The out-of-state licensee supplies such other information as the board may request; and

(v) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in 410 IAC 5-3-24(b)(1) except by transfer to a person:

(A) Specifically licensed by the board or by another licensing state to receive such material, or

(B) Exempt from the requirements for a license for such material under 410 IAC 5-3-4.

(2) Notwithstanding the provisions of 410 IAC 5-3-24(b)(1), any person who holds a specific license issued by a licensing state authorizing the holder to manufacture, transfer, install, or service a device described in 410 IAC 5-3-7(d)(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate or service such a device in Indiana provided that:

(i) Such person shall file a report with the board within 30 days after the end of each calendar quarter in which any device is transferred to or installed in Indiana. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

(ii) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by a licensing state;

(iii) Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and

(iv) The holder of the specific license shall furnish to each general licensee to whom he transfers such device or on

whose premises he installs such device a copy of the general license contained in 410 IAC 5-3-7(d).

(3) The board may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by a licensing state or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.90; filed May 26, 1978, 3:30 pm: 1 IR 164; filed Feb 29, 1984, 10:10 am: 7 IR 877; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-3-25 Transportation of radioactive materials

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 25. No person shall deliver radioactive material to a carrier for transport or transport radioactive material except as authorized in a general or specific license issued by the board or as exempted in 410 IAC 5-3-25.1. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.100; filed May 26, 1978, 3:30 pm: 1 IR 166; filed Feb 29, 1984, 10:10 am: 7 IR 879; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; errata filed Feb 3, 2010, 2:21 p.m.: 20100224-IR-410100062ACA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-3-25.1 Exemption of transporters

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 25.1. (a) Common, contract and private carriers, freight forwarders, and warehousemen who are subject to the requirements of the U.S. Department of Transportation in 49 CFR 170 through 189 or the U.S. Postal Service in the Postal Service Manual (Domestic Mail Manual), Section 124.3 incorporated by reference, 39 CFR 111.11 (1974), are exempt from 410 IAC 5 to the extent that they transport or store radioactive material in the regular course of their carriage for another or storage incident thereto. Common, contract and private carriers who are not subject to the requirements of the U.S. Department of Transportation or U.S. Postal Service are subject to 410 IAC 5-3-25 and other applicable sections of 410 IAC 5.

(b) Any licensee is exempt from 410 IAC 5-3-25 to the extent that he delivers to a carrier for transport packages each of which contains radioactive material having a specific activity less than, or equal to, 0.002 microcurie per gram.

(c) Any licensee who delivers radioactive material to a carrier for transport, where such transport is subject to the regulations of the U.S. Postal Service, is exempt from the provisions of 410 IAC 5-3-25. *(Indiana State Department of Health; 410 IAC 5-3-25.1; filed Feb 29, 1984, 10:10 am: 7 IR 879; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-3-25.2 General licenses for carriers

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 25.2. (a) A general license is hereby issued to any common or contract carrier not exempt under 410 IAC 5-3-25.1 to receive, possess, transport, and store radioactive material in the regular course of their carriage for another or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.[14/]

(b) A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident

reporting.[14/]

[14/] Any notification of incidents referred to in those U.S. Department of Transportation requirements shall be filed with, or made to, the board.

(c) Persons who transport radioactive material pursuant to the general licenses in 410 IAC 5-3-25.2(a) or (b) are exempt from the requirements of 410 IAC 5-4 and 410 IAC 5-10 to the extent that they transport radioactive material. *(Indiana State Department of Health; 410 IAC 5-3-25.2; filed Feb 29, 1984, 10:10 am: 7 IR 879; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-3-25.3 General licenses for delivery of materials to carriers

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 25.3. A general license is hereby issued to deliver radioactive material to a carrier[15/] for transport provided that:

(a) The licensee complies with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the packaging of radioactive material, and to the monitoring, marking, and labeling of those packages;

(b) The licensee has established procedures for safely opening and closing packages in which radioactive material is transported and to assure that, prior to the delivery to a carrier for transport, each package is properly closed for transport; and

(c) Prior to delivery of a package to a carrier for transport, the licensee shall assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee.

[15/] For the purpose of 410 IAC 5, a licensee who transports his own licensed material as a private carrier is considered to have delivered such material to a carrier for transport. *(Indiana State Department of Health; 410 IAC 5-3-25.3; filed Feb 29, 1984, 10:10 am: 7 IR 880; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-3-25.4 Advance notice of transport of nuclear waste

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 25.4. (a) Prior to the transport of any nuclear waste outside of the confines of the licensee's facility or other place of use or storage, or prior to the delivery of any nuclear waste to a carrier for transport, each licensee shall provide advance notification of such transport to the governor, or governor's designee,[16/] of each state through which the waste will be transported. For the purpose of 410 IAC 5-3-25.4 "nuclear waste" means any large quantity of source, byproduct, or special nuclear material required to be in Type B packaging while transported to, through, or across state boundaries to a disposal site, or to a collection point for transport to a disposal site.

[16/] A list of the mailing addresses of the governors and governor's designees is available upon request from the Director, Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(b) Each advance notification required by 410 IAC 5-3-25.4 shall contain the following information:

(1) the name, address, and telephone number of the shipper, carrier, and receiver of the shipment;

(2) a description of the nuclear waste contained in the shipment as required by the regulations of the U.S. Department of Transportation, 49 CFR 172.202 and 172.203(d);

(3) the point of origin of the shipment and the 7-day period during which departure of the shipment is estimated to occur;

(4) the 7-day period during which arrival of the shipment at state boundaries is estimated to occur;

(5) the destination of the shipment, and the 7-day period during which arrival of the shipment is estimated to occur; and

(6) a point of contact with a telephone number for current shipment information.

(c) The notification required by 410 IAC 5-3-25.4 shall be made in writing to the office of each appropriate governor or governor's designee and to the board. A notification delivered by mail must be postmarked at least 7 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur. A notification delivered by messenger must reach

the office of the governor, or governor's designee, at least 4 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur. A copy of the notification shall be retained by the licensee for 1 year.

(d) The licensee shall notify each appropriate governor, or governor's designee, and the board of any changes to schedule information provided pursuant to 410 IAC 5-3-25.4. Such notification shall be by telephone to a responsible individual in the office of the governor, or governor's designee, of the appropriate state or states. The licensee shall maintain for 1 year a record of the name of the individual contacted.

(e) Each licensee who cancels a nuclear waste shipment, for which advance notification has been sent, shall send a cancellation notice to the governor, or governor's designee, of each appropriate state and to the board. A copy of this notice shall be retained by the licensee for 1 year. *(Indiana State Department of Health; 410 IAC 5-3-25.4; filed Feb 29, 1984, 10:10 am: 7 IR 880; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-3-26 Schedule of exempt concentrations

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 26.

SCHEDULE A

EXEMPT CONCENTRATIONS

Element (atomic number)	Isotope	Column I Gas concentration μCi/ml[1/]	Column II Liquid and solid concentration μCi/ml[2/]
Antimony (51)	Sb-122		3×10^{-4}
	Sb-124		2×10^{-4}
	Sb-125		1×10^{-3}
Argon (18)	Ar-37	1×10^{-3}	
	Ar-41	4×10^{-7}	
Arsenic (33)	As-73		5×10^{-3}
	As-74		5×10^{-4}
	As-76		2×10^{-4}
	As-77		8×10^{-4}
Barium (56)	Ba-131		2×10^{-3}
	Ba-140		3×10^{-4}
Beryllium (4)	Be-7		2×10^{-2}
Bismuth (83)	Bi-206		4×10^{-4}
Bromine (35)	Br-82	4×10^{-7}	3×10^{-3}
Cadmium (48)	Cd-109		2×10^{-3}
	Cd-115m		3×10^{-4}
	Cd-115		3×10^{-4}
Calcium (20)	Ca-45		9×10^{-5}
	Ca-47		5×10^{-4}
Carbon (6)	C-14	1×10^{-6}	8×10^{-3}
Cerium (58)	Ce-141		9×10^{-4}

	Ce-143		4×10^{-4}
	Ce-144		1×10^{-4}
Cesium (55)	Cs-131		2×10^{-2}
	Cs-134m		6×10^{-2}
	Cs-134		9×10^{-5}
Chlorine (17)	Cl-38	9×10^{-7}	4×10^{-3}
Chromium (24)	Cr-51		2×10^{-2}
Cobalt (27)	Co-57		5×10^{-3}
	Co-58		1×10^{-3}
	Co-60		5×10^{-4}
Copper (29)	Cu-64		3×10^{-3}
Dysprosium (66)	Dy-165		4×10^{-3}
	Dy-166		4×10^{-4}
Erbium (68)	Er-169		9×10^{-4}
	Er-171		1×10^{-3}
Europium (63)	Eu-152		6×10^{-4}
	(T_r=9.2 h)		
	Eu-155		2×10^{-3}
Fluorine (9)	F-18	2×10^{-6}	8×10^{-3}
Gadolinium (64)	Gd-153		2×10^{-3}
	Gd-159		8×10^{-4}
Gallium (31)	Ga-72		4×10^{-4}
Germanium (32)	Ge-71		2×10^{-2}
Gold (79)	Au-196		2×10^{-3}
	Au-198		5×10^{-4}
	Au-199		2×10^{-3}
Hafnium (72)	Hf-181		7×10^{-4}
Hydrogen (1)	H-3	5×10^{-6}	3×10^{-2}
Indium (49)	In-113m		1×10^{-2}
	In-114m		2×10^{-4}
Iodine (53)	I-126	3×10^{-9}	2×10^{-5}
	I-131	3×10^{-9}	2×10^{-5}
	I-132	8×10^{-8}	6×10^{-4}
	I-133	1×10^{-8}	7×10^{-5}
	I-134	2×10^{-7}	1×10^{-3}
Iridium (77)	Ir-190		2×10^{-3}
	Ir-192		4×10^{-4}
	Ir-194		3×10^{-4}
Iron (26)	Fe-55		8×10^{-3}

	Fe-59		6×10^{-4}
Krypton (36)	Kr-85m	1×10^{-6}	
	Kr-85	3×10^{-6}	
Lanthanum (57)	La-140		2×10^{-4}
Lead (82)	Pb-203		4×10^{-3}
Lutetium (71)	Lu-177		1×10^{-3}
Manganese (25)	Mn-52		3×10^{-4}
	Mn-54		1×10^{-3}
	Mn-56		1×10^{-3}
Mercury (80)	Hg-197m		2×10^{-3}
	Hg-197		3×10^{-3}
	Hg-203		2×10^{-4}
Molybdenum (42)	Mo-99		2×10^{-3}
Neodymium (60)	Nd-147		6×10^{-4}
	Nd-149		3×10^{-3}
Nickel (28)	Ni-65		1×10^{-3}
Niobium	Nb-95		1×10^{-3}
(Columbium) (41)	Nb-97		9×10^{-3}
Osmium (76)	Os-185		7×10^{-4}
	Os-191m		3×10^{-2}
	Os-191		2×10^{-3}
	Os-193		6×10^{-4}
Palladium (46)	Pd-103		3×10^{-3}
	Pd-109		9×10^{-4}
Phosphorus (15)	P-32		2×10^{-4}
Platinum (78)	Pt-191		1×10^{-3}
	Pt-193m		1×10^{-2}
	Pt-197m		1×10^{-2}
	Pt-197		1×10^{-3}
Potassium (19)	K-42		3×10^{-3}
Praseodymium (59)	Pr-142		3×10^{-4}
	Pr-143		5×10^{-4}
Promethium (61)	Pm-147		2×10^{-3}
	Pm-149		4×10^{-4}
Rhenium (75)	Re-183		6×10^{-3}
	Re-186		9×10^{-4}
	Re-188		6×10^{-4}
Rhodium (45)	Rh-103m		1×10^{-1}
	Rh-105		1×10^{-3}

Rubidium (37)	Rb-86		7×10^{-4}
Ruthenium (44)	Ru-97		4×10^{-3}
	Ru-103		8×10^{-4}
	Ru-105		1×10^{-3}
	Ru-106		1×10^{-4}
Samarium (62)	Sm-153		8×10^{-4}
Scandium (21)	Sc-46		4×10^{-4}
	Sc-47		9×10^{-4}
	Sc-48		3×10^{-4}
Selenium (34)	Se-75		3×10^{-3}
Silicon (14)	Si-31		9×10^{-3}
Silver (47)	Ag-105		1×10^{-3}
	Ag-110m		3×10^{-4}
	Ag-111		4×10^{-4}
Sodium (11)	Na-24		2×10^{-3}
Strontium (38)	Sr-85		1×10^{-3}
	Sr-89		1×10^{-4}
	Sr-91		7×10^{-4}
	Sr-92		7×10^{-4}
Sulfur (16)	S-35	9×10^{-8}	6×10^{-4}
Tantalum (73)	Ta-182		4×10^{-4}
Technetium (43)	Tc-96m		1×10^{-1}
	Tc-96		1×10^{-3}
Tellurium (52)	Te-125m		2×10^{-3}
	Te-127m		6×10^{-4}
	Te-127		3×10^{-3}
	Te-129m		3×10^{-4}
	Te-131m		6×10^{-4}
	Te-132		3×10^{-4}
Terbium (65)	Tb-160		4×10^{-4}
Thallium (81)	Tl-200		4×10^{-3}
	Tl-201		3×10^{-3}
	Tl-202		1×10^{-3}
	Tl-204		1×10^{-3}
Thulium (69)	Tm-170		5×10^{-4}
	Tm-171		5×10^{-3}
Tin (50)	Sn-113		9×10^{-4}
	Sn-125		2×10^{-4}
Tungsten	W-181		4×10^{-3}

(Wolfram) (74)	W-187		7×10^{-4}
Vanadium (23)	V-48		3×10^{-4}
Xenon (54)	Xe-131m	4×10^{-6}	
	Xe-133	3×10^{-6}	
	Xe-135	1×10^{-6}	
Ytterbium (70)	Yb-175		1×10^{-3}
Yttrium (39)	Y-90		2×10^{-4}
	Y-91m		3×10^{-2}
	Y-91		3×10^{-4}
	Y-92		6×10^{-4}
	Y-93		3×10^{-4}
Zinc (30)	Zn-65		1×10^{-3}
	Zn-69m		7×10^{-4}
	Zn-69		2×10^{-2}
Zirconium (40)	Zr-95		6×10^{-4}
	Zr-97		2×10^{-4}
Beta and/or gamma emitting radioactive material not listed above with half-life of less than 3 years.		1×10^{-10}	1×10^{-6}

[1/]Values are given in Column I only for those materials normally used as gases.

[2/]μCi/g are for solids.

NOTE 1: Many radioisotopes transform into isotopes which are also radioactive. In expressing the concentrations in Schedule A, the activity stated is that of the parent isotope and takes into account the daughters.

NOTE 2: For purposes of 410 IAC 5-3-4 where there is involved a combination of isotopes, the limit for the combination should be derived as follows: Determine for each isotope in the product the ratio between the radioactivity concentration present in the product and the exempt radioactivity concentration established in Schedule A for the specific isotope when not in combination. The sum of such ratios may not exceed "1".

EXAMPLE:

$$\frac{\text{Concentration of Isotope A in Product}}{\text{Exempt concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in Product}}{\text{Exempt concentration of Isotope B}} \leq 1$$

NOTE 3: To convert μCi/ml to SI units of megabecquerels per liter multiply the above values by 37.

EXAMPLE: Zirconium (40) Zr-97 (2×10^{-4} μCi/ml multiplied by 37 is equivalent to 74×10^{-4} MB/q/l). *(Indiana State Department of Health; Rule HRH-2,PT C,Schedule A; filed May 26, 1978, 3:30 pm: 1 IR 168; filed Feb 29, 1984, 10:10 am: 7 IR 881; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-3-27 Schedule of exempt quantities

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 27.

SCHEDULE B

EXEMPT QUANTITIES

Radioactive Material	Microcuries
Antimony-122 (Sb 122)	100
Antimony-124 (Sb 124)	10
Antimony-125 (Sb 125)	10
Arsenic-73 (As 73)	100
Arsenic-74 (As 74)	10
Arsenic-76 (As 76)	10
Arsenic-77 (As 77)	100
Barium-131 (Ba 131)	10
Barium-133 (Ba 133)	10
Barium-140 (Ba 140)	10
Bismuth-210 (Bi 210)	1
Bromine-82 (Br 82)	10
Cadmium-109 (Cd 109)	10
Cadmium-115m (Cd 115m)	10
Cadmium-115 (Cd 115)	100
Calcium-45 (Ca 45)	10
Calcium-47 (Ca 47)	10
Carbon-14 (C 14)	100
Cerium-141 (Ce 141)	100
Cerium-143 (Ce 143)	100
Cerium-144 (Ce 144)	1
Cesium-129 (Cs 129)	100
Cesium-131 (Cs 131)	1,000
Cesium-134m (Cs 134m)	100
Cesium-134 (Cs 134)	1
Cesium-135 (Cs 135)	10
Cesium-136 (Cs 136)	10
Cesium-137 (Cs 137)	10
Chlorine-36 (Cl 36)	10
Chlorine-38 (Cl 38)	10
Chromium-51 (Cr 51)	1,000
Cobalt-57 (Co 57)	100
Cobalt-58m (Co 58m)	10
Cobalt-58 (Co 58)	10
Cobalt-60 (Co 60)	1

Copper-64 (Cu 64)	100
Dysprosium-165 (Dy 165)	10
Dysprosium-166 (Dy 166)	100
Erbium-169 (Er 169)	100
Erbium-171 (Er 171)	100
Europium-152 (Eu 152) 9.2h	100
Europium-152 (Eu 152) 13 yr	1
Europium-154 (Eu 154)	1
Europium-155 (Eu 155)	10
Flourine-18 *[sic., Fluorine]* (F 18)	1,000
Gadolinium-153 (Gd 153)	10
Gadolinium-159 (Gd 159)	100
Gallium-67 (Ga 67)	100
Gallium-72 (Ga 72)	10
Germanium-68 (Ge 68)	100
Germanium-71 (Ge 71)	100
Gold-195 (Au 195)	100
Gold-198 (Au 198)	100
Gold-199 (Au 199)	100
Hafnium-181 (Hf 181)	10
Holmium-166 (Ho 166)	100
Hydrogen-3 (H 3)	1,000
Indium-111 (In 111)	100
Indium-113m (In 113m)	100
Indium-114m (In 114m)	10
Indium-115m (In 115m)	100
Indium-115 (In 115)	10
Iodine-123 (I 123)	100
Iodine-125 (I 125)	1
Iodine-126 (I 126)	1
Iodine-129 (I 129)	0.
Iodine-131 (I 131)	1
Iodine-132 (I 132)	10
Iodine-133 (I 133)	1
Iodine-134 (I 134)	10
Iodine-135 (I 135)	10
Iridium-192 (Ir 192)	10
Iridium-194 (Ir 194)	100
Iron-52 (Fe 52)	10

Iron-55 (Fe 55)	100
Iron-59 (Fe 59)	10
Krypton-85 (Kr 85)	100
Krypton-87 (Kr 87)	10
Lanthanum-140 (La 140)	10
Lutetium-177 (Lu 177)	100
Manganese-52 (Mn 52)	10
Manganese-54 (Mn 54)	10
Manganese-56 (Mn 56)	10
Mercury-197m (Hg 197m)	100
Mercury-197 (Hg 197)	100
Mercury-203 (Hg 203)	10
Molybdenum-99 (Mo 99)	100
Neodymium-147 (Nd 147)	100
Neodymium-149 (Nd 149)	100
Nickel-59 (Ni 59)	100
Nickel-63 (Ni 63)	10
Nickel-65 (Ni 65)	100
Niobium-93m (Nb 93m)	10
Niobium-95 (Nb 95)	10
Niobium-97 (Nb 97)	10
Osmium-185 (Os 185)	10
Osmium-191m (Os 191m)	100
Osmium-191 (Os 191)	100
Osmium-193 (Os 193)	100
Palladium-103 (Pd 103)	100
Palladium-109 (Pd 109)	100
Phosphorus-32 (P 32)	10
Platinum-191 (Pt 191)	100
Platinum-193m (Pt 193m)	100
Platinum-193 (Pt 193)	100
Platinum-197m (Pt 197m)	100
Platinum-197 (Pt 197)	100
Polonium-210 (Po 210)	0.1
Potassium-42 (K 42)	10
Potassium-43 (K 43)	10
Praseodymium-142 (Pr 142)	100
Praseodymium-143 (Pr 142)	100
Promethium-147 (Pm 147)	10

Promethium-149 (Pm 149)	10
Radium-226 (Ra 226)	1
Rhenium-186 (Re 186)	100
Rhenium-188 (Re 188)	100
Rhodium-103m (Rh 103m)	100
Rhodium-105 (Rh 105)	100
Rubidium-81 (Rb 81)	10
Rubidium-86 (Rb 86)	10
Rubidium-87 (Rb 87)	10
Ruthenium-97 (Ru 97)	100
Ruthenium-103 (Ru 103)	10
Ruthenium-105 (Ru 105)	10
Ruthenium-106 (Ru 106)	1
Samarium-151 (Sm 151)	10
Samarium-153 (Sm 153)	100
Scandium-46 (Sc 46)	10
Scandium-47 (Sc 47)	100
Scandium-48 (Sc 48)	10
Selenium-75 (Se 75)	10
Silicon-31 (Si 31)	100
Silver-105 (Ag 105)	10
Silver-110m (Ag 110m)	1
Silver-111 (Ag 111)	100
Sodium-22 (Na 22)	10
Sodium-24 (Na 24)	10
Strontium-85 (Sr 85)	10
Strontium-89 (Sr 89)	1
Strontium-90 (Sr 90)	0.1
Strontium-91 (Sr 91)	10
Strontium-92 (Sr 92)	10
Sulphur-35 (S 35)	100
Tantalum-182 (Ta 182)	10
Technetium-96 (Tc 96)	10
Technetium-97m (Tc 97m)	100
Technetium-97 (Tc 97)	100
Technetium-99m (Tc 99m)	100
Technetium-99 (Tc 99)	10
Tellurium-125m (Te 125m)	10
Tellurium-127m (Te 127m)	10

Tellurium-127 (Te 127)	100
Tellurium-129m (Te 129m)	10
Tellurium-129 (Te 129)	100
Tellurium-131m (Te 131m)	10
Tellurium-132 (Te 132)	10
Terbium-160 (Tb 160)	10
Thallium-200 (Tl 200)	100
Thallium-201 (Tl 201)	100
Thallium-202 (Tl 202)	100
Thallium-204 (Tl 204)	10
Thulium-170 (Tm 170)	10
Thulium-171 (Tm 171)	10
Tin-113 (Sn 113)	10
Tin-125 (Sn 125)	10
Tungsten-181 (W 181)	10
Tungsten-185 (W 185)	10
Tungsten-187 (W 187)	100
Vanadium-48 (V 48)	10
Xenon-131m (Xe 131m)	1,000
Xenon-133 (Xe 133)	100
Xenon-135 (Xe 135)	100
Ytterbium-175 (Yb 175)	100
Yttrium-87 (Y 87)	10
Yttrium-88 (Y 88)	10
Yttrium-90 (Y 90)	10
Yttrium-91 (Y 91)	10
Yttrium-92 (Y 92)	100
Yttrium-93 (Y 93)	100
Zinc-65 (Zn 65)	10
Zinc-69m (Zn 69m)	100
Zinc-69 (Zn 69)	1,000
Zirconium-93 (Zr 93)	10
Zirconium-95 (Zr 95)	10
Zirconium-97 (Zr 97)	10
Any radioactive material not listed above other than alpha emitting radioactive material	0.1

NOTE 1: For purposes of 410 IAC 5-3-10(f)(1)(ii) where there is involved a combination of isotopes, the limit for the combination should be derived as follows:

Determine the amount of each isotope possessed and 1,000 times the amount in Schedule B for each of those isotopes when not in combination. The sum of the ratios of those quantities may not exceed 1.

EXAMPLE:

$$\frac{\text{Amt. of Isotope A possessed}}{1000 \times \text{Schedule B quantity for Isotope A}} + \frac{\text{Amt. of Isotope B Possessed}}{1000 \times \text{Schedule B quantity for Isotope B}} \leq 1$$

NOTE 2: To convert microcuries (µCi) to SI units of kilobecquerels (kBq), multiply the above values by 37.
EXAMPLE: Zirconium-97 (10µCi mulitiplied *[sic.]* by 37 is equivalent to 370 kBq). *(Indiana State Department of Health; Rule HRH-2,PT C,Schedule B; filed May 26, 1978, 3:30 pm: 1 IR 168; filed Feb 29, 1984, 10:10 am: 7 IR 883; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; errata filed Feb 3, 2010, 2:21 p.m.: 20100224-IR-410100062ACA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-3-28 Schedule of medical use groups

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 28. Schedule C

Group I. Use of prepared radiopharmaceuticals for certain diagnostic studies involving measurements of uptake, dilution and excretion (does not include uses involving imaging and tumor localizations)

(1) Chromium-51 as sodium chromate or labeled human serum albumin.
(2) Cobalt-57 as labeled cyanocobalamin.
(3) Cobalt-58 as labeled cyanocobalamin.
(4) Cobalt-60 as labeled cyanocobalamin.
(5) Iodine-123 as sodium iodide.
(6) Iodine-125 as sodium iodide, iodinated human serum albumin, oleic acid, or sodium iothalamate.
(7) Iodine-131 as sodium iodide, iodinated human serum albumin, labeled rose bengal, triolein, or sodium iodohippurate.
(8) Iron-59 as citrate.
(9) Potassium-42 as chloride.
(10) Sodium-24 as chloride.
(11) Technetium-99m as pertechnetate.
(12) Any radioactive material in a radiopharmaceutical and for a diagnostic use involving measurements of uptake, dilution or excretion for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or a "New Drug Application" (NDA) has been accepted by the Food and Drug Administration (FDA).

Group II. Use of prepared radiopharmaceuticals for diagnostic studies involving imaging and tumor localizations

(1) Chromium-51 as human serum albumin.
(2) Fluorine-18 in solution.
(3) Gallium-67 as citrate.
(4) Gold-198 in colloidal form.
(5) Indium-113m as chloride.
(6) Iodine-123 as sodium iodide.
(7) Iodine-125 as sodium iodide or fibrinogen.
(8) Iodine-131 as sodium iodide, iodinated human serum albumin, macroaggregated iodinated human serum albumin, colloidal (microaggregated) iodinated human serum albumin, rose bengal, or sodium iodohippurate.
(9) Mercury-197 as chlormerodrin.
(10) Mercury-203 as chlormerodrin.
(11) Selenium-75 as selenomethionine.
(12) Strontium-85 as nitrate.
(13) Strontium-87m as chloride.
(14) Technetium-99m as pertechnetate, sulfur colloid, or macroaggregated human serum albumin.
(15) Thallium-201 as chloride.
(16) Ytterbium-169 as pentatate sodium.

(17) Any radioactive material in a radiopharmaceutical prepared from a reagent kit listed in (3) of Group III.

(18) Any radioactive material in a radiopharmaceutical and for a diagnostic use involving imaging except those in gaseous forms for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or a "New Drug Application" (NDA) has been accepted by the Food and Drug Administration (FDA).

Group III. Use of generators and reagent kits for the preparation and use of radiopharmaceuticals containing radioactive material for certain diagnostic uses

(1) Molybdenum-99/technetium-99m generators for the elution of technetium-99m as pertechnetate.

(2) Technetium-99m as pertechnetate for use with reagent kits for preparation and use of radiopharmaceuticals containing technetium-99m as provided in (3) and (6) of this group.

(3) Reagent kits for preparation of technetium-99m labeled:

(i) sulfur colloid;

(ii) pentatate sodium;

(iii) human serum albumin microspheres;

(iv) polyphosphates;

(v) macroaggregated human serum albumin;

(vi) etidronate sodium;

(vii) stannous pyrophosphate;

(viii) human serum albumin;

(ix) medronate sodium;

(x) gluceptate sodium; and

(xi) oxidronate sodium.

(4) Tin-113/indium-113m generators for the elution of indium-113m as chloride.

(5) Yttrium-87/strontium-87m generators for the elution of strontium-87m.

(6) Any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material for which generator or reagent kit a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the Food and Drug Administration (FDA).

Group IV. Use of prepared radiopharmaceuticals for certain therapeutic uses that do not normally require hospitalization for purposes of radiation safety

(1) Iodine-131 as iodide for treatment of hyperthyroidism and cardiac dysfunction.

(2) Phosphorus-32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metastases.

(3) Phosphorus-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions.

(4) Any radioactive material in a radiopharmaceutical and for a therapeutic use not normally requiring hospitalization for purposes of radiation safety for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or a "New Drug Application" (NDA) has been accepted by the Food and Drug Administration (FDA).

Group V. Use of prepared radiopharmaceuticals for certain therapeutic uses that normally require hospitalization for purposes of radiation safety

(1) Gold-198 as colloid for intracavitary treatment of malignant effusions.

(2) Iodine-131 as iodide for treatment of thyroid carcinoma.

(3) Any radioactive material in a radiopharmaceutical and for a therapeutic use normally requiring hospitalization for radiation safety reasons for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or a "New Drug Application" (NDA) has been accepted by the Food and Drug Administration (FDA).

Group VI. Use of sources and devices containing radioactive material for certain medical uses

(1) Americium-241 as a sealed source in a device for bone mineral analysis.

(2) Cesium-137 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer.

(3) Cobalt-60 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer.

(4) Gold-198 as seeds for interstitial treatment of cancer.

(5) Iodine-125 as a sealed source in a device for bone mineral analysis.

(6) Iodine-125 as seeds for interstitial treatment of cancer.

(7) Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer.

(8) Radon-222 as seeds for topical, interstitial, and intracavitary treatment of cancer.

(9) Radium-226 as a sealed source for topical, interstitial, and intracavitary treatment of cancer.

(10) Strontium-90 sealed in an applicator for treatment of superficial eye conditions.

(Indiana State Department of Health; Rule HRH-2,PT C,Schedule C; filed May 26, 1978, 3:30 pm: 1 IR 170; filed Feb 29, 1984, 10:10 am: 7 IR 885; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-3-29 Schedule of limits for broad licenses

Authority: IC 16-41-35-26; IC 16-41-35-29

Affected: IC 16-41-35

Sec. 29.

SCHEDULE D

LIMITS FOR BROAD LICENSES

Radioactive Material	Col.I curies	Col.II curies
Antimony-122	1	0.01
Antimony-124	1	0.01
Antimony-125	1	0.01
Arsenic-73	10	0.1
Arsenic-74	1	0.01
Arsenic-76	1	0.01
Arsenic-77	10	0.1
Barium-131	10	0.1
Barium-140	1	0.01
Beryllium-7	10	0.1
Bismuth-210	0.1	0.001
Bromine-82	10	0.1
Cadmium-109	1	0.01
Cadmium-115m	1	0.01
Cadmium-115	10	0.1
Calcium-45	1	0.01
Calcium-47	10	0.1
Carbon-14	100	1.
Cerium-141	10	0.1
Cerium-143	10	0.1
Cerium-144	0.1	0.001
Cesium-131	100	1.
Cesium-134m	100	1.
Cesium-134	0.1	0.001
Cesium-135	1	0.01
Cesium-136	10	0.1

Cesium-137	0.1	0.001
Chlorine-36	1	0.01
Chlorine-38	100	1.
Chromium-51	100	1.
Cobalt-57	10	0.1
Cobalt-58m	100	1.
Cobalt-58	1	0.01
Cobalt-60	0.1	0.001
Copper-64	10	0.1
Dysprosium-165	100	1.
Dysprosium-166	10	0.1
Erbium-169	10	0.1
Erbium-171	10	0.1
Europium-152 (9.2 h)	10	0.1
Europium-152 (13 y)	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1	0.01
Fluorine-18	100	1.
Gadolinium-153	1	0.01
Gadolinium-159	10	0.1
Gallium-72	10	0.1
Germanium-71	100	1.
Gold-198	10	0.1
Gold-199	10	0.1
Hafnium-181	1	0.01
Holmium-166	10	0.1
Hydrogen-3	100	1.
Indium-113m	100	1.
Indium-114m	1	0.01
Indium-115m	100	1.
Indium-115	1	0.01
Iodine-125	0.1	0.001
Iodine-126	0.1	0.001
Iodine-129	0.1	0.001
Iodine-131	0.1	0.001
Iodine-132	10	0.1
Iodine-133	1	0.01
Iodine-134	10	0.1
Iodine-135	1	0.01

Iridium-192	1	0.01
Iridium-194	10	0.1
Iron-55	10	0.1
Iron-59	1	0.01
Krypton-85	100	1.
Krypton-87	10	0.1
Lanthanum-140	1	0.01
Lutetium-177	10	0.1
Manganese-52	1	0.01
Manganese-54	1	0.01
Manganese-56	10	0.1
Mercury-197m	10	0.1
Mercury-197	10	0.1
Mercury-203	1	0.01
Molybdenum-99	10	0.1
Neodymium-147	10	0.1
Neodymium-149	10	0.1
Nickel-59	10	0.1
Nickel-63	1	0.01
Nickel-65	10	0.1
Niobium-93m	1	0.01
Niobium-95	1	0.01
Niobium-97	100	1.
Osmium-185	1	0.01
Osmium-191m	100	1.
Osmium-191	10	0.1
Osmium-193	10	0.1
Palladium-103	10	0.1
Palladium-109	10	0.1
Phosphorus-32	1	0.01
Platinum-191	10	0.1
Platinum-193m	100	1.
Platinum-193	10	0.1
Platinum-197m	100	1.
Platinum-197	10	0.1
Polonium-210	0.01	0.0001
Potassium-42	1	0.01
Praseodymium-142	10	0.1
Praseodymium-143	10	0.1

Promethium-147	1	0.01
Promethium-149	10	0.1
Radium-226	0.01	0.0001
Rhenium-186	10	0.1
Rhenium-188	10	0.1
Rhodium-103m	1,000	10.
Rhodium-105	10	0.1
Rubidium-86	1	0.01
Rubidium-87	1	0.01
Ruthenium-97	100	1.
Ruthenium-103	1	0.01
Ruthenium-105	10	0.1
Ruthenium-106	0.1	0.001
Samarium-151	1	0.01
Samarium-153	10	0.1
Scandium-46	1	0.01
Scandium-47	10	0.1
Scandium-48	1	0.01
Selenium-75	1	0.01
Silicon-31	10	0.1
Silver-105	1	0.01
Silver-110m	0.1	0.001
Silver-111	10	0.1
Sodium-22	0.1	0.001
Sodium-24	1	0.01
Strontium-85m	1,000	10.
Strontium-85	1	0.01
Strontium-89	1	0.01
Strontium-90	0.01	0.0001
Strontium-91	10	0.1
Strontium-92	10	0.1
Sulphur-35	10	0.1
Tantalum-182	1	0.01
Technetium-96	10	0.1
Technetium-97m	10	0.1
Technetium-97	10	0.1
Technetium-99m	100	1.
Technetium-99	1	0.01
Tellurium-125m	1	0.01

Tellurium-127m	1	0.01
Tellurium-127	10	0.1
Tellurium-129m	1	0.01
Tellurium-129	100	1.
Tellurium-131m	10	0.1
Tellurium-132	1	0.01
Terbium-160	1	0.01
Thallium-200	10	0.1
Thallium-201	10	0.1
Thallium-202	10	0.1
Thallium-204	1	0.01
Thulium-170	1	0.01
Thulium-171	1	0.01
Tin-113	1	0.01
Tin-125	1	0.01
Tungsten-181	1	0.01
Tungsten-185	1	0.01
Tungsten-187	10	0.1
Vanadium-48	1	0.01
Xenon-131m	1,000	10.
Xenon-133	100	1.
Xenon-135	100	1.
Ytterbium-175	10	0.1
Yttrium-90	1	0.01
Yttrium-91	1	0.01
Yttrium-92	10	0.1
Yttrium-93	1	0.01
Zinc-65	1	0.01
Zinc-69m	10	0.1
Zinc-69	100	1.
Zirconium-93	1	0.01
Zirconium-95	1	0.01
Zirconium-97	1	0.01
Any radioactive material other than source material, special nuclear material, or alpha emitting radioactive material not listed above.	0.1	0.001

NOTE 1: to convert curies (Ci) to SI units of gigabecquerels (GBq), multiply the above values by 37.

EXAMPLE: Zirconium-97 (Col. II) (0.01 Ci multiplied by 37 is equivalent to 0.37 GBq). *(Indiana State Department of Health; Rule HRH-2,PT C,Schedule E; filed May 26, 1978, 3:30 pm: 1 IR 172; filed Feb 29, 1984, 10:10 am: 7 IR 889; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed*

Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-3-30 Certification of medical use under general license (form U)

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 30. Board Form "U"

(Date)

CERTIFICATE-MEDICAL USE OF RADIOACTIVE MATERIAL UNDER GENERAL LICENSE

410 IAC 5-3-7(h) establishes a general license authorizing physicians to possess certain small quantities of I-125, I-131, Co-57, Co-58, Co-60, and Cr-51 for specified diagnostic uses. Possession of radioactive material under 410 IAC 5-3-7(h) is not authorized until the physician has filed board form U and received from the board a validated copy of board form U with certification number assigned.

INSTRUCTIONS

Submit this form in triplicate to the Medical Radiology Services Division, Indiana State Department of Health. A certification number will be assigned and a validated copy of board form U will be returned. Please print or type your name and address (including ZIP Code), within the lines below:

Certification Number:

(Leave this space blank-number to be assigned by the board)

I am a duly licensed physician [authorized to dispense drugs] in the practice of medicine. My Indiana license number is: _____.

CERTIFICATE

I hereby certify that:

1. All information in this certificate is true and complete.
2. I have appropriate radiation measuring instruments to carry out the diagnostic procedures for which I will use radioactive material under the general license of 410 IAC 5-3-7(h) and I am competent in the use of such instruments.
3. I understand that board rules require that any change in the information furnished on this certificate be reported to the board within 30 days from the date of such change.
4. I have read and understand the provisions of 410 IAC 5-3-7(h) of the Indiana Rule for Radiation Control [410 IAC 5]; and I understand that I am required to comply with those provisions as to all radioactive material which I receive, possess, use, or transfer under the general license for which this certificate is filed with the board:

Date: _____ By: _____

(Signature of person filing form)

CONDITIONS AND LIMITATIONS OF
GENERAL LICENSE 410 IAC 5-3-7(h)

Medical Diagnostic Uses

(1) A general license is hereby issued to any physician to receive, possess, transfer, or use radioactive material set forth below for the stated diagnostic uses, provided, however, that the use is in accordance with the provisions of 410 IAC 5-3-7(h)(2), (3), and (4), the radioactive material is in the form of capsules, disposable syringes, or other prepackaged individual doses; and the radioactive material has been manufactured in accordance with the specific license issued by the board pursuant to 410 IAC 5-3-13(g) or by the U.S. Nuclear Regulatory Commission, any agreement state, or a licensing state pursuant to

equivalent regulations authorizing distribution to persons generally licensed pursuant to 410 IAC 5-3-7(h) or its equivalent:

(i) chromium-51 as sodium radiochromate for determination of red blood cell volumes and studies of red blood cell survival time;

(ii) cobalt-57 for the measurement of intestinal absorption of cyanocobalamin;

(iii) cobalt-58 for the measurement of intestinal absorption of cyanocobalamin;

(iv) cobalt-60 for the measurement of intestinal absorption of cyanocobalamin;

(v) iodine-125 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;

(vi) iodine-131 as sodium iodide for measurement of thyroid uptake; and

(vii) iodine-131 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume.

(2) No physician shall receive, possess, use or transfer radioactive material pursuant to the general license established by 410 IAC 5-3-7(h)(1) until he has filed board form "U," "Certificate–Medical Use of Radioactive Material Under General License" with the board and received from the board a validated copy of the board form "U" with certification number assigned. The generally licensed physician shall furnish on board form "U" the following information and such other information as may be required by that form:

(i) name and address of the generally licensed physician;

(ii) a statement that the generally licensed physician is a duly licensed physician [authorized to dispense drugs] in the practice of medicine in this state; and

(iii) a statement that the generally licensed physician has appropriate radiation measuring instruments to carry out the diagnostic procedures for which he proposes to use radioactive material under the general license of 410 IAC 5-3-7(h) and that he is competent in the use of such instruments.

(3) A physician who receives, possesses or uses a pharmaceutical containing radioactive material pursuant to the general license established by 410 IAC 5-3-7(h)(1) shall comply with the following:

(i) he shall not possess at any one time, pursuant to the general license in 410 IAC 5-3-7(h)(1) more than

(A) 200 microcuries of iodine-131,

(B) 200 microcuries of iodine-125,

(C) 5 microcuries of cobalt-57,

(D) 5 microcuries of cobalt-58,

(E) 5 microcuries of cobalt-60, and

(F) 200 microcuries of chromium-51;

(ii) he shall store the pharmaceutical until administered in the original shipping container, or a container providing equivalent radiation protection;

(iii) he shall use the pharmaceutical only for the uses authorized by 410 IAC 5-3-7(h)(1);

(iv) he shall not administer the pharmaceutical to a woman with confirmed pregnancy or to a person under 18 years of age; and

(v) he shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the board, the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, or in any manner other than in the unopened, labeled shipping container as received from the supplier, except by administering it to a patient.

(4) The generally licensed physician possessing or using radioactive material under the general license of 410 IAC 5-3-7(h)(1) shall report in duplicate to the board, any changes in the information furnished by him in the "Certificate–Medical Use of Radioactive Material Under General License," board form "U." The report shall be submitted within 30 days after the effective date of such change.

(5) Any person using radioactive material pursuant to the general license of 410 IAC 5-3-7(h)(1) is exempt from the requirements of 410 IAC 5-4 and 410 IAC 5-10 with respect to the radioactive material covered by the general license.

NOTE: 410 IAC 5-3-13(g) requires manufacturers of radiopharmaceuticals which are under the general license in this paragraph to include one of the following statements in the label affixed to the container or in the leaflet or brochure which accompanies the radiopharmaceutical:

This radioactive drug may be received, possessed, and used only by physicians licensed [to dispense drugs] in the practice of medicine. Its receipt, possession, use, and transfer are subject to the regulations and a general license or its equivalent of the U.S. Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory

authority.

_____
(Name of Manufacturer)

This radioactive drug may be received, possessed, and used only by physicians licensed [to dispense drugs] in the practice of medicine. Its receipt, possession, use, and transfer are subject to the rules and a general license or its equivalent of a licensing state.

_____
(Name of Manufacturer)

NOTE

If larger quantities or other forms of radioactive material than those specified in the general license of 410 IAC 5-3-7(h) are required, the physician should file an "Application for Radioactive Material License," and obtain a specific radioactive material license. Copies of application and certification forms may be obtained from the Medical Radiology Services Division, Indiana State Department of Health. *(Indiana State Department of Health; 410 IAC 5-3-30; filed Feb 29, 1984, 10:10 am: 7 IR 891; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; errata filed Feb 3, 2010, 2:21 p.m.: 20100224-IR-410100062ACA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-3-31 Certification of in vitro testing under general license (form V)

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 31. Board Form "V"

(Date)

CERTIFICATE–IN VITRO TESTING WITH
RADIOACTIVE MATERIAL UNDER
GENERAL LICENSE

410 IAC 5-3-7(i)(1) establishes a general license authorizing physicians, veterinarians, clinical laboratories, and hospitals to possess certain small quantities of radioactive material for in vitro clinical or laboratory tests not involving the internal or external administration of the radioactive material or the radiation therefrom to human beings or animals. Possession of radioactive material under 410 IAC 5-3-7(i) is not authorized until the physician, veterinarian, clinical laboratory, or hospital has filed board form V and received from the board a validated copy of board form V with certification number.

INSTRUCTIONS

Submit this form in triplicate to the Medical Radiology Services Division, Indiana State Department of Health. A certification number will be assigned and a validated copy of board form V will be returned.

_____

1. Please print or type within the lines, below, the name and address (including ZIP Code) of the physician, veterinarian, clinical laboratory, or hospital for whom or for which this form is filed.

2. I hereby apply for a certification pursuant to 410 IAC 5-3-7(i) for use of radioactive material for (Please check one):
   a. Myself, a duly licensed physician [authorized to dispense drugs] in the practice of medicine.
   b. The above-named clinical laboratory.
   c. The above-named hospital.
   d. Myself, a duly licensed veterinarian.
3. To be completed by the board.

Certification number:

(Leave this space blank–number to be assigned by the board)

4. If place of use is different from address in item 1, please give complete address:

_____

5. Certification:

I hereby certify that:

a. All information in this certification is true and complete.

b. Appropriate radiation measuring instruments are available to carry out the tests for which radioactive material will be used under the general license of 410 IAC 5-3-7(i). The tests will be performed only by personnel competent in the use of the instruments and in the handling of the radioactive material.

c. I understand that board rules require that any change in the information furnished on this certificate be reported to the board, within 30 days from the effective date of such change.

d. I have read and understand the provisions of 410 IAC 5-3-7(i); and I understand that compliance with those provisions is required as to all radioactive material which is received, acquired, possessed, used, or transferred under the general license for which this certificate is filed with the board.

Date: _____ By: _____

(Signature of person filing form)

_____

(Printed name and title of position of person filing form)

CONDITIONS AND LIMITATIONS OF GENERAL
LICENSE 410 IAC 5-3-7(i)

General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing

(1) A general license is hereby issued to any physician, veterinarian, clinical laboratory, or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of 410 IAC 5-3-7(i)(2), (3), (4), (5), and (6), the following radioactive materials in prepackaged units for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

(i) Carbon-14, in units not exceeding 10 microcuries each.

(ii) Cobalt-57, in units not exceeding 10 microcuries each.

(iii) Hydrogen-3 (tritium), in units not exceeding 50 microcuries each.

(iv) Iodine-125, in units not exceeding 10 microcuries each.

(v) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each.

(vi) Iodine-131, in units not exceeding 10 microcuries each.

(vii) Iron-59, in units not exceeding 20 microcuries each.

(viii) Selenium-75, in units not exceeding 10 microcuries each.

(2) No person shall receive, acquire, possess, use, or transfer radioactive material pursuant to the general license established by 410 IAC 5-3-7(i)(1) until he has filed board form "V," "Certificate–In Vitro Testing with Radioactive Material Under General License," with the board and received from the board a validated copy of board form "V" with certification number assigned, or until he has been authorized pursuant to 410 IAC 5-3-11(c)(3) to use radioactive material under the general license in 410 IAC 5-3-7(i). The physician, veterinarian, clinical laboratory, or hospital shall furnish on board form "V" the following information and such other information as may be required by that form:

(i) name and address of the physician, veterinarian, clinical laboratory, or hospital;

(ii) the location of use; and

(iii) a statement that the physician, veterinarian, clinical laboratory, or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general

license in 410 IAC 5-3-7(i)(1) and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

(3) A person who receives, acquires, possesses, or uses radioactive material pursuant to the general license established by 410 IAC 5-3-7(i)(1) shall comply with the following:

(i) The general licensee shall not possess at any one time, pursuant to the general license in 410 IAC 5-3-7(i)(1), at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-175, iron-59, and/or cobalt-57 in excess of 200 microcuries.

(ii) The general licensee shall store the radioactive material until used, in the original shipping container or in a container providing equivalent radiation protection.

(iii) The general licensee shall use the radioactive material only for the uses authorized by 410 IAC 5-3-7(i)(1).

(iv) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the board, the U.S. Nuclear Regulatory Commission, any agreement state, or licensing state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(v) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in 410 IAC 5-3-7(i)(1)(viii) as required by 410 IAC 5-4-16.

(4) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to 410 IAC 5-3-7(i)(1):

(i) Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 410 IAC 5-3-13(h) or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, any agreement state or licensing state which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under 410 IAC 5-3-7(i) or its equivalent, and

(ii) Unless one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on the label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

(A) This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the rules and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority.

_____

Name of Manufacturer

(B) This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of a licensing state.

_____

Name of Manufacturer

(5) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of 410 IAC 5-3-7(i)(1) shall report in writing to the board, any changes in the information furnished by him in the "Certificate–In Vitro Testing with Radioactive Material Under General License," board form "V." The report shall be furnished within 30 days after the effective date of such change.

(6) Any person using radioactive material pursuant to the general license of 410 IAC 5-3-7(i)(1) is exempt from the requirements of 410 IAC 5-4 and 410 IAC 5-10 with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in 410 IAC 5-3-7(i)(1)(viii) shall comply with the provisions of 410 IAC 5-4-16, 410 IAC 5-4-22, and 410 IAC 5-4-23.

NOTE

If larger quantities or other forms of radioactive material than those specified in the general license of 410 IAC 5-3-7(i) are required, an "Application for Radioactive Material License," should be filed to obtain a specific radioactive material license. Copies

of application and certification forms may be obtained from the Medical Radiology Services Division, Indiana State Department of Health. *(Indiana State Department of Health; 410 IAC 5-3-31; filed Feb 29, 1984, 10:10 am: 7 IR 893; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; errata filed Feb 3, 2010, 2:21 p.m.: 20100224-IR-410100062ACA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-3-32 Certification of use of depleted uranium under general license (form W)

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 32. Board Form "W"

(Date)

REGISTRATION CERTIFICATE–USE OF DEPLETED
URANIUM UNDER GENERAL LICENSE

410 IAC 5-3-6(d) establishes a general license authorizing the use of depleted uranium contained in industrial products or devices for mass-volume applications. This form W shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium.

INSTRUCTIONS

1. Submit this form in triplicate to:
   Medical Radiology Services Division
   Indiana State Department of Health
   2 North Meridian Street
   Indianapolis, Indiana 46204
2. Please print or type the name and address (including ZIP Code) of the registrant for whom this form is filed. Position the first letter of the address below the left dot and do not extend the address beyond the right dot. (A file number will be assigned and a copy of form W will be returned.)
3. I hereby file form W pursuant to 410 IAC 5-3-6(d), for use of depleted uranium contained in industrial products or devices for mass-volume applications.
4. To be completed by the board.

FILE NUMBER: (Leave this space blank–number to be assigned by board.)

5. Name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in 410 IAC 5-3-6(d).

_____

6. Certification:

   I hereby certify that:

   a. All information in this registration certificate is true and complete.

   b. The registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 410 IAC 5-3-6(d) and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium.

   c. I understand that board rules require that any changes in information furnished by a registrant on this registration certificate be reported in writing to the board within 30 days after the effective date of such change.

   d. I understand that the registrant is required to comply with the provisions of 410 IAC 5-3-6(d) (reprinted as part of this form) with respect to all depleted uranium which he receives, acquires, uses, or transfers under the general license for which this registration certificate is filed with the board.

Date:_____ By: _____

(Signature of person filing form)

_____

(Printed name and title of person filing form)

Depleted Uranium in Industrial Products and Devices

(1) A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of 410 IAC 5-3-6(d)(2), (3), (4), and (5), depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

(2) The general license in 410 IAC 5-3-6(d)(1) applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to 410 IAC 5-3-13(m) or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an agreement state which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an agreement state.

(3)(i) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by 410 IAC 5-3-6(d)(1) shall file board form W "Registration Certificate–Use of Depleted Uranium Under General License," with the board. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The registrant shall furnish on board form W the following information and such other information as may be required by that form:

(A) Name and address of the registrant;

(B) A statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 410 IAC 5-3-6(d)(1) and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(C) Name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in 410 IAC 5-3-6(d)(3)(i)(B).

(ii) The registrant possessing or using depleted uranium under the general license established by 410 IAC 5-3-6(d)(1) shall report in writing to the board any changes in information furnished by him in board form W "Registration Certificate–Use of Depleted Uranium Under General License." The report shall be submitted within 30 days after the effective date of such change.

(4) A person who receives, acquires, possesses or uses depleted uranium pursuant to the general license established by 410 IAC 5-3-6(d)(1):

(i) Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium.

(ii) Shall not abandon such depleted uranium.

(iii) Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 410 IAC 5-3-22. In the case where the transferee receives the depleted uranium pursuant to the general license established by 410 IAC 5-3-6(d)(1), the transferor shall furnish the transferee a copy of 410 IAC 5 and a copy of board form W. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission's or agreement state's regulation equivalent to 410 IAC 5-3-6(d)(1), the transferor shall furnish the transferee a copy of 410 IAC 5 and a copy of board form W accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or agreement state under requirements substantially the same as those in 410 IAC 5.

(iv) Within 30 days of any transfer, shall report in writing to the board the name and address of the person receiving the depleted uranium pursuant to such transfer.

(v) Shall not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.

(5) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by 410 IAC 5-3-6(d)(1) is exempt from the requirements of 410 IAC 5-4 and 410 IAC 5-10 with respect to the depleted uranium covered by that general license.

(Indiana State Department of Health; 410 IAC 5-3-32; filed Feb 29, 1984, 10:10 am: 7 IR 895; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; errata filed Feb 3, 2010, 2:21 p.m.: 20100224-IR-410100062ACA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

Rule 4. Protection and Exposure Standards

410 IAC 5-4-1 Scope of rule

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 1. (a) 410 IAC 5-4-1 establishes standards for protection against radiation hazards. Except as otherwise specifically provided, 410 IAC 5-4 applies to all licensees or registrants. It is the purpose of 410 IAC 5-4 to control the possession, use, and transfer of sources of radiation by any licensee or registrant in such a manner that the total dose to an individual does not exceed the standards of radiation protection prescribed in 410 IAC 5-4. Nothing in 410 IAC 5-4 shall be interpreted as limiting the intentional exposure of patients to radiation for the purpose of medical diagnosis or therapy.

(b) In addition to complying with the rules set forth in 410 IAC 5-4, every reasonable effort should be made to maintain radiation exposures, and releases of radioactive materials in effluents to unrestricted areas, as low as is reasonably achievable. The term "as low as is reasonably achievable" means as low as is reasonably achievable taking into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety, and other societal and socio-economic considerations, and in relation to the utilization of ionizing radiation in the public interest. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.1; filed May 26, 1978, 3:30 pm: 1 IR 174; filed Feb 29, 1984, 10:10 am: 7 IR 897; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-4-2 Radiation dose to individuals in restricted areas[1/]

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 2. (a) In accordance with the provisions of 410 IAC 5-4-3(a), and except as provided in 410 IAC 5-4-2(b), no licensee or registrant shall possess, use, receive, or transfer sources of radiation in such a manner as to cause any individual in a restricted area to receive in any period of one calendar quarter from all sources of radiation in the licensee's or registrant's possession a total occupational dose in excess of the standards specified in the following table:

	Rems per Calendar Quarter
Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads.	1 1/4
Hands and forearms; feet and ankles.	18 3/4
Skin of whole body.	7 1/2

[1/] For determining the doses specified in 410 IAC 5-4-2 a dose from x or gamma rays up to 10 MeV may be assumed to be equivalent to the exposure measured by a properly calibrated appropriate instrument in air at or near the body surface in the region of the highest dose rate.

(b) A licensee or registrant may permit an individual in a restricted area to receive a total occupational dose to the whole body greater than that permitted under 410 IAC 5-4-2(a), provided:

(1) During any calendar quarter, the total occupational dose to the whole body from sources of radiation in the licensee's or registrant's possession shall not exceed 3 rems;

(2) The dose to the whole body, when added to the accumulated occupational dose to the whole body, shall not exceed 5(N-18) rems where "N" equals the individual's age in years at his last birthday; and

(3) The licensee or registrant has determined the individual's accumulated occupational dose to the whole body on board form "Y" or on a clear and legible record containing all the information required in that form and has otherwise complied with the requirements of 410 IAC 5-4-3. As used in 410 IAC 5-4-2(b), "dose to the whole body" shall be deemed to include any dose to the whole body, gonads, active bloodforming organs, head and trunk, or lens of eye.

(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.101; filed May 26, 1978, 3:30 pm: 1 IR 174; filed Feb 29, 1984, 10:10 am: 7 IR 897; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-4-3 Disclosure of prior exposure; certification for excess exposure (form Y)

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 3. (a)(1) Each licensee or registrant shall require any individual, prior to first entry of the individual into the licensee's or registrant's restricted area during each employment or work assignment under such circumstances that the individual will receive or is likely to receive in any period of 1 calendar quarter an occupational dose in excess of 25 percent of the applicable standards specified in 410 IAC 5-4-2(a) and 410 IAC 5-4-5(a), to disclose in a written, signed statement, either:

(i) That the individual had no prior occupational dose during the current calendar quarter, or

(ii) The nature and amount of any occupational dose which the individual may have received during the specifically identified current calendar quarter, from sources of radiation possessed or controlled by other persons.

(2) Each licensee or registrant shall maintain records of such statements until the board authorizes disposition.

(b) Before permitting, pursuant to 410 IAC 5-4-2(b), any individual in a restricted area to receive an occupational radiation dose in excess of the standards specified in 410 IAC 5-4-2(a), each licensee or registrant shall:

(1) obtain a certificate on board form "Y" or on a clear and legible record containing all the information required in that form, signed by the individual, showing each period of time after the individual attained the age of 18 in which the individual received an occupational dose of radiation; and

(2) calculate on board form "Y" in accordance with the instructions appearing therein, or on a clear and legible record containing all the information required in that form, the previously accumulated occupational dose received by the individual and the additional dose allowed for that individual under 410 IAC 5-4-2(b).

(c)(1) In the preparation of board form "Y," or a clear and legible record containing all the information required in that form, the licensee or registrant shall make a reasonable effort to obtain reports of the individual's previously accumulated occupational dose. For each period for which the licensee or registrant obtains such reports, he shall use the dose shown in the report in preparing the form. In any case where a licensee or registrant is unable to obtain reports of the individual's occupational dose for a previous complete calendar quarter, it shall be assumed that the individual has received the occupational dose specified in whichever of the following columns that apply:

Part of Body	Column 1 Assumed Dose in Rems for Calendar Quarters Prior to January 1, 1961	Column 2 Assumed Dose in Rems for Calendar Quarters Beginning on or After January 1, 1961
Whole body, gonads, active blood-forming organs, head and trunk, lens of eye	3¾	1¼

(2) The licensee or registrant shall retain and preserve records used in preparing board form "Y" until the board authorizes their disposition. If calculation of the individual's accumulated occupational dose for all periods prior to January 1, 1961, yields a result higher than the applicable accumulated dose value for the individual as of that date, as specified in 410 IAC 5-4-2(b)(2), the excess may be disregarded. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.102; filed May 26, 1978, 3:30 pm: 1 IR 175; filed Feb 29, 1984, 10:10 am: 7 IR 897; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-4-4 Airborne radiation exposure; restricted areas

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 4. (a)(1) No licensee or registrant shall possess, use, or transfer radioactive material in such a manner as to permit any individual in a restricted area to inhale a quantity of radioactive material in any period of 1 calendar quarter greater than the quantity which would result from inhalation for 40 hours per week for 13 weeks at uniform concentrations of radioactive material in air specified in Appendix A, 410 IAC 5-4-27, Table I, Column 1.[2/3/4/] If the radioactive material is of such form that intake by absorption through the skin is likely, individual exposures to radioactive material shall be controlled so that the uptake of radioactive material by any organ from either inhalation or absorption or both routes of intake[5/6/] in any calendar quarter does not exceed that which would result from inhaling such radioactive material for 40 hours per week for 13 weeks at uniform concentrations specified in Appendix A, 410 IAC 5-4-27, Table I, Column 1.

(2) No licensee or registrant shall possess, use, or transfer mixtures of U-234, U-235, and U-238 in soluble form in such a manner as to permit any individual in a restricted area to inhale a quantity of such material in excess of the intake limits specified in Appendix A, 410 IAC 5-4-27, Table I, Column 1. If such soluble uranium is of a form such that absorption through the skin is likely, individual exposures to such material shall be controlled so that the uptake of such material by any organ from either inhalation or absorption or both routes of intake[5/] does not exceed that which would result from inhaling such material at the limits specified in Appendix A, 410 IAC 5-4-27, Table I, Column 1 and footnote 5 thereto.

(3) For purposes of determining compliance with the requirements of 410 IAC 5-4-4 the licensee or registrant shall use suitable measurements of concentrations of radioactive material in air for detecting and evaluating airborne radioactivity in restricted areas and in addition, as appropriate, shall use measurements of radioactivity in the body, measurements of radioactivity excreted from the body or any combination of such measurements as may be necessary for timely detection and assessment of individual intakes of radioactivity by exposed individuals. It is assumed that an individual inhales radioactive material at the airborne concentration in which he is present unless he uses respiratory protective equipment pursuant to 410 IAC 5-4-4(c). When assessment of a particular individual's intake of radioactive material is necessary, intakes less than those which would result from inhalation for 2 hours in any 1 day or for 10 hours in any 1 week at uniform concentrations specified in Appendix A, 410 IAC 5-4-27, Table I, Column 1 need not be included in such assessment, provided that for any assessment in excess of these amounts the entire amount is included.

[2/] Since the concentration specified for tritium oxide vapor assumes equal intakes by skin absorption and inhalation, the total intake permitted is twice that which would result from inhalation alone at the concentration specified in H-3 (S) in Appendix A, 410 IAC 5-4-27, Table I, Column 1 for 40 hours per week for 13 weeks.

[3/] For radon-222, the limiting quantity is that inhaled in a period of one calendar year. For radioactive material designated "Sub" in the "Isotope" column of the table, the concentration value specified is based upon exposure to the material as an external radiation source. Individual exposures to these materials may be accounted for as part of the limitation on individual dose in 410 IAC 5-4-2. These materials shall be subject to the precautionary procedures required in 410 IAC 5-4-4(b)(1).

[4/] Multiply the concentration values specified in Appendix A, 410 IAC 5-4-27, Table I, Column 1 by 6.3×10^8 milliliters to obtain the quarterly quantity limit. Multiply the concentration value specified in Appendix A, 410 IAC 5-4-27, Table I, Column 1 by 2.5×10^9 milliliters to obtain the annual quantity limit for Rn-222.

[5/] Significant intake by ingestion or injection is presumed to occur only as a result of circumstances such as accident, inadvertence, poor procedure, or similar special conditions. Such intakes must be evaluated and accounted for by techniques and procedures as may be appropriate to the circumstances of the occurrence. Exposures so evaluated shall be included in determining whether the limitation on individual exposures in 410 IAC 5-4-4(a)(1) has been exceeded.

[6/] Regulatory guidance on assessment of individual intakes of radioactive material is given in U.S. Nuclear Regulatory Commission Regulatory Guide 8.9, "Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program." Single copies of Regulatory Guide 8.9 are available from the Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, upon written request.

(b)(1) The licensee or registrant shall, as a precautionary procedure, use process or other engineering controls, to the extent practicable, to limit concentrations of radioactive materials in air to levels below those which delimit an airborne radioactivity area as defined in 410 IAC 5-1-2.

(2) When it is impracticable to apply process or other engineering controls to limit concentrations of radioactive material in air below those defined in 410 IAC 5-1-2, other precautionary procedures, such as increased surveillance, limitation of working times, or provision of respiratory protective equipment, shall be used to maintain intake of radioactive material by any individual within any period of 7 consecutive days as far below that intake of radioactive material which would result from inhalation of such material for 40 hours at the uniform concentrations specified in Appendix A, 410 IAC 5-4-27, Table I, Column 1 as is reasonably

achievable. Whenever the intake of radioactive material by any individual exceeds this 40-hour control measure, the licensee shall make such evaluations and take such actions as are necessary to assure against recurrence. The licensee shall maintain records of such occurrences, evaluations, and actions taken in a clear and readily identifiable form suitable for summary review and evaluation.

(c) When respiratory protective equipment is used to limit the inhalation of airborne radioactive material pursuant to 410 IAC 5-4-4(b)(2), the licensee may make allowance for such use in estimating exposures of individuals to such materials provided that such equipment is used as stipulated in U.S. Nuclear Regulatory Commission Regulatory Guide 8.15, "Acceptable Programs for Respiratory Protection."[7/]

[7/] Single copies of U.S. Nuclear Regulatory Commission Regulatory Guide 8.15 are available from the Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, upon written request.

(d) Notwithstanding the provisions of 410 IAC 5-4-4(b) and (c), the board may impose further restrictions:

(1) On the extent to which a licensee may make allowance for use of respirators in lieu of provision of process, containment, ventilation, or other engineering controls, if application of such controls is found to be practicable; and

(2) As might be necessary to assure that the respiratory protective program of the licensee is adequate in limiting exposures of personnel to airborne radioactive material.

(e) The licensee or registrant shall notify, in writing, the board at least 30 days before the date that respiratory protective equipment is first used under the provisions of 410 IAC 5-4-4.

(f) A licensee or registrant who is authorized to make allowance for use of respiratory protective equipment shall bring his respiratory protective program into conformance with the requirements of 410 IAC 5-4-4(c) within 1 year. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.103; filed May 26, 1978, 3:30 pm: 1 IR 175; filed Feb 29, 1984, 10:10 am: 7 IR 898; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-4-5 Exposure of minors[8/]

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 5. (a) No licensee or registrant shall possess, use, or transfer sources of radiation in such a manner as to cause any individual within a restricted area, who is under 18 years of age, to receive in any period of 1 calendar quarter from all sources of radiation in such licensee's or registrant's possession a dose in excess of 10 percent of the standards specified in the table in 410 IAC 5-4-2(a).

(b) No licensee or registrant shall possess, use, or transfer radioactive material in such a manner as to cause any individual within a restricted area, who is under 18 years of age to be exposed to airborne radioactive material in an average concentration in excess of the limits specified in Appendix A, 410 IAC 5-4-27, Table II. For purposes of this paragraph, concentrations may be averaged over periods not greater than a week.

(c) The provisions of 410 IAC 5-4-4(b)(2) and 410 IAC 5-4-4(c) shall apply to exposures subject to 410 IAC 5-4-5(b) except that the references in 410 IAC 5-4-4(b)(2) and 410 IAC 5-4-4(c) to Appendix A, 410 IAC 5-4-27, Table I, Column 1 shall be deemed to be references to Appendix A, 410 IAC 5-4-27, Table II, Column 1.

[8/] For determining the doses specified in 410 IAC 5-4-5, a dose from x or gamma radiation up to 10 MeV may be assumed to be equivalent to the exposure measured by a properly calibrated appropriate instrument in air at or near the body surface in the region of the highest dose rate. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.104; filed May 26, 1978, 3:30 pm: 1 IR 177; filed Feb 29, 1984, 10:10 am: 7 IR 900; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-4-6 Permissible levels of radiation from external sources in unrestricted areas[9/]

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 6. (a) Except as authorized by the board pursuant to 410 IAC 5-4-6(b) no licensee or registrant shall possess, use, or

transfer sources of radiation in such a manner as to create in any unrestricted area from such sources of radiation in his possession:

(1) Radiation levels which, if an individual were continuously present in the area, could result in his receiving a dose in excess of 2 millirems in any 1 hour; or

(2) Radiation levels which, if an individual were continuously present in the area could result in his receiving a dose in excess of 100 millirems in any 7 consecutive days.

(b) Any person may apply to the board for proposed limits upon levels of radiation in unrestricted areas in excess of those specified in 410 IAC 5-4-6(a) resulting from the applicant's possession or use of sources of radiation. Such applications should include information as to anticipated average radiation levels and anticipated occupancy times for each unrestricted area involved. The board will approve the proposed limits if the applicant demonstrates to the satisfaction of the board that the proposed limits are not likely to cause any individual to receive a dose to the whole body in any period of 1 calendar year in excess of 0.5 rem.

[9/] It is the intent of 410 IAC 5-4-6 to limit radiation levels so that it is unlikely that individuals in unrestricted areas would receive a dose to the whole body in excess of 0.5 rem in any one year. If in specific instances, it is determined by the board that this intent is not met, the board may, pursuant to 410 IAC 5-1-7, impose such additional requirements on the licensee or registrant as may be necessary to meet the intent. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.105; filed May 26, 1978, 3:30 pm: 1 IR 177; filed Feb 29, 1984, 10:10 am: 7 IR 900; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-4-7 Effluent concentration limits in unrestricted areas

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 7. (a) A licensee or registrant shall not possess, use, or transfer licensed material so as to release to an unrestricted area radioactive material in concentrations which exceed the limits specified in Appendix A, 410 IAC 5-4-27, Table II, except as authorized pursuant to 410 IAC 5-4-17 or 410 IAC 5-4-7(b). For purposes of 410 IAC 5-4-7, concentrations may be averaged over a period not greater than 1 year.

(b) An application for a license or amendment may include proposed limits higher than those specified in 410 IAC 5-4-7(a). The board will approve the proposed limits if the applicant demonstrates:

(1) That the applicant has made a reasonable effort to minimize the radioactivity contained in effluents to unrestricted areas; and

(2) That it is not likely that radioactive material discharged in the effluent would result in the exposure of an individual to concentrations of radioactive material in air or water exceeding the limits specified in Appendix A, 410 IAC 5-4-27, Table II.

(c) An application for higher limits pursuant to 410 IAC 5-4-7(b) shall include information demonstrating that the applicant has made a reasonable effort to minimize the radioactivity discharged in effluents to unrestricted areas, and shall include, as pertinent:

(1) Information as to flow rates, total volume of effluent, peak concentration of each radionuclide in the effluent, and concentration of each radionuclide in the effluent averaged over a period of 1 year at the point where the effluent leaves a stack, tube, pipe, or similar conduit;

(2) A description of the properties of the effluents, including:

(i) Chemical composition,

(ii) Physical characteristics, including suspended solids content in liquid effluents, and nature of gas or aerosol for air effluents,

(iii) The hydrogen ion concentration (pH) of liquid effluents, and

(iv) The size range of particulates in effluents released into air;

(3) A description of the anticipated human occupancy in the unrestricted area where the highest concentration of radioactive material from the effluent is expected, and, in the case of a river or stream, a description of water uses downstream from the point of release of the effluent;

(4) Information as to the highest concentration of each radionuclide in an unrestricted area, including anticipated concentrations averaged over a period of 1 year:

(i) In air at any point of human occupancy, or

(ii) In water at points of use downstream from the point of release of the effluent;

(5) The background concentration of radionuclides in the receiving river or stream prior to the release of liquid effluent;

(6) A description of the environmental monitoring equipment, including sensitivity of the system, and procedures and calculations to determine concentrations of radionuclides in the unrestricted area and possible reconcentrations of radionuclides; and

(7) A description of the waste treatment facilities and procedures used to reduce the concentration of radionuclides in effluents prior to their release.

(d) For the purposes of 410 IAC 5-4-7, the concentration limits in Appendix A, 410 IAC 5-4-27, Table II, shall apply at the boundary of the restricted area. The concentration of radioactive material discharged through a stack, pipe or similar conduit may be determined with respect to the point where the material leaves the conduit. If the conduit discharges within the restricted area, the concentration at the boundary may be determined by applying appropriate factors for dilution, dispersion, or decay between the point of discharge and the boundary.

(e) In addition to limiting concentrations in effluent streams, the board may limit quantities of radioactive material released in air or water during a specified period of time if it appears that the daily intake of radioactive material from air, water, or food by a suitable sample of an exposed population group, averaged over a period not exceeding 1 year, would otherwise exceed the daily intake resulting from continuous exposure to air or water containing one-third (1/3) the concentration of radioactive material specified in Appendix A, 410 IAC 5-4-27, Table II.

(f) The provisions of 410 IAC 5-4-7 do not apply to disposal of radioactive material into sanitary sewerage systems, which is governed by 410 IAC 5-4-18.

(g) In addition to other requirements of this part *[410 IAC 5-4]*, licensees engaged in uranium fuel cycle operations subject to the provisions of 410 IAC 5-3-13 shall also comply with the provisions of 40 CFR Part 190, "Environmental Radiation Protection Standards for Nuclear Power Operations." *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.106; filed May 26, 1978, 3:30 pm: 1 IR 177; filed Feb 29, 1984, 10:10 am: 7 IR 901; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-4-8 Bioassay services

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 8. Where necessary or desirable in order to aid in determining the extent of an individual's exposure to concentrations of radioactive material, the board may incorporate license provisions or issue an order requiring a licensee or registrant to make available to the individual appropriate bioassay services and to furnish a copy of the reports of such services to the board. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.107; filed May 26, 1978, 3:30 pm: 1 IR 178; filed Feb 29, 1984, 10:10 am: 7 IR 902; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-4-9 Surveys

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 9. Each licensee or registrant shall make or cause to be made such surveys as may be necessary for him to establish compliance with 410 IAC 5. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.201; filed May 26, 1978, 3:30 pm: 1 IR 178; filed Feb 29, 1984, 10:10 am: 7 IR 902; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-4-10 Personnel monitoring requirements[9.5/]

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 10. Each licensee or registrant shall supply appropriate personnel monitoring equipment to, and shall require the use of such equipment by:

(a) Each individual who enters a restricted area under such circumstances that he receives, or is likely to receive, a dose in any calendar quarter in excess of 25 percent of the applicable value specified in 410 IAC 5-4-2(a);

(b) Each individual under 18 years of age who enters a restricted area under such circumstances that he receives, or is likely to receive, a dose in any calendar quarter in excess of 5 percent of the applicable value specified in 410 IAC 5-4-2(a);

(c) Each individual who enters a high radiation area.

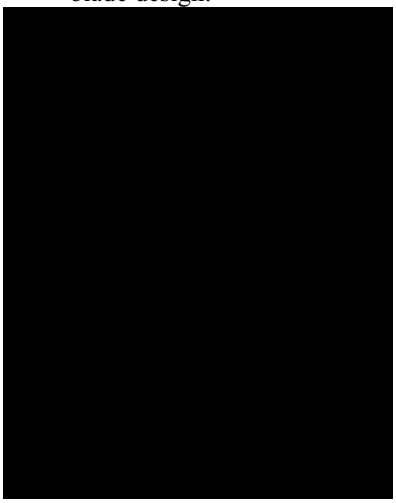
[9.5/] After July 1, 1984, all required personnel monitoring equipment must be obtained from personnel dosimetry processors having an accreditation program approved by the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Bureau of Standards. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.202; filed May 26, 1978, 3:30 pm: 1 IR 178; filed Feb 29, 1984, 10:10 am: 7 IR 902; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-4-11 Caution signs and labels; alarm signals

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 11. (a) General.

(1) Except as otherwise authorized by the board, symbols prescribed by 410 IAC 5-4-11 shall use the conventional radiation caution colors (magenta or purple on yellow background). The symbol prescribed by this section is the conventional three-blade design:



(A) Cross-hatch area is to be magenta or purple.

(B) Background is to be yellow.

(2) In addition to the contents of signs and labels prescribed in this section, a licensee or registrant may provide on or near such signs and labels any additional information which may be appropriate in aiding individuals to minimize exposure to radiation.

(b) Radiation Areas. Each radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION[10/]

RADIATION AREA

(c) High Radiation Areas.

(1) Each high radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION[10/]
HIGH RADIATION AREA

(2) Each entrance or access point to a high radiation area shall be:

(i) Equipped with a control device which shall cause the level of radiation to be reduced below that at which an individual might receive a dose of 100 millirems in 1 hour upon entry into the area; or

(ii) Equipped with a control device which shall energize a conspicuous visible or audible alarm signal in such a manner that the individual entering the high radiation area and the licensee or a supervisor of the activity are made aware of the entry; or

(iii) Maintained locked except during periods when access to the area is required, with positive control over each individual entry.

(3) The controls required by 410 IAC 5-4-11(c)(2) shall be established in such a way that no individual will be prevented from leaving a high radiation area.

(4) In the case of a high radiation area established for a period of 30 days or less, direct surveillance to prevent unauthorized entry may be substituted for the controls required by 410 IAC 5-4-11(c)(2).

(5) Any licensee or registrant may apply to the board for approval of methods not included in 410 IAC 5-4-11(c)(2) and (4) for controlling access to high radiation areas. The board will approve the proposed alternatives if the licensee or registrant demonstrates that the alternative methods of control will prevent unauthorized entry into a high radiation area, and that the requirement of 410 IAC 5-4-11(c)(3) is met.

(6) Each area in which there may exist radiation levels in excess of 500 rems in 1 hour at 1 meter from a sealed radioactive source that is used to irradiate materials shall have entry control devices and alarms meeting the criteria specified in Section 20.203(c)(6) of 10 CFR Part 20.

(7) The requirements of 410 IAC 5-4-11(c)(6) shall not apply to radioactive sources that are used in teletherapy, industrial radiography, or in completely self-contained irradiators. In the case of open field irradiators in which certain of the criteria specified in 410 IAC 5-4-11(c)(6) are impracticable, equivalent protection shall be provided by license conditions.

(d) Airborne Radioactivity Areas. Each airborne radioactivity area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION[10/]
AIRBORNE RADIOACTIVITY AREA

(e) Additional Requirements.

(1) Each area or room in which any radioactive material, other than natural uranium or thorium, is used or stored in an amount exceeding 10 times the quantity of radioactive material specified in Appendix B, 410 IAC 5-4-28, shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION[10/]
RADIOACTIVE MATERIAL

(2) Each area or room in which natural uranium or thorium is used or stored in an amount exceeding 100 times the quantity specified in Appendix B, 410 IAC 5-4-28, shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION[10/]
RADIOACTIVE MATERIAL

(f) Containers.

(1) Except as provided in 410 IAC 5-4-11(f)(3) each container of radioactive material shall bear a durable, clearly visible label identifying the radioactive contents.

(2) A label required pursuant to 410 IAC 5-4-11(f)(1) shall bear the radiation caution symbol and the words:

CAUTION[10/]
RADIOACTIVE MATERIAL

It shall also provide sufficient information[11/] to permit individuals handling or using the containers, or working in the vicinity

thereof, to take precautions to avoid or minimize exposures.

(3) Notwithstanding the provisions of 410 IAC 5-4-11(f)(1) labeling is not required:

(i) For containers that do not contain radioactive material in quantities greater than the applicable quantities listed in Appendix B, 410 IAC 5-4-28;

(ii) For containers containing only natural uranium or thorium in quantities no greater than 10 times the applicable quantities listed in Appendix B, 410 IAC 5-4-28;

(iii) For containers that do not contain radioactive material in concentrations greater than the applicable concentrations listed in Appendix A, 410 IAC 5-4-27, Table I, Column 2;

(iv) For containers when they are attended by an individual who takes the precautions necessary to prevent the exposure of any individual to radiation or radioactive material in excess of the limits established by 410 IAC 5-4;

(v) For containers when they are in transport and packaged and labeled in accordance with regulations published by the U.S. Department of Transportation;

(vi) For containers which are accessible only to individuals authorized to handle or use them[12/] or to work in the vicinity thereof, provided that the contents are identified to such individuals by a readily available written record; and

(vii) For manufacturing and process equipment such as piping and tanks.

(4) Each licensee or registrant shall, prior to disposal of an empty uncontaminated container to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive material.

(g) All radiation machines shall be labeled in a manner which cautions individuals that radiation is produced when the machine is being operated.

[10/] Or "Danger."

[11/] As appropriate, the information will include radiation levels, kinds of material, estimate of activity, date for which activity is estimated, etc.

[12/] For example, containers in locations such as water-filled canals, storage vaults, or hot cells. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.203; filed May 26, 1978, 3:30 pm: 1 IR 178; filed Feb 29, 1984, 10:10 am: 7 IR 903; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-4-12 Exceptions to posting requirements

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 12. Notwithstanding the provisions of 410 IAC 5-4-11:

(a) A room or area is not required to be posted with a caution sign because of the presence of a sealed source, provided the radiation level 12 inches from the surface of the source container or housing does not exceed 5 millirem per hour.

(b) Rooms or other areas in hospitals are not required to be posted with caution signs, and control of entrance or access thereto pursuant to 410 IAC 5-4-11(c) is not required, because of the presence of patients containing radioactive material provided that there are personnel in attendance who will take the precautions necessary to prevent the exposure of any individual to radiation or radioactive material in excess of the limits established in 410 IAC 5-4.

(c) Caution signs are not required to be posted in areas or rooms containing radioactive material for periods of less than 8 hours provided that (1) the material is constantly attended during such periods by an individual who shall take the precautions necessary to prevent the exposure of any individual to radiation or radioactive material in excess of the limits established in 410 IAC 5-4, and (2) such area or room is subject to the licensee's or registrant's control.

(d) A room or other area is not required to be posted with a caution sign, and control is not required for each entrance or access point to a room or other area which is a high radiation area solely because of the presence of radioactive material prepared for transport and packaged and labeled in accordance with regulations of the U.S. Department of Transportation. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.204; filed May 26, 1978, 3:30 pm: 1 IR 180; filed Feb 29, 1984, 10:10 am: 7 IR 904; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-4-13 Instruction of personnel

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 13. Instructions required for individuals working in or frequenting any portion of a restricted area are specified in 410 IAC 5-10-3. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.205; filed May 26, 1978, 3:30 pm: 1 IR 180; filed Feb 29, 1984, 10:10 am: 7 IR 905; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-4-14 Storage of radiation sources

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 14. (a) Sources of radiation shall be secured against unauthorized removal from the place of storage.

(b) Sources of radiation in an unrestricted area and not in storage shall be tended under the constant surveillance and immediate control of the licensee or registrant. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.206; filed May 26, 1978, 3:30 pm: 1 IR 180; filed Feb 29, 1984, 10:10 am: 7 IR 905; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-4-15 Procedures for receiving packages

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 15. (a)(1) Each licensee or registrant who expects to receive a package containing quantities of radioactive material in excess of the Type A quantities specified in the table of exempt and type A quantities in this section shall:

(i) Make arrangements to receive the package when it is offered for delivery by the carrier if the package is to be delivered to the licensee's or registrant's facility by the carrier; or

(ii) Make arrangements to receive notification from the carrier of the arrival of the package, at the time of arrival if the package is to be picked up by the licensee or registrant at the carrier's terminal.

(2) Each licensee or registrant who picks up a package of radioactive material from a carrier's terminal shall pick up the package expeditiously upon receipt of notification from the carrier of its arrival.

(b)(1) Each licensee or registrant, upon receipt of a package of radioactive material, shall monitor the external surfaces of the package for radioactive contamination caused by leakage of the radioactive contents. The monitoring shall be performed as soon as practicable after receipt, but no later than 3 hours after the package is received at the licensee's facility if received during the licensee's normal working hours or 18 hours if received after normal working hours. Such monitoring need not be performed on:

(i) Packages containing no more than the exempt quantity specified in the table of exempt and type A quantities in this section;

(ii) Packages containing no more than 10 millicuries of radioactive material consisting solely of tritium, carbon-14, sulfur-35, or iodine-125;

(iii) Packages containing only radioactive material as gases or in special form;

(iv) Packages containing only radioactive material in other than liquid form, including Mo-99/Tc-99m generators, and not exceeding the Type A quantity limit specified in the table following 410 IAC 5-4-15(b); and

(v) Packages containing only radionuclides with half-lives of less than 30 days and a total quantity of no more than 100 millicuries.

(2) If removable radioactive contamination in excess of 0.01 microcurie (22,200 transformations per minute) per 100 square centimeters of package surface is found on the external surfaces of the package, the licensee or registrant shall immediately notify by telephone or mailagram, the final delivering carrier and the board.

Table of Exempt and Type A Quantities

Transport Group [13/]	Exempt Quantity Limit (Millicuries)	Type A Quantity Limit (Curies)
I	0.01	0.001
II	0.1	0.050
III	1	3
IV	1	20
V	1	20
VI	1	1,000
VII	25,000	1,000
Special form [13/]	1	20

[13/]The definitions of "transport group" and "special form" are specified in 410 IAC 5-1-2.

(c)(1) Each licensee or registrant, upon receipt of a package containing quantities of radioactive material in excess of the Type A quantities specified in the table of exempt and type A quantities above, other than those transported by exclusive use vehicle, shall monitor the radiation levels external to the package. The package shall be monitored as soon as practicable after receipt, but no later than three hours after the package is received at the licensee's facility if received during the licensee's normal working hours or 18 hours if received after normal working hours.

(2) If radiation levels are found on the external surface of the package in excess of 200 millirems per hour, or in excess of 10 millirems per hour at 3 feet from the external surface of the package, the licensee or registrant shall immediately notify, by telephone and telegraph, the final delivering carrier and the board.

(d) Each licensee or registrant shall establish and maintain procedures for safely opening packages in which radioactive material is received and shall assure that such procedures are followed and that due consideration is given to special instructions for the type of package being opened. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.207; filed May 26, 1978, 3:30 pm: 1 IR 180; filed Feb 29, 1984, 10:10 am: 7 IR 905; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-4-16 Waste disposal; general provisions

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 16. General Requirement. No licensee or registrant shall dispose of any radioactive material except:

(a) By transfer to an authorized recipient as provided in 410 IAC 5-3-22, or

(b) As authorized pursuant to 410 IAC 5-4-7, 410 IAC 5-4-17, 410 IAC 5-4-18 or 410 IAC 5-4-19. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.301; filed May 26, 1978, 3:30 pm: 1 IR 181; filed Feb 29, 1984, 10:10 am: 7 IR 906; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-4-17 Approval of proposed disposal procedures

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 17. (a) Any person may apply to the board for approval of proposed procedures to dispose of radioactive material in a manner not otherwise authorized in this section. Each application shall include a description of the radioactive material, including the quantities and kinds of radioactive material and levels of radioactivity involved, and the proposed manner and conditions of disposal. The application, where appropriate, should also include an analysis and evaluation of pertinent information as to the nature of the environment, including topographical, geological, meterological, and hydrological characteristics; usage of ground and surface waters in the general area; the nature and location of other potentially affected facilities; and procedures to be observed to minimize the risk of unexpected or hazardous exposures.

(b) The board will not approve any application for a license to receive radioactive material from other persons for disposal on land not owned by a state or the federal government. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.302; filed May 26, 1978, 3:30 pm: 1 IR 181; filed Feb 29, 1984, 10:10 am: 7 IR 906; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-4-18 Release into sanitary sewerage system

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 18. (a) No licensee or registrant shall discharge radioactive material into a sanitary sewerage system unless:

(1) it is readily soluble or dispersible in water;

(2) the quantity of any radioactive material released into the system by the licensee in any one day does not exceed the larger of:

(i) The quantity which, if diluted by the average daily quantity of sewage released into the sewer by the licensee, will result in an average concentration not greater than the limits specified in Appendix A, 410 IAC 5-4-27, Table I, Column 2, or

(ii) 10 times the quantity of such material specified in Appendix B, 410 IAC 5-4-28;

(3) The quantity of any radioactive material released in any one month, if diluted by the average monthly quantity of water released by the licensee, will not result in an average concentration exceeding the limits specified in Appendix A, 410 IAC 5-4-27, Table I, Column 2; and

(4) The gross quantity of radioactive material, excluding hydrogen-3 and carbon-14, released into the sewage system by the licensee does not exceed 1 curie per year. The quantities of hydrogen-3 and carbon-14 released into the sanitary sewage system may not exceed 5 curies per year for hydrogen-3 and 1 curie per year for carbon-14.

(b) No licensee or registrant shall discharge radioactive material into an individual sewage disposal system used for the treatment of wastewater serving only a single dwelling, office building, industrial plant, or institution except as specifically approved by the board pursuant to 410 IAC 5-4-7 and 410 IAC 5-4-17.

(c) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material shall be exempt from any limitations contained in 410 IAC 5-4-18. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.303; filed May 26, 1978, 3:30 pm: 1 IR 181; filed Feb 29, 1984, 10:10 am: 7 IR 907; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-4-19 Burial in soil

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 19. No licensee shall dispose of radioactive material by burial in soil except as specifically approved by the board pursuant to 410 IAC 5-4-17. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.304; filed May 26, 1978, 3:30 pm: 1 IR 182; filed Feb 29, 1984, 10:10 am: 7 IR 907; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-4-20 Incineration

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 20. No licensee shall incinerate radioactive material for the purpose of disposal or preparation for disposal except as specifically approved by the board pursuant to 410 IAC 5-4-7 and 410 IAC 5-4-17. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.305; filed May 26, 1978, 3:30 pm: 1 IR 182; filed Feb 29, 1984, 10:10 am: 7 IR 907; readopted filed Jul 11, 2001,*

2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-4-20.5 Exceptions to disposal requirements

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 20.5. (a) Any licensee or registrant may dispose of the following radioactive material without regard to its radioactivity:

(1) 0.05 microcurie or less of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting, and

(2) 0.05 microcurie or less of hydrogen-3 or carbon-14 per gram of animal tissue averaged over the weight of the entire animal; provided, however, tissue may not be disposed of under 410 IAC 5-4-20.5 in a manner that would permit its use either as food for humans or as animal feed.

(b) Nothing in 410 IAC 5-4-20.5(a), however, relieves the licensee or registrant of maintaining records showing the receipt, transfer and disposal of such radioactive material as specified in 410 IAC 5-1-4.

(c) Nothing in 410 IAC 5-4-20.5(a) relieves the licensee or registrant from complying with other applicable federal, state, and local rules and regulations governing any other toxic or hazardous property of these materials. *(Indiana State Department of Health; 410 IAC 5-4-20.5; filed Feb 29, 1984, 10:10 am: 7 IR 907; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-4-21 Recordkeeping requirements

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 21. (a) Each licensee or registrant shall maintain records showing the radiation exposures of all individuals for whom personnel monitoring is required under 410 IAC 5-4-10. Such records shall be kept on board form "Z", in accordance with the instructions contained in that form, or on clear and legible records containing all the information required by board form "Z". The doses entered on the forms or records shall be for periods of time not exceeding 1 calendar quarter.

(b) Each licensee or registrant shall maintain records in the same units used in 410 IAC 5-4, showing the results of surveys required by 410 IAC 5-4-9, monitoring required by 410 IAC 5-4-15(b) and (c), and disposals made under 410 IAC 5-4-17, 410 IAC 5-4-18, and 410 IAC 5-4-19.

(c)(1) Records of individual exposure to radiation and to radioactive material which must be maintained pursuant to the provisions of 410 IAC 5-4-21(a) and records of bioassays, including results of whole body counting examinations, made pursuant to 410 IAC 5-4-8 shall be preserved until the board authorizes their disposition.

(2) Records of the results of surveys and monitoring which must be maintained pursuant to 410 IAC 5-4-21(b) shall be preserved for 2 years after the completion of the survey except that the following records shall be maintained until the board authorizes their disposition:

(i) records of the results of surveys to determine compliance with 410 IAC 5-4-4(a);

(ii) in the absence of personnel monitoring data, records of the results of surveys to determine external radiation dose; and

(iii) records of the results of surveys used to evaluate the release of radioactive effluents to the environment.

(3) Records of disposal of licensed material made pursuant to 410 IAC 5-4-17, 410 IAC 5-4-18 or 410 IAC 5-4-19 shall be maintained until the board authorizes their disposition.

(4) Records which must be maintained pursuant to 410 IAC 5-4-21 may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by board rules.

(5) If there is a conflict between the board's rules in 410 IAC 5-4-21, license condition, or other written board approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the rules in 410 IAC 5-4-21 for such records shall apply unless the board, pursuant to 410 IAC 5-1-3(a), has granted a specific exemption from the record retention requirements specified in 410 IAC 5-4-21.

(d) The discontinuance of, or curtailment of, activities does not relieve the licensee or registrant of responsibility for retaining

all records required by 410 IAC 5-4-21. A licensee or registrant may, however, request the board to accept such records. The acceptance of the records by the board relieves the licensee or registrant of subsequent responsibility only in respect to their preservation as required by 410 IAC 5-4-21. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.401; filed May 26, 1978, 3:30 pm: 1 IR 182; filed Feb 29, 1984, 10:10 am: 7 IR 908; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-4-22 Theft or loss of sources; reporting

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 22. Each licensee or registrant shall report by telephone or mailgram to the board the theft or loss of any source of radiation immediately after such occurrence becomes known. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.402; filed May 26, 1978, 3:30 pm: 1 IR 182; filed Feb 29, 1984, 10:10 am: 7 IR 908; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-4-23 Incident reports

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 23. (a) Immediate Notification. Each licensee or registrant shall immediately notify the board by telephone and telegraph of any incident involving any source of radiation possessed by him and which may have caused or threatens to cause:

(1) a dose to the whole body of any individual of 25 rems or more of radiation; a dose to the skin of the whole body of any individual of 150 rems or more of radiation; or a dose to the feet, ankles, hands, or forearms of any individual of 375 rems or more of radiation; or

(2) the release of radioactive material in concentrations which, if averaged over a period of 24 hours, would exceed 5,000 times the limits specified for such materials in Appendix A, 410 IAC 5-4-27, Table II; or

(3) a loss of 1 working week or more of the operation of any facilities affected; or

(4) damage to property in excess of $200,000.

(b) Twenty-four Hour Notification. Each licensee or registrant shall within 24 hours notify the board by telephone or mailgram of any incident involving any source of radiation possessed by him and which may have caused or threatens to cause:

(1) A dose to the whole body of any individual of 5 rems or more of radiation; a dose to the skin of the whole body of any individual of 30 rems or more of radiation; or a dose to the feet, ankles, hands, or forearms of 75 rems or more of radiation; or

(2) The release of radioactive material in concentrations which, if averaged over a period of 24 hours, would exceed 500 times the limits specified for such materials in Appendix A, 410 IAC 5-4-27, Table II; or

(3) A loss of 1 day or more of the operation of any facilities affected; or

(4) Damage to property in excess of $2,000.

(c) Any report filed with the board pursuant to 410 IAC 5-4-23 shall be prepared in such a manner that names of individuals who have received excessive doses will be stated in a separate part of the report. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.403; filed May 26, 1978, 3:30 pm: 1 IR 182; filed Feb 29, 1984, 10:10 am: 7 IR 909; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-4-24 Overexposure reports

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 24. (a) In addition to any notification required by 410 IAC 5-4-23, each licensee or registrant shall make a report in

writing within 30 days to the board of:

(1) each exposure of an individual to radiation in excess of the applicable standards in 410 IAC 5-4-2 or 410 IAC 5-4-5(a) or the license;

(2) each exposure of an individual to radioactive material in excess of the applicable limits in 410 IAC 5-4-4(a)(1), 410 IAC 5-4-4(a)(2), 410 IAC 5-4-5(b) or the license;

(3) levels of radiation or concentrations of radioactive material in a restricted area in excess of any other applicable limit in the license;

(4) any incident for which notification is required by 410 IAC 5-4-23; and

(5) levels of radiation or concentrations of radioactive material, whether or not involving excessive exposure of any individual, in an unrestricted area in excess of 10 times any applicable limit set forth in this part *[410 IAC 5-4]* or in the license.

(b) Each report required under 410 IAC 5-4-24 shall describe the extent of exposure of individuals to radiation or to radioactive material, including estimates of each individual's exposure as required by 410 IAC 5-4-24; levels of radiation and concentrations of radioactive material involved; the cause of the exposure, levels or concentrations; and corrective steps taken or planned to assure against a recurrence.

(c) Any report filed with the board pursuant to 410 IAC 5-4-24 shall include for each individual exposed the name, social security number, and the date of birth, and an estimate of the individual's dose. The report shall be prepared so that this information is stated in a separate part of the report. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.405; filed May 26, 1978, 3:30 pm: 1 IR 183; filed Feb 29, 1984, 10:10 am: 7 IR 909; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-4-25 Vacating premises; decontamination

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 25. Each specific licensee or registrant shall, no less than 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of his activities, notify the board in writing of intent to vacate. When deemed necessary by the board, the licensee or registrant shall decontaminate the premises in such a manner as the board may specify. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.407; filed May 26, 1978, 3:30 pm: 1 IR 183; filed Feb 29, 1984, 10:10 am: 7 IR 910; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-4-26 Notice and report to exposed individuals

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 26. (a) Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in 410 IAC 5-10-4.

(b) When a licensee or registrant is required pursuant to 410 IAC 5-4-24 to report to the board any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the board, and shall comply with the provisions of 410 IAC 5-10-4(a). *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.408; filed May 26, 1978, 3:30 pm: 1 IR 183; filed Feb 29, 1984, 10:10 am: 7 IR 910; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-4-27 Concentrations in air and water above natural background; Appendix A

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 27.

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
Actinium (89)	Ac-227	S	20×10^{-12}	6×10^{-5}	8×10^{-14}	2×10^{-6}
		I	3×10^{-11}	9×10^{-3}	9×10^{-13}	3×10^{-4}
	Ac-228	S	8×10^{-8}	3×10^{-3}	3×10^{-9}	9×10^{-5}
		I	2×10^{-8}	3×10^{-3}	6×10^{-10}	9×10^{-5}
Americium (95)	Am-241	S	6×10^{-12}	1×10^{-4}	2×10^{-13}	4×10^{-6}
		I	1×10^{-10}	8×10^{-4}	4×10^{-12}	3×10^{-5}
	Am-242m	S	6×10^{-12}	1×10^{-4}	2×10^{-13}	4×10^{-6}
		I	3×10^{-10}	3×10^{-3}	9×10^{-12}	9×10^{-5}
	Am-242	S	4×10^{-8}	4×10^{-3}	1×10^{-9}	1×10^{-4}
		I	5×10^{-8}	4×10^{-3}	2×10^{-9}	1×10^{-4}
	Am-243	S	6×10^{-12}	1×10^{-4}	2×10^{-13}	4×10^{-6}
		I	1×10^{-10}	8×10^{-4}	4×10^{-12}	3×10^{-5}
	Am-244	S	4×10^{-6}	1×10^{-1}	1×10^{-7}	5×10^{-3}
		I	2×10^{-5}	1×10^{-1}	8×10^{-7}	5×10^{-3}
Antimony (51)	Sb-122	S	2×10^{-7}	8×10^{-4}	6×10^{-9}	3×10^{-5}
		I	1×10^{-7}	8×10^{-4}	5×10^{-9}	3×10^{-5}
	Sb-124	S	2×10^{-7}	7×10^{-4}	5×10^{-9}	2×10^{-5}
		I	2×10^{-8}	7×10^{-4}	7×10^{-10}	2×10^{-5}
	Sb-125	S	5×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	3×10^{-8}	3×10^{-3}	9×10^{-10}	1×10^{-4}
Argon (18)	Ar-37	Sub[2/]	6×10^{-3}	_____	1×10^{-4}	_____
	Ar-41	Sub	2×10^{-6}	_____	4×10^{-8}	_____
Arsenic (33)	As-73	S	2×10^{-6}	1×10^{-2}	7×10^{-8}	5×10^{-4}
		I	4×10^{-7}	1×10^{-2}	1×10^{-8}	5×10^{-4}
	As-74	S	3×10^{-7}	2×10^{-3}	1×10^{-10}	5×10^{-5}
		I	1×10^{-7}	2×10^{-3}	4×10^{-9}	5×10^{-5}
	As-76	S	1×10^{-7}	6×10^{-4}	4×10^{-9}	2×10^{-5}
		I	1×10^{-7}	6×10^{-4}	3×10^{-9}	2×10^{-5}
	As-77	S	5×10^{-7}	2×10^{-3}	2×10^{-8}	8×10^{-5}
		I	4×10^{-7}	2×10^{-3}	1×10^{-8}	8×10^{-5}
Astatine (85)	At-211	S	7×10^{-9}	5×10^{-5}	2×10^{-10}	2×10^{-6}
		I	3×10^{-8}	2×10^{-3}	1×10^{-9}	7×10^{-5}
Barium (56)	Ba-131	S	1×10^{-6}	5×10^{-3}	4×10^{-8}	2×10^{-4}
		I	4×10^{-7}	5×10^{-3}	1×10^{-8}	2×10^{-4}
	Ba-140	S	1×10^{-7}	8×10^{-4}	4×10^{-9}	3×10^{-5}

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
		I	4×10^{-8}	7×10^{-4}	1×10^{-9}	2×10^{-5}
Berkelium (97)	Bk-249	S	9×10^{-10}	2×10^{-2}	3×10^{-11}	6×10^{-4}
		I	1×10^{-7}	2×10^{-2}	4×10^{-9}	6×10^{-4}
	Bk-250	S	1×10^{-7}	6×10^{-3}	5×10^{-9}	2×10^{-4}
		I	1×10^{-6}	6×10^{-3}	4×10^{-8}	2×10^{-4}
Beryllium (4)	Be-7	S	6×10^{-6}	5×10^{-2}	2×10^{-7}	2×10^{-3}
		I	1×10^{-6}	5×10^{-2}	4×10^{-8}	2×10^{-3}
Bismuth (83)	Bi-206	S	2×10^{-7}	1×10^{-3}	6×10^{-9}	4×10^{-5}
		I	1×10^{-7}	1×10^{-3}	5×10^{-9}	4×10^{-5}
	Bi-207	S	2×10^{-7}	2×10^{-3}	6×10^{-9}	6×10^{-5}
		I	1×10^{-8}	2×10^{-3}	5×10^{-10}	6×10^{-5}
	Bi-210	S	6×10^{-9}	1×10^{-3}	2×10^{-10}	4×10^{-5}
		I	6×10^{-9}	1×10^{-3}	2×10^{-10}	4×10^{-5}
	Bi-212	S	1×10^{-7}	1×10^{-2}	3×10^{-9}	4×10^{-4}
		I	2×10^{-7}	1×10^{-2}	7×10^{-9}	4×10^{-4}
Bromine (35)	Br-82	S	1×10^{-6}	8×10^{-3}	4×10^{-8}	3×10^{-4}
		I	2×10^{-7}	1×10^{-3}	6×10^{-9}	4×10^{-5}
Cadmium (48)	Cd-109	S	5×10^{-8}	5×10^{-3}	2×10^{-9}	2×10^{-4}
		I	7×10^{-8}	5×10^{-3}	3×10^{-9}	2×10^{-4}
	Cd-115m	S	4×10^{-8}	7×10^{-4}	1×10^{-9}	3×10^{-5}
		I	4×10^{-8}	7×10^{-4}	1×10^{-9}	3×10^{-5}
	Cd-115	S	2×10^{-7}	1×10^{-3}	8×10^{-9}	3×10^{-5}
		I	2×10^{-7}	1×10^{-3}	6×10^{-9}	4×10^{-5}
Calcium (20)	Ca-45	S	3×10^{-8}	3×10^{-4}	1×10^{-9}	9×10^{-6}
		I	1×10^{-7}	5×10^{-3}	4×10^{-9}	2×10^{-4}
	Ca-47	S	2×10^{-7}	1×10^{-3}	6×10^{-9}	5×10^{-5}
		I	2×10^{-7}	1×10^{-3}	6×10^{-9}	3×10^{-5}
Californium (98)	Cf-249	S	2×10^{-12}	1×10^{-4}	5×10^{-14}	4×10^{-6}
		I	1×10^{-10}	7×10^{-4}	3×10^{-12}	2×10^{-5}
	Cf-250	S	5×10^{-12}	4×10^{-4}	2×10^{-13}	1×10^{-5}
		I	1×10^{-10}	7×10^{-4}	3×10^{-12}	3×10^{-5}
	Cf-251	S	2×10^{-12}	1×10^{-4}	6×10^{-14}	4×10^{-6}
		I	1×10^{-10}	8×10^{-4}	3×10^{-12}	3×10^{-5}
	Cf-252	S	6×10^{-12}	2×10^{-4}	2×10^{-13}	7×10^{-6}
		I	3×10^{-11}	2×10^{-4}	1×10^{-12}	7×10^{-6}
	Cf-253	S	8×10^{-10}	4×10^{-3}	3×10^{-11}	1×10^{-4}

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
		I	8×10^{-10}	4×10^{-3}	3×10^{-11}	1×10^{-4}
	Cf-254	S	5×10^{-12}	4×10^{-6}	2×10^{-13}	1×10^{-7}
		I	5×10^{-12}	4×10^{-6}	2×10^{-13}	1×10^{-7}
Carbon (6)	C-14	S	4×10^{-6}	2×10^{-2}	1×10^{-7}	8×10^{-4}
	(Co_2)	Sub[2/]	5×10^{-5}	_____	1×10^{-6}	_____
Cerium (58)	Ce-141	S	4×10^{-7}	3×10^{-3}	2×10^{-8}	9×10^{-5}
		I	2×10^{-7}	3×10^{-3}	5×10^{-9}	9×10^{-5}
	Ce-143	S	3×10^{-7}	1×10^{-3}	9×10^{-9}	4×10^{-5}
		I	2×10^{-7}	1×10^{-3}	7×10^{-9}	4×10^{-5}
	Ce-144	S	1×10^{-8}	3×10^{-4}	3×10^{-10}	1×10^{-5}
		I	6×10^{-9}	3×10^{-4}	2×10^{-10}	1×10^{-5}
Cesium (55)	Cs-131	S	1×10^{-5}	7×10^{-2}	4×10^{-7}	2×10^{-3}
		I	3×10^{-6}	3×10^{-2}	1×10^{-7}	9×10^{-4}
	Cs-134m	S	4×10^{-5}	2×10^{-1}	1×10^{-6}	6×10^{-3}
		I	6×10^{-6}	3×10^{-2}	2×10^{-7}	1×10^{-3}
	Cs-134	S	4×10^{-8}	3×10^{-4}	1×10^{-9}	9×10^{-6}
		I	1×10^{-8}	1×10^{-3}	4×10^{-10}	4×10^{-5}
	Cs-135	S	5×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	9×10^{-8}	7×10^{-3}	3×10^{-9}	2×10^{-4}
	Cs-136	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	9×10^{-5}
		I	2×10^{-7}	2×10^{-3}	6×10^{-9}	6×10^{-5}
	Cs-137	S	6×10^{-8}	4×10^{-4}	2×10^{-9}	2×10^{-5}
		I	1×10^{-8}	1×10^{-3}	5×10^{-10}	4×10^{-5}
Chlorine (17)	Cl-36	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	8×10^{-5}
		I	2×10^{-8}	2×10^{-3}	8×10^{-10}	6×10^{-5}
	Cl-38	S	3×10^{-6}	1×10^{-2}	9×10^{-8}	4×10^{-4}
		I	2×10^{-6}	1×10^{-2}	7×10^{-8}	4×10^{-4}
Chromium (24)	Cr-51	S	1×10^{-5}	5×10^{-2}	4×10^{-7}	2×10^{-3}
		I	2×10^{-6}	5×10^{-2}	8×10^{-8}	2×10^{-3}
Cobalt (27)	Co-57	S	3×10^{-6}	2×10^{-2}	1×10^{-7}	5×10^{-4}
		I	2×10^{-7}	1×10^{-2}	6×10^{-9}	4×10^{-4}
	Co-58m	S	2×10^{-5}	8×10^{-2}	6×10^{-7}	3×10^{-3}
		I	9×10^{-6}	6×10^{-2}	3×10^{-7}	2×10^{-3}
	Co-58	S	8×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	5×10^{-8}	3×10^{-3}	2×10^{-9}	9×10^{-5}
	Co-60	S	3×10^{-7}	1×10^{-3}	1×10^{-8}	5×10^{-5}

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
		I	9×10^{-9}	1×10^{-3}	3×10^{-10}	3×10^{-5}
Copper (29)	Cu-64	S	2×10^{-6}	1×10^{-2}	7×10^{-8}	3×10^{-4}
		I	1×10^{-6}	6×10^{-3}	4×10^{-8}	2×10^{-4}
Curium (96)	Cm-242	S	1×10^{-10}	7×10^{-4}	4×10^{-12}	2×10^{-5}
		I	2×10^{-10}	7×10^{-4}	6×10^{-12}	2×10^{-5}
	Cm-243	S	6×10^{-12}	1×10^{-4}	2×10^{-13}	5×10^{-6}
		I	1×10^{-10}	7×10^{-4}	3×10^{-12}	2×10^{-5}
	Cm-244	S	9×10^{-12}	2×10^{-4}	3×10^{-13}	7×10^{-6}
		I	1×10^{-10}	8×10^{-4}	3×10^{-12}	3×10^{-5}
	Cm-245	S	5×10^{-12}	1×10^{-4}	2×10^{-13}	4×10^{-6}
		I	1×10^{-10}	8×10^{-4}	4×10^{-12}	3×10^{-5}
	Cm-246	S	5×10^{-12}	1×10^{-4}	2×10^{-13}	4×10^{-6}
		I	1×10^{-10}	8×10^{-4}	4×10^{-12}	3×10^{-5}
	Cm-247	S	5×10^{-12}	1×10^{-4}	2×10^{-13}	4×10^{-6}
		I	1×10^{-10}	6×10^{-4}	4×10^{-12}	2×10^{-5}
	Cm-248	S	6×10^{-13}	1×10^{-5}	2×10^{-14}	4×10^{-7}
		I	1×10^{-11}	4×10^{-5}	4×10^{-13}	1×10^{-6}
	Cm-249	S	1×10^{-5}	6×10^{-2}	4×10^{-7}	2×10^{-3}
		I	1×10^{-5}	6×10^{-2}	4×10^{-7}	2×10^{-3}
Dysprosium (66)	Dy-165	S	3×10^{-6}	1×10^{-2}	9×10^{-8}	4×10^{-4}
		I	2×10^{-6}	1×10^{-2}	7×10^{-8}	4×10^{-4}
	Dy-166	S	2×10^{-7}	1×10^{-3}	8×10^{-9}	4×10^{-5}
		I	2×10^{-7}	1×10^{-3}	7×10^{-9}	4×10^{-5}
Einsteinium (99)	Es-253	S	8×10^{-10}	7×10^{-4}	3×10^{-11}	2×10^{-5}
		I	6×10^{-10}	7×10^{-4}	2×10^{-11}	2×10^{-5}
	Es-254m	S	5×10^{-9}	5×10^{-4}	2×10^{-10}	2×10^{-5}
		I	6×10^{-9}	5×10^{-4}	2×10^{-10}	2×10^{-5}
	Es-254	S	2×10^{-11}	4×10^{-4}	6×10^{-13}	1×10^{-5}
		I	1×10^{-10}	4×10^{-4}	4×10^{-12}	1×10^{-5}
	Es-255	S	5×10^{-10}	8×10^{-4}	2×10^{-11}	3×10^{-5}
		I	4×10^{-10}	8×10^{-4}	1×10^{-11}	3×10^{-5}
Erbium (68)	Er-169	S	6×10^{-7}	3×10^{-3}	2×10^{-8}	9×10^{-5}
		I	4×10^{-7}	3×10^{-3}	1×10^{-8}	9×10^{-5}
	Er-171	S	7×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	6×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
Europium (63)	Eu-152	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
	(T_r=9.2 hrs)	I	3×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
	Eu-152	S	1×10^{-8}	2×10^{-3}	4×10^{-10}	8×10^{-5}
	(T_r=13 yrs)	I	2×10^{-8}	2×10^{-3}	6×10^{-10}	8×10^{-5}
	Eu-154	S	4×10^{-9}	6×10^{-4}	1×10^{-10}	2×10^{-5}
		I	7×10^{-9}	6×10^{-4}	2×10^{-10}	2×10^{-5}
	Eu-155	S	9×10^{-8}	6×10^{-3}	3×10^{-9}	2×10^{-4}
		I	7×10^{-8}	6×10^{-3}	3×10^{-9}	2×10^{-4}
Fermium (100)	Fm-254	S	6×10^{-8}	4×10^{-3}	2×10^{-9}	1×10^{-4}
		I	7×10^{-8}	4×10^{-3}	2×10^{-9}	1×10^{-4}
	Fm-255	S	2×10^{-8}	1×10^{-3}	6×10^{-10}	3×10^{-5}
		I	1×10^{-8}	1×10^{-3}	4×10^{-10}	3×10^{-5}
	Fm-256	S	3×10^{-9}	3×10^{-5}	1×10^{-10}	9×10^{-7}
		I	2×10^{-9}	3×10^{-5}	6×10^{-11}	9×10^{-7}
Fluorine (9)	F-18	S	5×10^{-6}	2×10^{-2}	2×10^{-7}	8×10^{-4}
		I	3×10^{-6}	1×10^{-2}	9×10^{-8}	5×10^{-4}
Gadolinium (64)	Gd-153	S	2×10^{-7}	6×10^{-3}	8×10^{-9}	2×10^{-4}
		I	9×10^{-8}	6×10^{-3}	3×10^{-9}	2×10^{-4}
	Gd-159	S	5×10^{-7}	2×10^{-3}	2×10^{-8}	8×10^{-5}
		I	4×10^{-7}	2×10^{-3}	1×10^{-8}	8×10^{-5}
Gallium (31)	Ga-72	S	2×10^{-7}	1×10^{-3}	8×10^{-9}	4×10^{-5}
		I	2×10^{-7}	1×10^{-3}	6×10^{-9}	4×10^{-5}
Germanium (32)	Ge-68	S	7×10^{-7}	3×10^{-3}	2×10^{-7}	9×10^{-4}
		I	2×10^{-8}	3×10^{-3}	5×10^{-9}	9×10^{-4}
	Ge-71	S	1×10^{-5}	5×10^{-2}	4×10^{-7}	2×10^{-3}
		I	6×10^{-6}	5×10^{-2}	2×10^{-7}	2×10^{-3}
Gold (79)	Au-195	S	2×10^{-7}	7×10^{-4}	7×10^{-8}	2×10^{-4}
		I	6×10^{-8}	7×10^{-4}	2×10^{-8}	2×10^{-4}
	Au-196	S	1×10^{-6}	5×10^{-3}	4×10^{-8}	2×10^{-4}
		I	6×10^{-7}	4×10^{-3}	2×10^{-8}	1×10^{-4}
	Au-198	S	3×10^{-7}	2×10^{-3}	1×10^{-8}	5×10^{-5}
		I	2×10^{-7}	1×10^{-3}	8×10^{-9}	5×10^{-5}
	Au-199	S	1×10^{-6}	5×10^{-3}	4×10^{-8}	2×10^{-4}
		I	8×10^{-7}	4×10^{-3}	3×10^{-8}	2×10^{-4}
Hafnium (72)	Hf-181	S	4×10^{-8}	2×10^{-3}	1×10^{-9}	7×10^{-5}
		I	7×10^{-8}	2×10^{-3}	3×10^{-9}	7×10^{-5}
Holmium (67)	Ho-166	S	2×10^{-7}	9×10^{-4}	7×10^{-9}	3×10^{-5}

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
		I	2×10^{-7}	9×10^{-4}	6×10^{-9}	3×10^{-5}
Hydrogen (1)	H-3	S	5×10^{-6}	1×10^{-1}	2×10^{-7}	3×10^{-3}
		I	5×10^{-6}	1×10^{-1}	2×10^{-7}	3×10^{-3}
		Sub[2/]	2×10^{-3}	_____	4×10^{-5}	_____
Indium (49)	In-113m	S	8×10^{-6}	4×10^{-2}	3×10^{-7}	1×10^{-3}
		I	7×10^{-6}	4×10^{-2}	2×10^{-7}	1×10^{-3}
	In-114m	S	1×10^{-7}	5×10^{-4}	4×10^{-9}	2×10^{-5}
		I	2×10^{-8}	5×10^{-4}	7×10^{-10}	2×10^{-5}
	In-115m	S	2×10^{-6}	1×10^{-2}	8×10^{-8}	4×10^{-4}
		I	2×10^{-6}	1×10^{-2}	6×10^{-8}	4×10^{-4}
	In-115	S	2×10^{-7}	3×10^{-3}	9×10^{-9}	9×10^{-5}
		I	3×10^{-8}	3×10^{-3}	1×10^{-9}	9×10^{-5}
Iodine (53)	I-125	S	5×10^{-9}	4×10^{-5}	8×10^{-11}	2×10^{-7}
		I	2×10^{-7}	6×10^{-3}	6×10^{-9}	2×10^{-4}
	I-126	S	8×10^{-9}	5×10^{-5}	9×10^{-11}	3×10^{-7}
		I	3×10^{-7}	3×10^{-3}	1×10^{-8}	9×10^{-5}
	I-129	S	2×10^{-9}	1×10^{-5}	2×10^{-11}	6×10^{-8}
		I	7×10^{-8}	6×10^{-3}	2×10^{-9}	2×10^{-4}
	I-131	S	9×10^{-9}	6×10^{-5}	1×10^{-10}	3×10^{-7}
		I	3×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
	I-132	S	2×10^{-7}	2×10^{-3}	3×10^{-9}	8×10^{-6}
		I	9×10^{-7}	5×10^{-3}	3×10^{-8}	2×10^{-4}
	I-133	S	3×10^{-8}	2×10^{-4}	4×10^{-10}	1×10^{-6}
		I	2×10^{-7}	1×10^{-3}	7×10^{-9}	4×10^{-5}
	I-134	S	5×10^{-7}	4×10^{-3}	6×10^{-9}	2×10^{-5}
		I	3×10^{-6}	2×10^{-2}	1×10^{-7}	6×10^{-4}
	I-135	S	1×10^{-7}	7×10^{-4}	1×10^{-9}	4×10^{-6}
		I	4×10^{-7}	2×10^{-3}	1×10^{-8}	7×10^{-5}
Iridium (77)	Ir-190	S	1×10^{-6}	6×10^{-3}	4×10^{-8}	2×10^{-4}
		I	4×10^{-7}	5×10^{-3}	1×10^{-8}	2×10^{-4}
	Ir-192	S	1×10^{-7}	1×10^{-3}	4×10^{-9}	4×10^{-5}
		I	3×10^{-8}	1×10^{-3}	9×10^{-10}	4×10^{-5}
	Ir-194	S	2×10^{-7}	1×10^{-3}	8×10^{-9}	3×10^{-5}
		I	2×10^{-7}	9×10^{-4}	5×10^{-9}	3×10^{-5}
Iron (26)	Fe-55	S	9×10^{-7}	2×10^{-2}	3×10^{-8}	8×10^{-4}
		I	1×10^{-6}	7×10^{-2}	3×10^{-8}	2×10^{-3}

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CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
	Fe-59	S	1×10^{-7}	2×10^{-3}	5×10^{-9}	6×10^{-5}
		I	5×10^{-8}	2×10^{-3}	2×10^{-9}	5×10^{-5}
Krypton (36)	Kr-85m	Sub[2/]	6×10^{-6}	_____	1×10^{-7}	_____
	Kr-85	Sub	1×10^{-5}	_____	3×10^{-7}	_____
	Kr-87	Sub	1×10^{-6}	_____	2×10^{-8}	_____
	Kr-88	Sub	1×10^{-6}	_____	2×10^{-8}	_____
Lanthanum (57)	La-140	S	2×10^{-7}	7×10^{-4}	5×10^{-9}	2×10^{-5}
		I	1×10^{-7}	7×10^{-4}	4×10^{-9}	2×10^{-5}
Lead (82)	Pb-203	S	3×10^{-6}	1×10^{-2}	9×10^{-8}	4×10^{-4}
		I	2×10^{-6}	1×10^{-2}	6×10^{-8}	4×10^{-4}
	Pb-210	S	1×10^{-10}	4×10^{-6}	4×10^{-12}	1×10^{-7}
		I	2×10^{-10}	5×10^{-3}	8×10^{-12}	2×10^{-4}
	Pb-212	S	2×10^{-8}	6×10^{-4}	6×10^{-10}	2×10^{-5}
		I	2×10^{-8}	5×10^{-4}	7×10^{-10}	2×10^{-5}
Lutetium (71)	Lu-177	S	6×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	5×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
Manganese (25)	Mn-52	S	2×10^{-7}	1×10^{-3}	7×10^{-9}	3×10^{-5}
		I	1×10^{-7}	9×10^{-4}	5×10^{-9}	3×10^{-5}
	Mn-54	S	4×10^{-7}	4×10^{-3}	1×10^{-8}	1×10^{-4}
		I	4×10^{-8}	3×10^{-3}	1×10^{-9}	1×10^{-4}
	Mn-56	S	8×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	5×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
Mercury (80)	Hg-197m	S	7×10^{-7}	6×10^{-3}	3×10^{-8}	2×10^{-4}
		I	8×10^{-7}	5×10^{-3}	3×10^{-8}	2×10^{-4}
	Hg-197	S	1×10^{-6}	9×10^{-3}	4×10^{-8}	3×10^{-4}
		I	3×10^{-6}	1×10^{-2}	9×10^{-8}	5×10^{-4}
	Hg-203	S	7×10^{-8}	5×10^{-4}	2×10^{-9}	2×10^{-5}
		I	1×10^{-7}	3×10^{-3}	4×10^{-9}	1×10^{-4}
Molybdenum (42)	Mo-99	S	7×10^{-7}	5×10^{-3}	3×10^{-8}	2×10^{-4}
		I	2×10^{-7}	1×10^{-3}	7×10^{-9}	4×10^{-5}
Neodymium (60)	Nd-144	S	8×10^{-11}	2×10^{-3}	3×10^{-12}	7×10^{-5}
		I	3×10^{-10}	2×10^{-3}	1×10^{-11}	8×10^{-5}
	Nd-147	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
		I	2×10^{-7}	2×10^{-3}	8×10^{-9}	6×10^{-5}
	Nd-149	S	2×10^{-6}	8×10^{-3}	6×10^{-8}	3×10^{-4}
		I	1×10^{-6}	8×10^{-3}	5×10^{-8}	3×10^{-4}

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CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
Neptunium (93)	Np-237	S	4×10^{-12}	9×10^{-5}	1×10^{-13}	3×10^{-6}
		I	1×10^{-10}	9×10^{-4}	4×10^{-12}	3×10^{-5}
	Np-239	S	8×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	7×10^{-7}	4×10^{-3}	2×10^{-8}	1×10^{-4}
Nickel (28)	Ni-59	S	5×10^{-7}	6×10^{-3}	2×10^{-8}	2×10^{-4}
		I	8×10^{-7}	6×10^{-2}	3×10^{-8}	2×10^{-3}
	Ni-63	S	6×10^{-8}	8×10^{-4}	2×10^{-9}	3×10^{-5}
		I	3×10^{-7}	2×10^{-2}	1×10^{-8}	7×10^{-4}
	Ni-65	S	9×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	5×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
Niobium (41)	Nb-93m	S	1×10^{-7}	1×10^{-2}	4×10^{-9}	4×10^{-4}
		I	2×10^{-7}	1×10^{-2}	5×10^{-9}	4×10^{-4}
	Nb-95	S	5×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	1×10^{-7}	3×10^{-3}	3×10^{-9}	1×10^{-4}
	Nb-97	S	6×10^{-6}	3×10^{-2}	2×10^{-7}	9×10^{-4}
		I	5×10^{-6}	3×10^{-2}	2×10^{-7}	9×10^{-4}
Osmium (76)	Os-185	S	5×10^{-7}	2×10^{-3}	2×10^{-8}	7×10^{-5}
		I	5×10^{-8}	2×10^{-3}	2×10^{-9}	7×10^{-5}
	Os-191m	S	2×10^{-5}	7×10^{-2}	6×10^{-7}	3×10^{-3}
		I	9×10^{-6}	7×10^{-2}	3×10^{-7}	2×10^{-3}
	Os-191	S	1×10^{-6}	5×10^{-3}	4×10^{-8}	2×10^{-4}
		I	4×10^{-7}	5×10^{-3}	1×10^{-8}	2×10^{-4}
	Os-193	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
		I	3×10^{-7}	2×10^{-3}	9×10^{-9}	5×10^{-5}
Palladium (46)	Pd-103	S	1×10^{-6}	1×10^{-2}	5×10^{-8}	3×10^{-4}
		I	7×10^{-7}	8×10^{-3}	3×10^{-8}	3×10^{-4}
	Pd-109	S	6×10^{-7}	3×10^{-3}	2×10^{-8}	9×10^{-5}
		I	4×10^{-7}	2×10^{-3}	1×10^{-8}	7×10^{-5}
Phosphorus (15)	P-32	S	7×10^{-8}	5×10^{-4}	2×10^{-9}	2×10^{-5}
		I	8×10^{-8}	7×10^{-4}	3×10^{-9}	2×10^{-5}
Platinum (78)	Pt-191	S	8×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	6×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
	Pt-193m	S	7×10^{-6}	3×10^{-2}	2×10^{-7}	1×10^{-3}
		I	5×10^{-6}	3×10^{-2}	2×10^{-7}	1×10^{-3}
	Pt-193	S	1×10^{-6}	3×10^{-2}	4×10^{-8}	9×10^{-4}
		I	3×10^{-7}	5×10^{-2}	1×10^{-8}	2×10^{-3}

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CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
	Pt-197m	S	6×10^{-6}	3×10^{-2}	2×10^{-7}	1×10^{-3}
		I	5×10^{-6}	3×10^{-2}	2×10^{-7}	9×10^{-4}
	Pt-197	S	8×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	6×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
Plutonium (94)	Pu-238	S	2×10^{-12}	1×10^{-4}	7×10^{-14}	5×10^{-6}
		I	3×10^{-11}	8×10^{-4}	1×10^{-12}	3×10^{-5}
	Pu-239	S	2×10^{-12}	1×10^{-4}	6×10^{-14}	5×10^{-6}
		I	4×10^{-11}	8×10^{-4}	1×10^{-12}	3×10^{-5}
	Pu-240	S	2×10^{-12}	1×10^{-4}	6×10^{-14}	5×10^{-6}
		I	4×10^{-11}	8×10^{-4}	1×10^{-12}	3×10^{-5}
	Pu-241	S	9×10^{-11}	7×10^{-3}	3×10^{-12}	2×10^{-4}
		I	4×10^{-8}	4×10^{-2}	1×10^{-9}	1×10^{-3}
	Pu-242	S	2×10^{-12}	1×10^{-4}	6×10^{-14}	5×10^{-6}
		I	4×10^{-11}	9×10^{-4}	1×10^{-12}	3×10^{-5}
	Pu-243	S	2×10^{-6}	1×10^{-2}	6×10^{-8}	3×10^{-4}
		I	2×10^{-6}	1×10^{-2}	8×10^{-8}	3×10^{-4}
	Pu-244	S	2×10^{-12}	1×10^{-4}	6×10^{-14}	4×10^{-6}
		I	3×10^{-11}	3×10^{-4}	1×10^{-12}	1×10^{-5}
Polonium (84)	Po-210	S	5×10^{-10}	2×10^{-5}	2×10^{-11}	7×10^{-7}
		I	2×10^{-10}	8×10^{-4}	7×10^{-12}	3×10^{-5}
Potassium (19)	K-42	S	2×10^{-6}	9×10^{-3}	7×10^{-8}	3×10^{-4}
		I	1×10^{-7}	6×10^{-4}	4×10^{-9}	2×10^{-5}
Praseodymium (59)	Pr-142	S	2×10^{-7}	9×10^{-4}	7×10^{-9}	3×10^{-5}
		I	2×10^{-7}	9×10^{-4}	5×10^{-9}	3×10^{-5}
	Pr-143	S	3×10^{-7}	1×10^{-3}	1×10^{-8}	5×10^{-5}
		I	2×10^{-7}	1×10^{-3}	6×10^{-9}	5×10^{-5}
Promethium (61)	Pm-147	S	6×10^{-8}	6×10^{-3}	2×10^{-9}	2×10^{-4}
		I	1×10^{-7}	6×10^{-3}	3×10^{-9}	2×10^{-4}
	Pm-149	S	3×10^{-7}	1×10^{-3}	1×10^{-8}	4×10^{-5}
		I	2×10^{-7}	1×10^{-3}	8×10^{-9}	4×10^{-5}
Protactinium (91)	Pa-230	S	2×10^{-9}	7×10^{-3}	6×10^{-11}	2×10^{-4}
		I	8×10^{-10}	7×10^{-3}	3×10^{-11}	2×10^{-4}
	Pa-231	S	1×10^{-12}	3×10^{-5}	4×10^{-14}	9×10^{-7}
		I	1×10^{-10}	8×10^{-4}	4×10^{-12}	2×10^{-5}
	Pa-233	S	6×10^{-7}	4×10^{-3}	2×10^{-8}	1×10^{-4}
		I	2×10^{-7}	3×10^{-3}	6×10^{-9}	1×10^{-4}

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CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
Radium (88)	Ra-223	S	2×10^{-9}	2×10^{-5}	6×10^{-11}	7×10^{-7}
		I	2×10^{-10}	1×10^{-4}	8×10^{-12}	4×10^{-6}
	Ra-224	S	5×10^{-9}	7×10^{-5}	2×10^{-10}	2×10^{-6}
		I	7×10^{-10}	2×10^{-4}	2×10^{-11}	5×10^{-6}
	Ra-226	S	3×10^{-11}	4×10^{-7}	3×10^{-12}	3×10^{-8}
		I	5×10^{-11}	9×10^{-4}	2×10^{-12}	3×10^{-5}
	Ra-228	S	7×10^{-11}	8×10^{-7}	2×10^{-12}	3×10^{-8}
		I	4×10^{-11}	7×10^{-4}	1×10^{-12}	3×10^{-5}
Radon (86)	Rn-220	S	3×10^{-7}	_____	1×10^{-8}	_____
		I	_____	_____	_____	_____
	Rn-222[3/]	S	3×10^{-8}	_____	3×10^{-9}	_____
Rhenium (75)	Re-183	S	3×10^{-6}	2×10^{-2}	9×10^{-8}	6×10^{-4}
		I	2×10^{-7}	8×10^{-3}	5×10^{-9}	3×10^{-4}
	Re-186	S	6×10^{-7}	3×10^{-3}	2×10^{-8}	9×10^{-5}
		I	2×10^{-7}	1×10^{-3}	8×10^{-9}	5×10^{-5}
	Re-187	S	9×10^{-6}	7×10^{-2}	3×10^{-7}	3×10^{-3}
		I	5×10^{-7}	4×10^{-2}	2×10^{-8}	2×10^{-3}
	Re-188	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
		I	2×10^{-7}	9×10^{-4}	6×10^{-9}	3×10^{-5}
Rhodium (45)	Rh-103m	S	8×10^{-5}	4×10^{-1}	3×10^{-6}	1×10^{-2}
		I	6×10^{-5}	3×10^{-1}	2×10^{-6}	1×10^{-2}
	Rh-105	S	8×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	5×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
Rubidium (37)	Rb-86	S	3×10^{-7}	2×10^{-3}	1×10^{-8}	7×10^{-5}
		I	7×10^{-8}	7×10^{-4}	2×10^{-9}	2×10^{-5}
	Rb-87	S	5×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	7×10^{-8}	5×10^{-3}	2×10^{-9}	2×10^{-4}
Ruthenium (44)	Ru-97	S	2×10^{-6}	1×10^{-2}	8×10^{-8}	4×10^{-4}
		I	2×10^{-6}	1×10^{-2}	6×10^{-8}	3×10^{-4}
	Ru-103	S	5×10^{-7}	2×10^{-3}	2×10^{-8}	8×10^{-5}
		I	8×10^{-8}	2×10^{-3}	3×10^{-9}	8×10^{-5}
	Ru-105	S	7×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	5×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
	Ru-106	S	8×10^{-8}	4×10^{-4}	3×10^{-9}	1×10^{-5}
		I	6×10^{-9}	3×10^{-4}	2×10^{-10}	1×10^{-5}
Samarium (62)	Sm-147	S	7×10^{-11}	2×10^{-3}	2×10^{-12}	6×10^{-5}

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CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
		I	3×10^{-10}	2×10^{-3}	9×10^{-12}	7×10^{-5}
	Sm-151	S	6×10^{-8}	1×10^{-2}	2×10^{-9}	4×10^{-4}
		I	1×10^{-7}	1×10^{-2}	5×10^{-9}	4×10^{-4}
	Sm-153	S	5×10^{-7}	2×10^{-3}	2×10^{-8}	8×10^{-5}
		I	4×10^{-7}	2×10^{-3}	1×10^{-8}	8×10^{-5}
Scandium (21)	Sc-46	S	2×10^{-7}	1×10^{-3}	8×10^{-9}	4×10^{-5}
		I	2×10^{-8}	1×10^{-3}	8×10^{-10}	4×10^{-5}
	Sc-57	S	6×10^{-7}	3×10^{-3}	2×10^{-8}	9×10^{-5}
		I	5×10^{-7}	3×10^{-3}	2×10^{-8}	9×10^{-5}
	Sc-48	S	2×10^{-7}	8×10^{-4}	6×10^{-9}	3×10^{-5}
		I	1×10^{-7}	8×10^{-4}	5×10^{-9}	3×10^{-5}
Selenium (34)	Se-75	S	1×10^{-6}	9×10^{-3}	4×10^{-8}	3×10^{-4}
		I	1×10^{-7}	3×10^{-3}	4×10^{-9}	3×10^{-4}
Silicon (14)	Si-31	S	6×10^{-6}	3×10^{-2}	2×10^{-7}	9×10^{-4}
		I	1×10^{-6}	6×10^{-3}	3×10^{-8}	2×10^{-4}
Silver (47)	Ag-105	S	6×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	8×10^{-8}	3×10^{-3}	3×10^{-9}	1×10^{-4}
	Ag-110m	S	2×10^{-7}	9×10^{-4}	7×10^{-9}	3×10^{-5}
		I	1×10^{-8}	9×10^{-4}	3×10^{-10}	3×10^{-5}
	Ag-111	S	3×10^{-7}	1×10^{-3}	1×10^{-8}	4×10^{-5}
		I	2×10^{-7}	1×10^{-3}	8×10^{-9}	4×10^{-5}
Sodium (11)	Na-22	S	2×10^{-7}	1×10^{-3}	6×10^{-9}	4×10^{-5}
		I	9×10^{-9}	9×10^{-4}	3×10^{-10}	3×10^{-5}
	Na-24	S	1×10^{-6}	6×10^{-3}	4×10^{-8}	2×10^{-4}
		I	1×10^{-7}	8×10^{-4}	5×10^{-9}	3×10^{-5}
Strontium (38)	Sr-85m	S	4×10^{-5}	2×10^{-1}	1×10^{-6}	7×10^{-3}
		I	3×10^{-5}	2×10^{-1}	1×10^{-6}	7×10^{-3}
	Sr-85	S	2×10^{-7}	3×10^{-3}	8×10^{-9}	1×10^{-4}
		I	1×10^{-7}	5×10^{-3}	4×10^{-9}	2×10^{-4}
	Sr-89	S	3×10^{-8}	3×10^{-4}	3×10^{-10}	3×10^{-6}
		I	4×10^{-8}	8×10^{-4}	1×10^{-9}	3×10^{-5}
	Sr-90	S	1×10^{-9}	1×10^{-5}	3×10^{-11}	3×10^{-7}
		I	5×10^{-9}	1×10^{-3}	2×10^{-10}	4×10^{-5}
	Sr-91	S	4×10^{-7}	2×10^{-3}	2×10^{-8}	7×10^{-5}
		I	3×10^{-7}	1×10^{-3}	9×10^{-9}	5×10^{-5}
	Sr-92	S	4×10^{-7}	2×10^{-3}	2×10^{-8}	7×10^{-5}

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Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
		I	3×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
Sulfur (16)	S-35	S	3×10^{-7}	2×10^{-3}	9×10^{-9}	6×10^{-5}
		I	3×10^{-7}	8×10^{-3}	9×10^{-9}	3×10^{-4}
Tantalum (73)	Ta-182	S	4×10^{-8}	1×10^{-3}	1×10^{-9}	4×10^{-5}
		I	2×10^{-8}	1×10^{-3}	7×10^{-10}	4×10^{-5}
Technetium (43)	Tc-96m	S	8×10^{-5}	4×10^{-1}	3×10^{-6}	1×10^{-2}
		I	3×10^{-5}	3×10^{-1}	1×10^{-6}	1×10^{-2}
	Tc-96	S	6×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	2×10^{-7}	1×10^{-3}	8×10^{-9}	5×10^{-5}
	Tc-97m	S	2×10^{-6}	1×10^{-2}	8×10^{-8}	4×10^{-4}
		I	2×10^{-7}	5×10^{-3}	5×10^{-9}	2×10^{-4}
	Tc-97	S	1×10^{-5}	5×10^{-2}	4×10^{-7}	2×10^{-3}
		I	3×10^{-7}	2×10^{-2}	1×10^{-8}	8×10^{-4}
	Tc-99m	S	4×10^{-5}	2×10^{-1}	1×10^{-6}	6×10^{-3}
		I	1×10^{-5}	8×10^{-2}	5×10^{-7}	3×10^{-3}
	Tc-00	S	2×10^{-6}	1×10^{-2}	7×10^{-8}	3×10^{-4}
		I	6×10^{-8}	5×10^{-3}	2×10^{-9}	2×10^{-4}
Tellurium (52)	Te-125m	S	4×10^{-7}	5×10^{-3}	1×10^{-8}	2×10^{-4}
		I	1×10^{-7}	3×10^{-3}	4×10^{-9}	1×10^{-4}
	Te-127m	S	1×10^{-7}	2×10^{-3}	5×10^{-9}	6×10^{-5}
		I	4×10^{-8}	2×10^{-3}	1×10^{-9}	5×10^{-5}
	Te-127	S	2×10^{-6}	8×10^{-3}	6×10^{-8}	3×10^{-4}
		I	9×10^{-7}	5×10^{-3}	3×10^{-8}	2×10^{-4}
	Te-129m	S	8×10^{-8}	1×10^{-3}	3×10^{-9}	3×10^{-5}
		I	3×10^{-8}	6×10^{-4}	1×10^{-9}	2×10^{-5}
	Te-129	S	5×10^{-6}	2×10^{-2}	2×10^{-7}	8×10^{-4}
		I	4×10^{-6}	2×10^{-2}	1×10^{-7}	8×10^{-4}
	Te-131m	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
		I	2×10^{-7}	1×10^{-3}	6×10^{-9}	4×10^{-5}
	Te-132	S	2×10^{-7}	9×10^{-4}	7×10^{-9}	3×10^{-5}
		I	1×10^{-7}	6×10^{-4}	4×10^{-9}	2×10^{-5}
Terbium (65)	Tb-165	S	1×10^{-7}	1×10^{-3}	3×10^{-9}	4×10^{-5}
		I	3×10^{-8}	1×10^{-3}	1×10^{-9}	4×10^{-5}
Thallium (81)	Tl-200	S	3×10^{-6}	1×10^{-2}	9×10^{-8}	4×10^{-4}
		I	1×10^{-6}	7×10^{-3}	4×10^{-8}	2×10^{-4}
	Tl-201	S	2×10^{-6}	9×10^{-3}	7×10^{-8}	3×10^{-4}

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
		I	9×10^{-7}	5×10^{-3}	3×10^{-8}	2×10^{-4}
	Tl-202	S	8×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	2×10^{-7}	2×10^{-3}	8×10^{-9}	7×10^{-5}
	Tl-204	S	6×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	3×10^{-8}	2×10^{-3}	9×10^{-10}	6×10^{-5}
Thorium (90)	Th-227	S	3×10^{-10}	5×10^{-4}	1×10^{-11}	2×10^{-5}
		I	2×10^{-10}	5×10^{-4}	6×10^{-12}	2×10^{-5}
	Th-228	S	9×10^{-12}	2×10^{-4}	3×10^{-13}	7×10^{-6}
		I	6×10^{-12}	4×10^{-4}	2×10^{-13}	1×10^{-5}
	Th-230	S	2×10^{-12}	5×10^{-5}	8×10^{-14}	2×10^{-6}
		I	1×10^{-11}	9×10^{-4}	3×10^{-13}	3×10^{-5}
	Th-231	S	1×10^{-6}	7×10^{-3}	5×10^{-8}	2×10^{-4}
		I	1×10^{-6}	7×10^{-3}	7×10^{-8}	2×10^{-4}
	Th-232	S	3×10^{-11}	5×10^{-5}	1×10^{-12}	2×10^{-6}
		I	3×10^{-11}	1×10^{-3}	1×10^{-12}	4×10^{-5}
	Th-natural	S	6×10^{-11}	6×10^{-5}	2×10^{-12}	2×10^{-6}
		I	6×10^{-11}	6×10^{-4}	2×10^{-12}	2×10^{-5}
	Th-234	S	6×10^{-8}	5×10^{-4}	2×10^{-9}	2×10^{-5}
		I	3×10^{-8}	5×10^{-4}	1×10^{-9}	2×10^{-5}
Thulium (69)	Tm-170	S	4×10^{-8}	1×10^{-3}	1×10^{-9}	5×10^{-5}
		I	3×10^{-8}	1×10^{-3}	1×10^{-9}	5×10^{-5}
	Tm-171	S	1×10^{-7}	1×10^{-2}	4×10^{-9}	5×10^{-4}
		I	2×10^{-7}	1×10^{-2}	8×10^{-9}	5×10^{-4}
Tin (50)	Sn-113	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	9×10^{-5}
		I	5×10^{-8}	2×10^{-3}	2×10^{-9}	8×10^{-5}
	Sn-125	S	1×10^{-7}	5×10^{-4}	4×10^{-9}	2×10^{-5}
		I	8×10^{-8}	5×10^{-4}	3×10^{-9}	2×10^{-5}
Tungsten (74)	W-181	S	2×10^{-6}	1×10^{-2}	8×10^{-8}	4×10^{-4}
		I	1×10^{-7}	1×10^{-2}	4×10^{-9}	3×10^{-4}
	W-185	S	8×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	1×10^{-7}	3×10^{-3}	4×10^{-9}	1×10^{-4}
	W-187	S	4×10^{-7}	2×10^{-3}	2×10^{-8}	7×10^{-5}
		I	3×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
Uranium (92)	U-230	S	3×10^{-10}	1×10^{-4}	1×10^{-11}	5×10^{-6}
		I	1×10^{-10}	1×10^{-4}	4×10^{-12}	5×10^{-6}
	U-232	S	1×10^{-10}	8×10^{-4}	3×10^{-12}	3×10^{-5}

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CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
		I	3×10^{-11}	8×10^{-4}	9×10^{-13}	3×10^{-5}
	U-233	S	5×10^{-10}	9×10^{-4}	2×10^{-11}	3×10^{-5}
		I	1×10^{-10}	9×10^{-4}	4×10^{-12}	3×10^{-5}
	U-234	S[4/]	6×10^{-10}	9×10^{-4}	2×10^{-11}	3×10^{-5}
		I	1×10^{-10}	9×10^{-4}	4×10^{-12}	3×10^{-5}
	U-235	S[4/]	5×10^{-10}	8×10^{-4}	2×10^{-11}	3×10^{-5}
		I	1×10^{-10}	8×10^{-4}	4×10^{-12}	3×10^{-5}
	U-236	S	6×10^{-10}	1×10^{-3}	2×10^{-11}	3×10^{-5}
		I	1×10^{-10}	1×10^{-3}	4×10^{-12}	3×10^{-5}
	U-238	S[4/]	7×10^{-11}	1×10^{-3}	3×10^{-12}	4×10^{-5}
		I	1×10^{-10}	1×10^{-3}	5×10^{-12}	4×10^{-5}
	U-240	S	2×10^{-7}	1×10^{-3}	8×10^{-9}	3×10^{-5}
		I	2×10^{-7}	1×10^{-3}	6×10^{-9}	3×10^{-5}
	U-natural	S[4/]	1×10^{-10}	1×10^{-3}	5×10^{-12}	3×10^{-5}
		I	1×10^{-10}	1×10^{-3}	5×10^{-12}	3×10^{-5}
Vanadium (23)	V-48	S	2×10^{-7}	9×10^{-4}	6×10^{-9}	3×10^{-5}
		I	6×10^{-8}	8×10^{-4}	2×10^{-9}	3×10^{-5}
Xenon (54)	Xe-131m	Sub[2/]	2×10^{-5}	_____	4×10^{-7}	_____
	Xe-133m	Sub	1×10^{-5}	_____	3×10^{-7}	_____
	Xe-133	Sub	1×10^{-5}	_____	3×10^{-7}	_____
	Xe-135	Sub	4×10^{-6}	_____	1×10^{-7}	_____
Ytterbium (70)	Yb-175	S	7×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	6×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
Yttrium (39)	Y-88	S	1×10^{-7}	2×10^{-4}	4×10^{-8}	8×10^{-5}
		I	5×10^{-8}	2×10^{-4}	2×10^{-8}	8×10^{-5}
	Y-90	S	1×10^{-7}	6×10^{-4}	4×10^{-9}	2×10^{-5}
		I	1×10^{-7}	6×10^{-4}	3×10^{-9}	2×10^{-5}
	Y-91m	S	2×10^{-5}	1×10^{-1}	8×10^{-7}	3×10^{-3}
		I	2×10^{-5}	1×10^{-1}	6×10^{-7}	3×10^{-3}
	Y-91	S	4×10^{-8}	8×10^{-4}	1×10^{-9}	3×10^{-5}
		I	3×10^{-8}	8×10^{-4}	1×10^{-9}	3×10^{-5}
	Y-92	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
		I	3×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
	Y-93	S	2×10^{-7}	8×10^{-4}	6×10^{-9}	3×10^{-5}
		I	1×10^{-7}	8×10^{-4}	5×10^{-9}	3×10^{-5}
Zinc (30)	Zn-65	S	1×10^{-7}	3×10^{-3}	4×10^{-9}	1×10^{-4}

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
		I	6×10^{-8}	5×10^{-3}	2×10^{-9}	2×10^{-4}
	Zn-69m	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	7×10^{-5}
		I	3×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
	Zn-69	S	7×10^{-6}	5×10^{-2}	2×10^{-7}	2×10^{-3}
		I	9×10^{-6}	5×10^{-2}	3×10^{-7}	2×10^{-3}
Zirconium (40)	Zr-93	S	1×10^{-7}	2×10^{-2}	4×10^{-9}	8×10^{-4}
		I	3×10^{-7}	2×10^{-2}	1×10^{-8}	8×10^{-4}
	Zr-95	S	1×10^{-7}	2×10^{-3}	4×10^{-9}	6×10^{-5}
		I	3×10^{-8}	2×10^{-3}	1×10^{-9}	6×10^{-5}
	Zr-97	S	1×10^{-7}	5×10^{-4}	4×10^{-9}	2×10^{-5}
		I	9×10^{-8}	5×10^{-4}	3×10^{-9}	2×10^{-5}
Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life less than 2 hours. ***	Sub[2/]		1×10^{-6}	_____	3×10^{-8}	_____
Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life greater than 2 hours.			3×10^{-9}	9×10^{-5}	1×10^{-10}	3×10^{-6}
Any single radionuclide not listed above, which decays by alpha emission or spontaneous fission.			6×10^{-13}	4×10^{-7}	$2\times^{-14}$	3×10^{-8}

[1/]Soluble (S); Insoluble (I).

[2/]"Sub" means that values given are for submersion in a semispherical infinite cloud of airborne material.

[3/]These radon concentrations are appropriate for protection from radon-222 combined with its short-lived daughters. Alternatively, the value in Table I may be replaced by 1/3 "working level." (A "working level" is defined as any combinations of short-lived radon-222 daughters, polonium-218, lead-214, bismuth-214, and polonium-214 in 1 liter of air, without regard to the degree of equilibrium, that will result in the ultimate emission of 1.3×10^{5} MeV of alpha particle energy.) The Table II value may be replaced by 1/30th of a "working level." The limit on radon-222 concentrations in restricted areas may be based on an annual average.

[4/]For soluble mixtures of U-238, U-234 and U-235 in air, chemical toxicity may be the limiting factor. If the percent by weight (enrichment) of U-235 is less than 5, the concentration value for a 40-hour workweek, Table I, is 0.2 milligrams uranium per cubic meter of air average. For any enrichment, the product of the average concentration and time of exposure during a 40-hour workweek shall not exceed 8×10^{-3} SA μCi-hr/ml, where SA is the specific activity of the uranium inhaled. The concentration value for Table II is 0.007 milligrams uranium per cubic meter of air. The specific activity for natural uranium is 6.77×10^{-7} curies per gram uranium. The specific activity for other mixtures of U-238, U-235 and U-234, if not known, shall be:

$SA = 3.6 \times 10^{-7}$ curies/gram U	U-depeleted
$SA = (0.4 + 0.38\ E + 0.0034\ E^2)$	$10^{-6}\ E \geq 0.72$

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Isotope[1/] Element (atomic number)	Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)

where E is the percentage by weight of U-235, expressed as percent.

Note: In any case where there is a mixture in air or water of more than one radionuclide, the limiting values for purposes of this appendix should be determined as follows:

1. If the identity and concentration of each radionuclide in the mixture are known, the limiting values should be derived as follows: Determine, for each radionuclide in the mixture, the ratio between the quantity present in the mixture and the limit otherwise established in Appendix "A" for the specific radionuclide when not in a mixture. The sum of such ratios for all the radionuclides in the mixture may not exceed "1" (i.e., "unity").

Example: If radionuclides a, b, and c are present in concentrations C_a, C_b, and C_c, and if the applicable maximum permissible concentrations (MPC's) are MPC_a, MPC_b, and MPC_c respectively, then the concentrations shall be limited so that the following relationship exists:

$$\frac{C_a}{MPC_a} + \frac{C_b}{MPC_b} + \frac{C_c}{MPC_c} \leq 1$$

2. If either the identity or the concentration of any radionuclide in the mixture is not known, the limiting values for purposes of Appendix "A" shall be:

a. For purposes of Table I, Col. 1. . . . . 6×10^{-13}

b. For purposes of Table I, Col. 2. . . . . 4×10^{-7}

c. For purposes of Table II, Col. 1. . . . . 2×10^{-14}

d. For purposes of Table II, Col. 2. . . . . 3×10^{-8}

3. If any of the conditions specified below are met, the corresponding values specified below may be used in lieu of those specified in paragraph 2 above.

a. If the identity of each radionuclide in the mixture is known but the concentration of one or more of the radionuclides in the mixture is not known, the concentration limit for the mixture is the limit specified in Appendix "A" for the radionuclide in the mixture having the lowest concentration limit: or

b. If the identity of each radionuclide in the mixture is not known, but it is known that certain radionuclides specified in Appendix "A" are not present in the mixture, the concentration limit for the mixture is the lowest concentration limit specified in Appendix "A" for any radionuclide which is not known to be absent from the mixture; or

c. Radionuclide	Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
If it is known that Sr-90, I-125, I-126, I-129, I-131, (I-133 Table II only), Pb-210, Po-210, At-211, Ra-223, Ra-224, Ra-226, Ac-227, Ra-228, Th-230, Pa-231, Th-232, Th-nat, Cm-248, Cf-254, and Fm-256 are not present.	_____	9×10^{-5}	_____	3×10^{-6}
If it is known that Sr-90, I-125, I-126, I-129, (I-131, I-133, Table II only), Pb-210, Po-210, Ra-223, Ra-226, Ra-228, Pa-231, Th-nat, Cm-248, Cf-254, and Fm-256 are not present..	_____	6×10^{-5}	_____	2×10^{-6}

If it is known that Sr-90, I-129, (I-125, I-126, I-131, Table II only), Pb-210, Ra-226, Ra-228, Cm-248, and Cf-254 are not present.	_____	2×10^{-5}	_____	6×10^{-7}
If it is known that (I-129, Table II only), Ra-226, and Ra-228 are not present.	_____	3×10^{-6}	_____	1×10^{-7}
If it is known that alpha-emitters and Sr-90, I-129, Pb-210, Ac-227, Ra-228, Pa-230, Pu-241, and Bk-249 are not present.	3×10^{-9}	_____	1×10^{-10}	_____
If it is known that alpha-emitters and Pb-210, Ac-227, Ra-228, and Pu-241 are not present..	3×10^{-10}	_____	1×10^{-11}	_____
If it is known that alpha-emitters and Ac-227 are not present.	3×10^{-11}	_____	1×10^{-12}	_____
If it is known that Ac-227, Th-230, Pa-231, Pu-238, Pu-239, Pu-240, Pu-242, Pu-244, Cm-248, Cf-249 and Cf-251 are not present.	3×10^{-12}	_____	1×10^{-13}	_____

4. If a mixture of radionuclides consists of uranium and its daughter products in ore dust prior to chemical separation of the uranium from the ore, the values specified below may be used for uranium and its daughters through radium-226, instead of those from paragraphs 1, 2, or 3 above.

a. For purposes of Table I, Column 1, 1×10^{-10} µCi/ml gross alpha activity; or 5×10^{-11} µCi/ml natural uranium; or 75 micrograms per cubic meter of air natural uranium.

b. For purposes of Table II, Column 1, 3×10^{-12} µCi/ml gross alpha activity; 2×10^{-12} µCi/ml natural uranium; or 3 micrograms per cubic meter of air natural uranium.

5. For purposes of this note, a radionuclide may be considered as not present in a mixture if (a) the ratio of the concentration of that radionuclide in the mixture (C_a) to the concentration limit for that radionuclide specified in Table II of Appendix "A" (MPC_a) does not exceed 1/10, (i.e., $C_a/MPC_a \leq 1/10$) and (b) the sum of such ratios for all radionuclides considered as not present in the mixture does not exceed 1/4, (i.e., $C_a/MPC_a + C_b/MPC_b + ... \leq 1/4$).

Note: To convert µCi/ml to SI unnts *[sic.]* of megabecquerels per liter, multiply the above values by 37.

Example: Zirconium (40) Zr-97 S (Table I, Column 1-Air) (1×10^{-7} µCi/ml multiplied by 37 is equivalent to 37×10^{-7} MBq/1.)

(Indiana State Department of Health; Rule HRH-2,PT D,Appendix A; filed May 26, 1978, 3:30 pm: 1 IR 184; filed Feb 29, 1984, 10:10 am: 7 IR 910; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-4-28 Appendix B; table for use with 410 IAC 5-4-11, 410 IAC 5-4-18, 410 IAC 5-4-19

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 28.

Part D

APPENDIX B

Material	Microcuries
Americium-241	0.01
Antinomy-122	100
Antinomy-124	10
Antinomy-125	10
Arsenic-73	100
Arsenic-74	10
Arsenic-76	10

Arsenic-77	100
Barium-131	10
Barium-133	10
Barium-140	10
Bismuth-210	1
Bromine-82	10
Cadmium-109	10
Cadmium-115m	10
Cadmium-115	100
Calcium-45	10
Calcium-47	10
Carbon-14	100
Cerium-141	100
Cerium-143	100
Cerium-144	1
Cesium-131	1,000
Cesium-134m	100
Cesium-134	1
Cesium-135	10
Cesium-136	10
Cesium-137	10
Chlorine-36	10
Chlorine-38	10
Chromium-51	1,000
Cobalt-58m	10
Cobalt-58	10
Cobalt-60	1
Copper-64	100
Dysprosium-165	10
Dysprosium-166	100
Erbium-169	100
Erbium-171	100
Europium-152 (9.2 h)	100
Europium-152 (13 yr)	1
Europium-154	1
Europium-155	10
Fluorine-18	1,000
Gadolinium-153	10
Gadolinium-159	100

Gallium-72	10
Germanium-71	100
Gold-198	100
Gold-199	100
Hafnium-181	10
Holmium-166	100
Hydrogen-3	1,000
Indium-113m	100
Indium-114m	10
Indium-115m	100
Indium-115	10
Iodine-125	1
Iodine-126	1
Iodine-129	0.1
Iodine-131	1
Iodine-132	10
Iodine-133	1
Iodine-134	10
Iodine-135	10
Iridium-192	10
Iridium-194	100
Iron-55	100
Iron-59	10
Krypton-85	100
Krypton-87	10
Lanthanum-140	10
Lutetium-177	100
Manganese-52	10
Manganese-54	10
Manganese-56	10
Mercury-197m	100
Mercury-197	100
Mercury-203	10
Molybdenum-99	100
Neodymium-147	100
Neodymium-149	100
Nickel-59	100
Nickel-63	10
Nickel-65	100

Niobium-93m	10
Niobium-95	10
Niobium-97	10
Osmium-185	10
Osmium-191m	100
Osmium-191	100
Osmium-193	100
Palladium-103	100
Palladium-109	100
Phosphorus-32	10
Platinum-191	100
Platinum-193m	100
Platinum-193	100
Platinum-197m	100
Platinum-197	100
Plutonium-239	0.01
Polonium-210	0.1
Potassium-42	10
Praseodymium-142	100
Praseodymium-143	100
Promethium-147	10
Promethium-149	10
Radium-226	0.01
Rhenium-186	100
Rhenium-188	100
Rhodium-103m	100
Rhodium-105	100
Rubidium-86	10
Rubidium-87	10
Ruthenium-97	100
Ruthenium-103	10
Ruthenium-105	10
Ruthenium-106	1
Samarium-151	10
Samarium-153	100
Scandium-46	10
Scandium-47	100
Scandium-48	10
Selenium-75	10

Silicon-31	100
Silver-105	10
Silver-110m	1
Silver-111	100
Sodium-22	10
Sodium-24	10
Strontium-85	10
Strontium-89	1
Strontium-90	0.1
Strontium-91	10
Strontium-92	10
Sulphur-35	100
Tantalum-182	10
Technetium-96	10
Technetium-97m	100
Technetium-97	100
Technetium-99m	100
Technetium-99	10
Tellurium-125m	10
Tellurium-127m	10
Tellurium-127	100
Tellurium-129m	10
Tellurium-129	100
Tellurium-131m	10
Tellurium-132	10
Terbium-160	10
Thallium-200	100
Thallium-201	100
Thallium-202	100
Thallium-204	10
Thorium (natural)[1/]	100
Thulium-170	10
Thulium-171	10
Tin-113	10
Tin-125	10
Tungsten-181	10
Tungsten-185	10
Tungsten-187	100
Uranium (natural)[2/]	100

Uranium-233	0.01
Uranium-234/235	0.01
Vanadium-48	10
Xenon-131m	1,000
Xenon-133	100
Xenon-135	100
Ytterbium-175	100
Yttrium-90	10
Yttrium-91	10
Yttrium-92	100
Yttrium-93	100
Zinc-65	10
Zinc-69m	100
Zinc-69	1,000
Zirconium-93	10
Zirconium-95	10
Zirconium-97	10
Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.01
Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition	0.1

[1/] Based on alpha disintegration rate of Th-232, Th-230 and their daughter products.

[2/] Based on alpha disintegration rate of U-238, U-234, and U-235.

NOTE: For purposes of 410 IAC 5-4-11, 410 IAC 5-4-18, and 410 IAC 5-4-19, where there is involved a combination of isotopes in known amounts, the limit for the combination should be derived as follows: Determine, for each isotope in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific isotope when not in combination. The sum of such ratios for all the isotopes in the combination may exceed "1" (i.e., "unity").

Example: For purposes of 410 IAC 5-4-19, if a particular batch contains 20,000 µCi of Au-198 and 50,000 µCi of C-14, it may also include not more than 300 µCi of I-131. This limit was determined as follows:

20,000 µCi Au-198/100,000 µCi + 50,000 µCi C-14/100,00 *[sic.]* µCi
+ 300 µCi I-131/1,000 µCi = 1

The denominator in each of the above ratios was obtained by multiplying the figure in the table by 1,000 as provided in 410 IAC 5-4-19.

Note: To convert microcuries (µCi) to SI units of kilobecquerels (kBq), multiply the above values by 37.

Example: Zirconium-97 (10 µCi)(37) = 370 kBq. (10 µCi multiplied by 37 is equivalent to 370 kBq) *(Indiana State Department of Health; Rule HRH-2,PT D,Appendix B; filed May 26, 1978, 3:30 pm: 1 IR 197; filed Feb 29, 1984, 10:10 am: 7 IR 924; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

Rule 5. Non-Medical Radiography

410 IAC 5-5-1 Scope of rule

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 1. The requirements in 410 IAC 5-5 establish radiation safety requirements for persons utilizing sources of radiation for non-medical radiography (i.e., industrial radiography, ionizing radiation gauging devices, NARM, and any other non-medical use). The requirements of 410 IAC 5-5 are in addition to, and not in substitution for, the other requirements of 410 IAC 5. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.1; filed May 26, 1978, 3:30 pm: 1 IR 199; filed Feb 29, 1984, 10:10 am: 7 IR 926; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-5-2 Applicability of rule

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 2. The requirements in 410 IAC 5-5 apply to all registrants who use sources of radiation for non-medical radiography. Except for those requirements of 410 IAC 5-5 clearly applicable only to sealed radioactive sources, both radiation machines and sealed radioactive sources are covered by 410 IAC 5-5. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.2; filed May 26, 1978, 3:30 pm: 1 IR 199; filed Feb 29, 1984, 10:10 am: 7 IR 927; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-5-3 Definitions

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 3. As used in 410 IAC 5-5, the following definitions apply:

"ANSI" means the American National Standards Institute.

"Enclosed radiography" means industrial radiography conducted in an enclosed cabinet or room and includes cabinet radiography and shielded room radiography.

(1) "Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet so shielded that every location on the exterior meets the limitations specified in 410 IAC 5-4-6.

(i) "Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure (hereinafter termed "cabinet") which, independent of existing architectural structures except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of x-radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airlines, railroads, bus terminals, and in similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.

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

(2) "Shielded-room radiography" means industrial radiography conducted in a room so shielded that radiation levels at every location on the exterior meet the limitations specified in 410 IAC 5-4-6.

"Gamma radiography" means industrial radiography using radioactive material that emits gamma rays (i.e., Ir 192, Co 60, Cs 137).

"Industrial radiography" means the use of penetrating radiation, such as x-rays, gamma rays, or neutrons, to make pictures of the insides of objects (i.e., metal castings or welds).

"Ionizing radiation gauging device" (gauge) means a mechanism designed and manufactured for the purpose of determining or controlling thickness, density, level, interface location, or qualitative or quantitative chemical composition.

"NARM" means any naturally occurring or accelerator produced radioactive material. It does not include by-product, source, or special nuclear material.

"Permanent radiographic installation" means an installation or structure designed or intended for radiography and in which radiography is regularly performed.

"Personal supervision" means supervision such that the supervisor is physically present at the site where sources of radiation and associated equipment are being used, watching the performance of the radiographer's assistant and in such proximity that contact can be maintained and immediate assistance given as required.

"Radiographer" means any individual who performs or provides personal supervision of industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of 410 IAC 5 and all license (and/or registration) conditions.

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

"Radiographic exposure device" means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.

"Shielded position" means the location within the radiographic exposure device or storage container which, by manufacturer's design, is the proper location for storage of the sealed source.

"Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those source changers also used for transporting and storage of sealed sources.

"Storage container" means a device in which sealed sources are transported or stored.

"Temporary job site" means any location where industrial radiography is performed other than the location(s) listed in a specific license or certificate of registration. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.3; filed May 26, 1978, 3:30 pm: 1 IR 199; filed Feb 29, 1984, 10:10 am: 7 IR 927; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-5-3.1 Additional requirements; safety programs

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 3.1. (a) Ionizing radiation gauging devices shall comply with applicable sections of ANSI N538 or its equivalent, in addition to 410 IAC 5-5-8 and other applicable sections of 410 IAC 5.

(b) The board may impose any additional requirement for the specific application of an ionizing radiation source to protect the health and safety of an employee and/or the public. The board shall weigh the impact of any such requirement against the hazards created without such a requirement, before imposing any additional requirements.

(c) All non-medical users of "NARM" and/or devices that produce x-rays either as part of their design or incidental to other design functions shall have an adequate radiation safety program.

(1) The adequacy of the program will be evaluated by the board.

(2) The program must meet the intent of 410 IAC 5.

(3) The program shall keep personnel exposure ALARA (as low as reasonably achievable).

(4) The program shall take under consideration the education and training of the personnel utilizing or in the environs of the radiation device.

(Indiana State Department of Health; 410 IAC 5-5-3.1; filed Feb 29, 1984, 10:10 am: 7 IR 928; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-5-3.2 Enclosed radiography; special provisions and exemptions

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 3.2. (a) Systems for enclosed radiography designed to allow admittance of individuals shall:
(1) Comply with 410 IAC 5-5-11, 410 IAC 5-5-11.5, 410 IAC 5-5-12, 410 IAC 5-5-13, 410 IAC 5-5-15, 410 IAC 5-5-16, and 410 IAC 5-5-18 of 410 IAC 5-5 and 410 IAC 5-4-6.
(2) Operating personnel must be provided with either a film badge or a thermoluminescent dosimeter and reports of the results must be maintained for inspection by the board.
(3) Be evaluated at intervals not to exceed 1 year to assure compliance with the applicable requirements as specified in 410 IAC 5-5-3.2(a)(1). Records of these evaluations shall be maintained for inspection by the board for a period of 2 years after the evaluation.
(b) Cabinet x-ray systems designed to exclude individuals are exempt from the requirements of 410 IAC 5-5-3.2 except that:
(1) No registrant shall permit any individual to operate a cabinet x-ray system until such individual has received a copy of instructions in the operating procedures for the unit and has demonstrated competence in its use. Records which demonstrate compliance with this subdivision shall be maintained for inspection by the board until disposition is authorized by the board;
(2) Tests for proper operation of high radiation area control devices or alarm systems, where applicable, must be conducted and recorded in accordance with 410 IAC 5-5-11.5; and
(3) The registrant shall perform or have done an evaluation, at intervals not to exceed 1 year, to determine conformance with 410 IAC 5-4-6. If such a system is a certified cabinet x-ray system, it shall be evaluated at intervals not to exceed 1 year to determine conformance with 21 CFR 1020.40. Records of these evaluations shall be maintained for inspection by the board for a period of 2 years after the evaluation.
(c) Certified cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40 unless prior approval has been granted by the board pursuant to 410 IAC 5-1-3(a). *(Indiana State Department of Health; 410 IAC 5-5-3.2; filed Feb 29, 1984, 10:10 am: 7 IR 928; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-5-4 Radiation limits for exposure devices and storage containers for gamma radiography
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 4. Radiographic exposure devices measuring less than 10 cm from the sealed source storage position to any exterior surface of the device shall have no radiation level in excess of 50 milliroentgens per hour at 15 cm from any exterior surface of the device. Radiographic exposure devices measuring a minimum of 10 cm from the sealed source storage position to any exterior surface of the device, and all storage containers for sealed sources or outer containers for radiographic exposure devices, shall have no radiation level in excess of 200 milliroentgens per hour at any exterior surface, and 10 milliroentgens per hour at 1 meter from any exterior surface. The radiation levels specified are with the sealed source in the shielded (i.e., "off") position. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.101; filed May 26, 1978, 3:30 pm: 1 IR 200; filed Feb 29, 1984, 10:10 am: 7 IR 929; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-5-5 Locking of sources for gamma radiography
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 5. (a) Each source of radiation shall be provided with a lock or lockable outer container designed to prevent unauthorized or accidental production of radiation or removal or exposure of a sealed source and shall be kept locked at all times except when under the direct surveillance of a radiographer or radiographer's assistant, or as may be otherwise authorized pursuant to 410 IAC 5-5-15. Each storage container and source changer likewise shall be provided with a lock and shall be kept locked when containing sealed sources except when the container is under the direct surveillance of a radiographer or radiographer's assistant.
(b) Radiographic exposure devices, source changers, and storage containers, prior to being moved from one location to another and also prior to being secured at a given location, shall be locked and surveyed to assure that the sealed source is in the shielded

position. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.102; filed May 26, 1978, 3:30 pm: 1 IR 200; filed Feb 29, 1984, 10:10 am: 7 IR 929; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-5-6 Security precautions for gamma radiography

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 6. Locked radiographic exposure devices, source changers, and storage containers shall be physically secured to prevent tampering or removal by unauthorized personnel. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.103; filed May 26, 1978, 3:30 pm: 1 IR 200; filed Feb 29, 1984, 10:10 am: 7 IR 929; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-5-7 Survey instruments for gamma and temporary job site radiography

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 7. (a) The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by 410 IAC 5-5-7 and 410 IAC 5-4-9 of 410 IAC 5. Instrumentation required by this section shall have such a range such that 2 milliroentgens per hour through 1 roentgen per hour can be measured.

(b) Each radiation survey instrument shall be calibrated:

(1) at energies appropriate for use and at intervals not to exceed 3 months and after each instrument servicing;

(2) such that accuracy within plus or minus 20 percent traceable to a national standard can be demonstrated; and

(3) at two or more widely separated points, other than zero, on each scale.

(c) Records of these calibrations shall be maintained for two years after the calibration date for inspection by the board. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.104; filed May 26, 1978, 3:30 pm: 1 IR 200; filed Feb 29, 1984, 10:10 am: 7 IR 929; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-5-8 Leak testing, replacement, and modification of NARM sealed sources

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 8. (a) The replacement of any "NARM" sealed source fastened to or contained in a radiographic exposure device and leak testing, repair, tagging, opening or any other modification of any sealed source shall be performed only by persons qualified by education and training.

(b) Each sealed source shall be tested for leakage at intervals not to exceed 6 months. In the absence of a certificate from a transferor that a test has been made within the 6 month period prior to the transfer, the sealed source shall not be put into use until tested.

(1) The board may grant exceptions to the leak test requirement for "NARM," when;

(i) The construction and history of a type of sealed source warrants a less frequent testing.

(ii) Access to the source places an undue burden on the registrant.

(2) Any "NARM" sealed source less than 100 times the quantity listed in Schedule B of 410 IAC 5-4 is excepted from leak tests.

(3) Any sealed source with a half-life less than 30 days and/or in gaseous form is excepted from leak tests.

(4) Any "NARM" sealed source 10µCi or less used as a check source is excepted.

(c) The leak test shall be capable of detecting the presence of 0.005 microcurie of removable contamination on the sealed

source. An acceptable leak test for sealed sources in the possession of a radiography licensee would be to test at the nearest accessible point to the sealed source storage position, or other appropriate measuring point. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the board for 6 months after the next required leak test is performed or until the sealed source is transferred or disposed of.

(d) Any test conducted pursuant to 410 IAC 5-5-8(b) and (c) which reveals the presence of 0.005 microcurie or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of, in accordance with rules of the board. Within 5 days after obtaining results of the test, the licensee shall file a report with the board describing the equipment involved, the test results, and the corrective action taken.

(e) A sealed source which is not fastened to or contained in a radiographic exposure device shall have permanently attached to it a durable tag bearing the prescribed radiation caution symbol in conventional colors, magenta or purple on a yellow background, and at least the instructions: "Danger–Radioactive Material." *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.105; filed May 26, 1978, 3:30 pm: 1 IR 200; filed Feb 29, 1984, 10:10 am: 7 IR 930; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-5-9 Quarterly inventory of sealed sources for gamma radiography

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 9. Each licensee shall conduct a quarterly physical inventory to account for all sealed sources received or possessed by him. The records of the inventories shall be maintained for 2 years from the date of the inventory for inspection by the board and shall include the quantities and kinds of radioactive material, the location of sealed sources, and the date of the inventory. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.106; filed May 26, 1978, 3:30 pm: 1 IR 201; filed Feb 29, 1984, 10:10 am: 7 IR 930; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-5-10 Utilization logs in gamma radiography

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 10. Each licensee or registrant shall maintain current logs, which shall be kept available for inspection by the board for 2 years from the date of the recorded event showing for each source of radiation the following information:

(a) A description (or make and model number) of each source of radiation or storage container in which the sealed source is located;

(b) The identity of the radiographer to whom assigned; and

(c) Locations where used and dates of use.

(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.107; filed May 26, 1978, 3:30 pm: 1 IR 201; filed Feb 29, 1984, 10:10 am: 7 IR 930; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-5-11 Inspection and maintenance of industrial exposure devices and storage containers

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 11. (a) Each licensee or registrant shall ensure that checks for obvious defects in radiation machines, radiographic exposure devices, storage containers, and source changers are performed prior to each day of use.

(b) The licensee or registrant shall conduct a program of at least quarterly inspection and maintenance of radiation machines,

radiographic exposure devices, storage containers, and source changers to assure proper functioning of components important to safety. All appropriate parts shall be maintained in accordance with manufacturers' specifications. Records of inspection and maintenance shall be maintained for inspection by the board until it authorizes their disposal.

(c) If any inspection conducted pursuant to 410 IAC 5-5-11(a) or (b) reveals damage to components critical to radiation safety, the device shall be removed from service until repairs have been made. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.108; filed May 26, 1978, 3:30 pm: 1 IR 201; filed Feb 29, 1984, 10:10 am: 7 IR 931; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-5-11.5 Permanent installations

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 11.5. Permanent radiographic installations having high radiation area entrance controls of the type described in 410 IAC 5-4-11(c)(2)(ii) and (iii) and (c)(4) shall also meet the following requirements:

(a) Each entrance that is used for personnel access to the high radiation area shall have both visible and audible warning signals to warn of the presence of radiation. The visible signal shall be activated by radiation. The audible signal shall be activated when an attempt is made to enter the installation while the source is exposed.

(b) The control device or alarm system shall be tested for proper operation at the beginning of each period of use. Records of these tests shall be maintained for inspection by the board until their disposal is authorized. *(Indiana State Department of Health; 410 IAC 5-5-11.5; filed Feb 29, 1984, 10:10 am: 7 IR 931; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-5-12 Personnel training and testing; internal audit of operating and emergency procedures

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 12. Training and testing (applies to all industrial radiography). (a) No licensee or registrant shall permit any individual to act as a radiographer, as defined in 410 IAC 5-5-12, until such individual:

(1) Has been instructed in the subjects outlined in 410 IAC 5-5-20 and shall have demonstrated understanding thereof;

(2) Has received copies of and instruction in the requirements contained in this section and the applicable sections of 410 IAC 5-4 and 410 IAC 5-10, appropriate license(s), and the licensee's or registrant's operating and emergency procedures, and shall have demonstrated understanding thereof;

(3) Has demonstrated competence to use the source of radiation, radiographic exposure devices, related handling tools, and radiation survey instruments which will be employed in his assignment; and

(4) Has demonstrated an understanding of the instructions of 410 IAC 5-5-12(a) by successful completion of a written test and a field examination on the subjects covered.

(b) No licensee or registrant shall permit any individual to act as a radiographer's assistant as defined in 410 IAC 5-5-12 until such individual:

(1) Has received copies of and instruction in the licensee's or registrant's operating and emergency procedures, and shall have demonstrated understanding thereof;

(2) Has demonstrated competence to use, under the personal supervision of the radiographer, the sources of radiation, radiographic exposure device(s), related handling tools, and radiation survey instruments which will be employed in his assignment; and

(3) Has demonstrated an understanding of the instructions in 410 IAC 5-5-12(b) by successful completion of a written or oral test and a field examination on the subjects covered.

(c) Records of the above training, including copies of written tests and dates of oral tests and field examinations, shall be maintained for inspection by the board for 3 years following termination of employment.

(d) Each licensee or registrant shall conduct an internal audit program to ensure that the board's radioactive material license

conditions and the licensee's or registrant's operating and emergency procedures are followed by each radiographer and radiographer's assistant. These internal audits shall be performed at least quarterly, and each radiographer shall be audited at least annually. Records of internal audits shall be maintained for inspection by the board for 2 years from the date of the audit. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.201; filed May 26, 1978, 3:30 pm: 1 IR 201; filed Feb 29, 1984, 10:10 am: 7 IR 931; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-5-13 Operating and emergency instructions

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 13. The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:

(a) The handling and use of sources of radiation to be employed such that no individual is likely to be exposed to radiation doses in excess of the limits established in 410 IAC 5-4;

(b) Methods and occasions for conducting radiation surveys;

(c) Methods for controlling access to radiographic areas;

(d) Methods and occasions for locking and securing sources of radiation;

(e) Personnel monitoring and the use of personnel monitoring equipment including steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale;

(f) Transportation to field locations, including packing of sources of radiation in the vehicles, posting of vehicles, and control of sources of radiation during transportation;

(g) Minimizing exposure of individuals in the event of an accident;

(h) The procedure for notifying proper personnel in the event of an accident;

(i) Maintenance of records; and

(j) The inspection and maintenance of radiographic exposure devices, source changers, storage containers, and radiation machines. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.202; filed May 26, 1978, 3:30 pm: 1 IR 201; filed Feb 29, 1984, 10:10 am: 7 IR 932; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-5-14 Personnel monitoring in gamma radiography

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 14. (a) No licensee or registrant shall permit any individual to act as a radiographer or as a radiographer's assistant unless, at all times during radiographic operations, each such individual shall wear a direct reading pocket dosimeter and either film badge or a thermoluminescent dosimeter. Pocket dosimeters shall have a range from zero to at least 200 milliroentgens and shall be recharged daily or at the start of each shift. Each film badge or thermoluminescent dosimeter shall be assigned to and worn by only one individual.

(b) Pocket dosimeters shall be read and exposures recorded daily. An individual's film badge or thermoluminescent dosimeter shall be immediately processed if his pocket dosimeter is discharged beyond its range. Reports received from the film badge or thermoluminescent dosimeter processor and records of pocket dosimeter readings shall be maintained for inspection by the board until it authorizes their disposal.

(c) Pocket dosimeters shall be checked for correct response to radiation at periods not to exceed one year. Acceptable dosimeters shall read within plus or minus 30 percent of the true radiation exposure. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.203; filed May 26, 1978, 3:30 pm: 1 IR 202; filed Feb 29, 1984, 10:10 am: 7 IR 932; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-5-14.5 Supervision of radiographer assistants in gamma radiography

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 14.5. Whenever a radiographer's assistant uses radiographic exposure devices, sealed sources, or related source handling tools, or conducts radiation surveys required by 410 IAC 5-5-17(b) and (c) to determine that the sealed source has returned to the shielded position after an exposure, the radiographer's assistant shall be under the personal supervision of a radiographer. *(Indiana State Department of Health; 410 IAC 5-5-14.5; filed Feb 29, 1984, 10:10 am: 7 IR 933; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-5-15 Security during operation

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 15. During each radiographic operation, the radiographer or radiographer's assistant shall maintain a direct surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in 410 IAC 5-1, except:

(a) Where the high radiation area is equipped with a control device or alarm system as described in 410 IAC 5-4-11(c)(2), or

(b) Where the high radiation area is locked to protect against unauthorized or accidental entry. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.301; filed May 26, 1978, 3:30 pm: 1 IR 202; filed Feb 29, 1984, 10:10 am: 7 IR 933; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-5-16 Posting of operation areas

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 16. Notwithstanding any provisions in 410 IAC 5-4-12(c), areas in which radiography is being performed shall be conspicuously posted as required by 410 IAC 5-4-11(b) and (c)(1). *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.302; filed May 26, 1978, 3:30 pm: 1 IR 202; filed Feb 29, 1984, 10:10 am: 7 IR 933; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-5-17 Surveys; records

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 17. (a) No radiographic operation shall be conducted unless calibrated and operable radiation survey instrumentation as described in 410 IAC 5-5-9 is available and used at each site where radiographic exposures are made.

(b) A physical radiation survey shall be made after each radiographic exposure utilizing radiographic exposure devices or sealed sources of radioactive material to determine that the sealed source has been returned to its shielded position. The entire circumference of the radiographic exposure device shall be surveyed. If the radiographic exposure device has a source guide tube, the survey shall also include the guide tube.

(c) A physical radiation survey shall be made to determine that each sealed source is in its shielded position prior to securing the radiographic exposure device or storage container as specified in 410 IAC 5-5-5.

(d) A physical radiation survey shall be made after each radiographic exposure using radiation machines to determine that the machine is "off."

(e) Records shall be kept of the surveys required by 410 IAC 5-5-17(c). Such records shall be maintained for inspection by the board for 2 years after completion of the survey. If the survey was used to determine an individual's exposure, however, the

records of the survey shall be maintained until the board authorizes their disposition. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.303; filed May 26, 1978, 3:30 pm: 1 IR 202; filed Feb 29, 1984, 10:10 am: 7 IR 933; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-5-18 Temporary job site records

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 18. Each licensee or registrant conducting industrial radiography at a temporary site shall have the following records available at that site for inspection by the board:

(a) Appropriate license, (or certificate of registration) or equivalent document;
(b) Operating and emergency procedures;
(c) Applicable rules;
(d) Survey records required pursuant to 410 IAC 5-5-17 for the period of operation at the site;
(e) Daily pocket dosimeter records for the period of operation at the site; and
(f) The latest instrument calibration and leak test record for specific devices in use at the site. Acceptable records include tags or labels which are affixed to the device or survey meter. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.304; filed May 26, 1978, 3:30 pm: 1 IR 202; filed Feb 29, 1984, 10:10 am: 7 IR 934; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-5-19 Enclosed radiography; exemption; special requirements *(Repealed)*

Sec. 19. *(Repealed by Indiana State Department of Health; filed Feb 29, 1984, 10:10 am: 7 IR 829)*

410 IAC 5-5-20 Instruction of radiographers; scope

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 20. Subjects to be Covered During the Instruction of Radiographers

(I) Fundamentals of Radiation Safety
(A) Characteristics of radiation
(B) Units of radiation dose (mrem) and quantity of radioactivity (curie)
(C) Significance of radiation dose
  (1) Radiation protection standards
  (2) Biological effects of radiation
(D) Levels of radiation from sources of radiation
(E) Methods of controlling radiation dose
  (1) Working time
  (2) Working distances
  (3) Shielding
(II) Radiation Detection Instrumentation to be Used
(A) Use of radiation survey instruments
  (1) Operation
  (2) Calibration
  (3) Limitations
(B) Survey techniques
(C) Use of personnel monitoring equipment
  (1) Film badges

(2) Thermoluminescent dosimeters
(3) Pocket dosimeters
(III) Radiographic Equipment to be Used
(A) Remote handling equipment
(B) Radiographic exposure devices and sealed sources
(C) Storage containers
(D) Operation and control of x-ray equipment
(IV) The Requirements of Pertinent Federal and State Rules
(V) The Licensee's or Registrant's Written Operating and Emergency Procedures
(VI) Case Histories of Radiography Accidents *(Indiana State Department of Health; Rule HRH-2,PT E,Appendix A; filed May 26, 1978, 3:30 pm: 1 IR 203; filed Feb 29, 1984, 10:10 am: 7 IR 934; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

Rule 6. X-Rays in the Healing Arts *(Repealed)*

(Repealed by Indiana State Department of Health; filed Oct 29, 1993, 5:00 p.m.: 17 IR 392)

Rule 6.1. X-Rays in the Healing Arts

410 IAC 5-6.1-1 Incorporation by reference

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 1. The following documents are incorporated by reference as a part of this rule:
(1) 21 CFR 1020.30(c) (HHS publication FDA 88-8035, April 1988). Sales of the Code of Federal Regulations are handled exclusively by the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402. This document is available for public review at the department.
(2) 21 CFR Subchapter J (HHS publication FDA 88-8035, April 1988). Sales of the Code of Federal Regulations are handled exclusively by the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402. This document is available for public review at the department.
(3) "A Protocol for the Determination of Absorbed Dose from High Energy Photon and Electron Beams": Medical Physics; Vol. 10; No. 6; Nov/Dec 1983; pp. 741–771. Copies may be obtained by writing to: American Institute of Physics, Single Copy Sales, 500 Sunnyside Blvd., Woodbury, New York 11791. This document is available for public review at the department.

(Indiana State Department of Health; 410 IAC 5-6.1-1; filed Oct 29, 1993, 5:00 p.m.: 17 IR 356; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-6.1-2 "ABHP" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 2. As used in this rule, "ABHP" means the American Board of Health Physics. *(Indiana State Department of Health; 410 IAC 5-6.1-2; filed Oct 29, 1993, 5:00 p.m.: 17 IR 356; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-3 "ABMP" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 3. As used in this rule, "ABMP" means the American Board of Medical Physics. *(Indiana State Department of Health; 410 IAC 5-6.1-3; filed Oct 29, 1993, 5:00 p.m.: 17 IR 357; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-4 "ABR" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 4. As used in this rule, "ABR" means the American Board of Radiology. *(Indiana State Department of Health; 410 IAC 5-6.1-4; filed Oct 29, 1993, 5:00 p.m.: 17 IR 357; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-5 "Absorbed dose" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 5. As used in this rule, "absorbed dose" means that amount of radiation which has been absorbed, measured in grays or rads. *(Indiana State Department of Health; 410 IAC 5-6.1-5; filed Oct 29, 1993, 5:00 p.m.: 17 IR 357; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-6 "Accessible surface" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 6. As used in this rule, "accessible surface" means the external surface of the enclosure or housing provided by the manufacturer. *(Indiana State Department of Health; 410 IAC 5-6.1-6; filed Oct 29, 1993, 5:00 p.m.: 17 IR 357; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-7 "ACR" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 7. As used in this rule, "ACR" means the American College of Radiology. *(Indiana State Department of Health; 410 IAC 5-6.1-7; filed Oct 29, 1993, 5:00 p.m.: 17 IR 357; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-8 "Air-kerma" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 8. As used in this rule, "air-kerma" means the sum of the initial kinetic energies of all charged particles liberated by indirectly ionizing particles in a volume element of air of known mass. *(Indiana State Department of Health; 410 IAC 5-6.1-8; filed Oct 29, 1993, 5:00 p.m.: 17 IR 357; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-9 "Air-kerma rate" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 9. As used in this rule, "air-kerma rate" means the air-kerma in a time interval. *(Indiana State Department of Health; 410 IAC 5-6.1-9; filed Oct 29, 1993, 5:00 p.m.: 17 IR 357; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-10 "Air-kerma strength" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 10. As used in this rule, "air-kerma strength" means the product of air-kerma rate in free space and the square of the distance of the calibration point from the source center along the perpendicular bisector. *(Indiana State Department of Health; 410 IAC 5-6.1-10; filed Oct 29, 1993, 5:00 p.m.: 17 IR 357; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-11 "Aluminum equivalent" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 11. As used in this rule, "aluminum equivalent" means that thickness of type 1100 aluminum alloy (compounded of ninety-nine percent (99%) aluminum, minimum, and twelve-hundredths percent (0.12%) copper, minimum) which affords the same attenuation as the material in question, under the same conditions. *(Indiana State Department of Health; 410 IAC 5-6.1-11; filed Oct 29, 1993, 5:00 p.m.: 17 IR 357; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-12 "Applicator" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 12. As used in this rule, "applicator" means a structure which determines the extent of the treatment field at a given distance from the virtual source. *(Indiana State Department of Health; 410 IAC 5-6.1-12; filed Oct 29, 1993, 5:00 p.m.: 17 IR 357; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-13 "ARRT" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 13. As used in this rule, "ARRT" means the American Registry of Radiologic Technologists. *(Indiana State Department of Health; 410 IAC 5-6.1-13; filed Oct 29, 1993, 5:00 p.m.: 17 IR 357; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-14 "Attenuation block" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 14. As used in this rule, "attenuation block" means a block or stack of aluminum equivalent material having dimensions twenty (20) cm by twenty (20) cm by three and eight-tenths (3.8) cm. *(Indiana State Department of Health; 410 IAC 5-6.1-14; filed Oct 29, 1993, 5:00 p.m.: 17 IR 357; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-15 "Automatic exposure control" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 15. As used in this rule, "automatic exposure control" means a device which automatically controls one (1) or more technique factors in order to obtain at a preselected location the required quantity of radiation. *(Indiana State Department of Health; 410 IAC 5-6.1-15; filed Oct 29, 1993, 5:00 p.m.: 17 IR 357; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-16 "Beam axis" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 16. As used in this rule, "beam axis" means a line from the source through the centers of the x-ray fields. *(Indiana State Department of Health; 410 IAC 5-6.1-16; filed Oct 29, 1993, 5:00 p.m.: 17 IR 358; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-17 "Beam-limiting device" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 17. As used in this rule, "beam-limiting device" means a device which provides a means to restrict the dimensions of an x-ray field. *(Indiana State Department of Health; 410 IAC 5-6.1-17; filed Oct 29, 1993, 5:00 p.m.: 17 IR 358; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-18 "Beam monitoring system" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 18. As used in this rule, "beam monitoring system" means a system which detects and measures radiation present in the useful beam. *(Indiana State Department of Health; 410 IAC 5-6.1-18; filed Oct 29, 1993, 5:00 p.m.: 17 IR 358; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-19 "Beam scattering filter" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 19. As used in this rule, "beam scattering filter" means a filter used to scatter a beam of electrons. *(Indiana State Department of Health; 410 IAC 5-6.1-19; filed Oct 29, 1993, 5:00 p.m.: 17 IR 358; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-20 "Blocking tray" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 20. As used in this rule, "blocking tray" means a device attached to the radiation head to support auxiliary beam-limiting material. *(Indiana State Department of Health; 410 IAC 5-6.1-20; filed Oct 29, 1993, 5:00 p.m.: 17 IR 358; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-21 "Calibration" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 21. As used in this rule, "calibration" means the determination of any of the following:
(1) The exposure or reading of an instrument relative to a known exposure or air-kerma.
(2) The exposure rate or air-kerma rate of the output of an x-ray or electron system.
(3) The absorbed dose rate from an x-ray or electron system.
(4) The air-kerma strength of a radioactive sealed source.
(Indiana State Department of Health; 410 IAC 5-6.1-21; filed Oct 29, 1993, 5:00 p.m.: 17 IR 358; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-6.1-22 "Central axis" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 22. As used in this rule, "central axis" means the line passing through the center of an x-ray system's virtual source and the center of the plane figure formed by the edges of the first beam-limiting device. *(Indiana State Department of Health; 410 IAC 5-6.1-22; filed Oct 29, 1993, 5:00 p.m.: 17 IR 358; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-23 "Certified component" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 23. As used in this rule, "certified component" means a component of an x-ray system which meets the requirements of 21 CFR Subchapter J. *(Indiana State Department of Health; 410 IAC 5-6.1-23; filed Oct 29, 1993, 5:00 p.m.: 17 IR 358; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-24 "Certified system" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 24. As used in this rule, "certified system" means any x-ray system which has one (1) or more certified components. *(Indiana State Department of Health; 410 IAC 5-6.1-24; filed Oct 29, 1993, 5:00 p.m.: 17 IR 358; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-25 "cm" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 25. As used in this rule, "cm" means centimeter. *(Indiana State Department of Health; 410 IAC 5-6.1-25; filed Oct 29, 1993, 5:00 p.m.: 17 IR 358; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-26 "Coefficient of variation" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 26. As used in this rule, "coefficient of variation" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{x} = \frac{1}{x}\left[\sum_{i=1}^{n} \frac{(X_i - X)}{n-1}\right]^{\frac{1}{2}}$$

Where: C = Coefficient of variation
s = Estimated standard deviation of the population
X = Mean value of observations in sample
X_i = Value of the ith observation in sample
n = Number of observations in sample

(Indiana State Department of Health; 410 IAC 5-6.1-26; filed Oct 29, 1993, 5:00 p.m.: 17 IR 358; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-6.1-27 "Commissioner" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 27. As used in this rule, "commissioner" means the department commissioner or his or her authorized representative. *(Indiana State Department of Health; 410 IAC 5-6.1-27; filed Oct 29, 1993, 5:00 p.m.: 17 IR 359; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-28 "Constancy check" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 28. As used in this rule, "constancy check" means a weekly procedure performed to assure that a previous calibration continues to be valid. *(Indiana State Department of Health; 410 IAC 5-6.1-28; filed Oct 29, 1993, 5:00 p.m.: 17 IR 359; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-29 "Contact therapy system" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 29. As used in this rule, "contact therapy system" means an x-ray system used for therapy with the x-ray tube port placed in contact with or within five (5) cm of the surface being treated. *(Indiana State Department of Health; 410 IAC 5-6.1-29; filed Oct 29, 1993, 5:00 p.m.: 17 IR 359; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-30 "Contrast ratio" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 30. As used in this rule, "contrast ratio" means the illumination inside the area three (3) mm from the edge of the light field (I_1), divided by the illumination outside the area three (3) mm from the edge of the light field (I_2). It is calculated using the following equation:

$$\text{Contrast ratio} = I_1/I_2$$

(Indiana State Department of Health; 410 IAC 5-6.1-30; filed Oct 29, 1993, 5:00 p.m.: 17 IR 359; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-6.1-31 "Control panel" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 31. As used in this rule, "control panel" means that part of the x-ray system or electron therapy system control upon which are mounted the switches, knobs, push buttons, and other hardware necessary for manually setting the technique factors. *(Indiana State Department of Health; 410 IAC 5-6.1-31; filed Oct 29, 1993, 5:00 p.m.: 17 IR 359; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-32 "Cooling curve" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 32. As used in this rule, "cooling curve" means the graphical relationship between heat stored and cooling time for a tube. *(Indiana State Department of Health; 410 IAC 5-6.1-32; filed Oct 29, 1993, 5:00 p.m.: 17 IR 359; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-33 "Dead-man switch" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 33. As used in this rule, "dead-man switch" means a control switch constructed so that its circuit remains closed only as long as the operator maintains pressure on the switch. *(Indiana State Department of Health; 410 IAC 5-6.1-33; filed Oct 29, 1993, 5:00 p.m.: 17 IR 359; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-34 "Department" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 34. As used in this rule, "department" means the Indiana state department of health or its authorized representative. *(Indiana State Department of Health; 410 IAC 5-6.1-34; filed Oct 29, 1993, 5:00 p.m.: 17 IR 359; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-35 "Diagnostic source assembly" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 35. As used in this rule, "diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached. *(Indiana State Department of Health; 410 IAC 5-6.1-35; filed Oct 29, 1993, 5:00 p.m.: 17 IR 359; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-36 "Diagnostic x-ray system" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 36. As used in this rule, "diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human body for diagnosis or visualization. *(Indiana State Department of Health; 410 IAC 5-6.1-36; filed Oct 29, 1993, 5:00 p.m.: 17 IR 359; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-37 "Direct scattered radiation" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 37. As used in this rule, "direct scattered radiation" means that radiation which has changed direction only by virtue of its contact with the materials irradiated by the useful beam. *(Indiana State Department of Health; 410 IAC 5-6.1-37; filed Oct 29, 1993, 5:00 p.m.: 17 IR 360; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-38 "Dose monitoring system" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 38. As used in this rule, "dose monitoring system" means a system of devices for the detection, measurement, and display of quantities of radiation. *(Indiana State Department of Health; 410 IAC 5-6.1-38; filed Oct 29, 1993, 5:00 p.m.: 17 IR 360; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-39 "Dose monitor unit" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 39. As used in this rule, "dose monitor unit" means a unit response from the dose monitoring system from which the absorbed dose can be calculated. *(Indiana State Department of Health; 410 IAC 5-6.1-39; filed Oct 29, 1993, 5:00 p.m.: 17 IR 360; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-40 "Field emission equipment" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 40. As used in this rule, "field emission equipment" means equipment which uses an x-ray tube in which electrons are emitted from the cathode due solely to an electromagnetic field. *(Indiana State Department of Health; 410 IAC 5-6.1-40; filed Oct 29, 1993, 5:00 p.m.: 17 IR 360; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-41 "Field size" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 41. As used in this rule, "field size" means the dimensions along the major axes of an area in a plane perpendicular to the specified direction of the beam of incident radiation at the normal treatment distance and defined by the intersection of the major axes and the fifty percent (50%) isodose line, for diagnostic applications. For therapeutic x-ray applications, "field size" means the two (2) longest perpendicular lengths, in combination, of a figure defined by the fifty percent (50%) isodose line at a cross section of the x-ray beam, measured in the plane perpendicular to the central axis of the x-ray beam at the normal treatment distance. In either case, field size is determined when material is placed in the beam so that maximum dose is achieved at the normal treatment distance. *(Indiana State Department of Health; 410 IAC 5-6.1-41; filed Oct 29, 1993, 5:00 p.m.: 17 IR 360; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-42 "Filter" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 42. As used in this rule, "filter" means material placed in the useful beam to absorb selected radiation. *(Indiana State Department of Health; 410 IAC 5-6.1-42; filed Oct 29, 1993, 5:00 p.m.: 17 IR 360; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-43 "Fluoroscopic imaging assembly" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 43. As used in this rule, "fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the following:
(1) A diagnostic source assembly.

(2) An image receptor.
(3) An image intensifier.
(4) A spot-film device.
(5) Electrical interlocks.
(6) Appurtenances.
(Indiana State Department of Health; 410 IAC 5-6.1-43; filed Oct 29, 1993, 5:00 p.m.: 17 IR 360; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-6.1-44 "Focal spot" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 44. As used in this rule, "focal spot" means that area of the x-ray tube anode struck by electrons from the cathode to produce the useful beam. *(Indiana State Department of Health; 410 IAC 5-6.1-44; filed Oct 29, 1993, 5:00 p.m.: 17 IR 360; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-45 "Gantry" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 45. As used in this rule, "gantry" means that part of a radiation therapy system supporting and which allows movement of the radiation head. *(Indiana State Department of Health; 410 IAC 5-6.1-45; filed Oct 29, 1993, 5:00 p.m.: 17 IR 360; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-46 "General purpose radiographic x-ray system" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 46. As used in this rule, "general purpose radiographic x-ray system" means any radiographic x-ray system which is used, or can be used, to visualize or measure any anatomical region, except fluoroscopic, intraoral dental, mammographic, special purpose, therapy, and veterinary x-ray systems. *(Indiana State Department of Health; 410 IAC 5-6.1-46; filed Oct 29, 1993, 5:00 p.m.: 17 IR 360; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-47 "Gonadal shield" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 47. As used in this rule, "gonadal shield" means a secondary protective barrier for the testes or ovaries. *(Indiana State Department of Health; 410 IAC 5-6.1-47; filed Oct 29, 1993, 5:00 p.m.: 17 IR 361; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-48 "Gray" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 48. As used in this rule, "gray" means a unit of measurement of radiation absorption. One (1) gray is equal to one (1) joule per kilogram, or one hundred (100) radiation absorbed doses. *(Indiana State Department of Health; 410 IAC 5-6.1-48; filed Oct 29, 1993, 5:00 p.m.: 17 IR 361; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-49 "Half-value layer" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 49. As used in this rule, "half-value layer" means the thickness of a specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half (1/2) of its original value. The contribution of all scattered radiation, other than any which might be present initially in the radiation beam concerned, is excluded from this definition. *(Indiana State Department of Health; 410 IAC 5-6.1-49; filed Oct 29, 1993, 5:00 p.m.: 17 IR 361; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-50 "Healing arts screening" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 50. As used in this rule, "healing arts screening" means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment. *(Indiana State Department of Health; 410 IAC 5-6.1-50; filed Oct 29, 1993, 5:00 p.m.: 17 IR 361; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-51 "Image intensifier" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 51. As used in this rule, "image intensifier" means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density. *(Indiana State Department of Health; 410 IAC 5-6.1-51; filed Oct 29, 1993, 5:00 p.m.: 17 IR 361; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-52 "Image receptor" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 52. As used in this rule, "image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations. *(Indiana State Department of Health; 410 IAC 5-6.1-52; filed Oct 29, 1993, 5:00 p.m.: 17 IR 361; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep*

11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-6.1-53 "Interruption" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 53. As used in this rule, "interruption" means temporary cessation of irradiation with the possibility that irradiation will be resumed without resetting the operating conditions on the x-ray system control panel. *(Indiana State Department of Health; 410 IAC 5-6.1-53; filed Oct 29, 1993, 5:00 p.m.: 17 IR 361; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-54 "Irradiation" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 54. As used in this rule, "irradiation" means the exposure of matter to ionizing radiation. *(Indiana State Department of Health; 410 IAC 5-6.1-54; filed Oct 29, 1993, 5:00 p.m.: 17 IR 361; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-55 "Isocenter" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 55. As used in this rule, "isocenter" means a fixed point in space located at the center of the smallest sphere through which the central axis of the x-ray beam passes in all conditions. *(Indiana State Department of Health; 410 IAC 5-6.1-55; filed Oct 29, 1993, 5:00 p.m.: 17 IR 361; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-56 "Isodose line" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 56. As used in this rule, "isodose line" means a line, usually in a plane, along which the absorbed dose is constant. *(Indiana State Department of Health; 410 IAC 5-6.1-56; filed Oct 29, 1993, 5:00 p.m.: 17 IR 361; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-57 "kV" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 57. As used in this rule, "kV" means kilovolts. *(Indiana State Department of Health; 410 IAC 5-6.1-57; filed Oct 29, 1993, 5:00 p.m.: 17 IR 361; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-58 "kVp" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 58. As used in this rule, "kVp" means kilovolts peak or peak tube potential, which is the maximum possible voltage drop across the tube during an exposure, measured in kV. *(Indiana State Department of Health; 410 IAC 5-6.1-58; filed Oct 29, 1993, 5:00 p.m.: 17 IR 362; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-59 "kWs" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 59. As used in this rule, "kWs" means kilowatt-second. *(Indiana State Department of Health; 410 IAC 5-6.1-59; filed Oct 29, 1993, 5:00 p.m.: 17 IR 362; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-60 "Lead equivalent" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 60. As used in this rule, "lead equivalent" means that thickness of lead which affords the same filtration of an x-ray beam as the material in question under the same conditions. *(Indiana State Department of Health; 410 IAC 5-6.1-60; filed Oct 29, 1993, 5:00 p.m.: 17 IR 362; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-61 "Leakage radiation" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 61. As used in this rule, "leakage radiation" means all radiation emanating from the diagnostic or therapeutic source assembly except the useful beam and that radiation produced when the exposure switch or timer is not activated. *(Indiana State Department of Health; 410 IAC 5-6.1-61; filed Oct 29, 1993, 5:00 p.m.: 17 IR 362; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-62 "Leakage technique factors" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 62. As used in this rule, "leakage technique factors" means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are as follows:

(1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum rated kVp, and the maximum rated number of exposures per hour at the maximum rated kVp, with a charge per exposure of ten (10) mAs or the minimum obtainable from the system, whichever is larger.

(2) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum rated kVp and the maximum rated number of x-ray pulses per hour for operation at the maximum rated kVp.

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

(Indiana State Department of Health; 410 IAC 5-6.1-62; filed Oct 29, 1993, 5:00 p.m.: 17 IR 362; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-6.1-63 "Lux" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 63. As used in this rule, "lux" means a unit of measurement for illumination equal to one (1) lumen per square meter. *(Indiana State Department of Health; 410 IAC 5-6.1-63; filed Oct 29, 1993, 5:00 p.m.: 17 IR 362; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-64 "mA" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 64. As used in this rule, "mA" means milliampere. *(Indiana State Department of Health; 410 IAC 5-6.1-64; filed Oct 29, 1993, 5:00 p.m.: 17 IR 362; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-65 "Mammographer" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 65. As used in this rule, "mammographer" means the diagnostic x-ray machine operator with specialized training and/or education in performing mammography. *(Indiana State Department of Health; 410 IAC 5-6.1-65; filed Oct 29, 1993, 5:00 p.m.: 17 IR 362; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-66 "mAs" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 66. As used in this rule, "mAs" means milliampere-second. *(Indiana State Department of Health; 410 IAC 5-6.1-66; filed Oct 29, 1993, 5:00 p.m.: 17 IR 362; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-67 "MeV" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 67. As used in this rule, "MeV" means one million (10^6) electron volts. *(Indiana State Department of Health; 410 IAC 5-6.1-67; filed Oct 29, 1993, 5:00 p.m.: 17 IR 362; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted*

filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-6.1-68 "Misadministration" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 68. As used in this rule, "misadministration" means the use of an x-ray therapy system or an electron therapy system as follows:

(1) Administration of radiation to the wrong individual or to the wrong treatment site.

(2) Administration of the wrong mode of treatment (electrons versus x-rays and/or stationary versus moving beam) to an individual.

(3) When a treatment prescribed for any treatment site consists of three (3) or fewer fractions, the total radiation dose actually administered at the treatment site differs from that prescribed for the site by a practitioner of the healing arts by more than ten percent (10%) of the total radiation dose prescribed for that treatment site.

(4) When the total weekly radiation dose actually administered at any treatment site differs from that prescribed for the site by a practitioner of the healing arts by more than thirty percent (30%) of the total weekly radiation dose prescribed for that treatment site.

(5) When the total radiation dose actually administered at any treatment site differs from that prescribed for the site by a practitioner of the healing arts by more than twenty percent (20%) of the total radiation dose prescribed for that treatment site. *(Indiana State Department of Health; 410 IAC 5-6.1-68; filed Oct 29, 1993, 5:00 p.m.: 17 IR 362; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-69 "mm" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 69. As used in this rule, "mm" means millimeter. *(Indiana State Department of Health; 410 IAC 5-6.1-69; filed Oct 29, 1993, 5:00 p.m.: 17 IR 363; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-70 "Mobile x-ray equipment" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 70. As used in this rule, "mobile x-ray equipment" means x-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled. *(Indiana State Department of Health; 410 IAC 5-6.1-70; filed Oct 29, 1993, 5:00 p.m.: 17 IR 363; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-71 "Moving beam therapy" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 71. As used in this rule, "moving beam therapy" means radiation therapy wherein the useful beam or the patient is moved during irradiation. Moving beam therapy includes arc therapy, skip therapy, and rotational therapy. *(Indiana State Department of Health; 410 IAC 5-6.1-71; filed Oct 29, 1993, 5:00 p.m.: 17 IR 363; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-*

410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-6.1-72 "mR" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 72. As used in this rule, "mR" means milliroentgen. *(Indiana State Department of Health; 410 IAC 5-6.1-72; filed Oct 29, 1993, 5:00 p.m.: 17 IR 363; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-73 "Normal treatment distance" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 73. As used in this rule, "normal treatment distance" means the following:

(1) For electron irradiation, the virtual source-to-surface distance along the central axis of the useful beam as specified by the manufacturer for the applicator.

(2) For x-ray irradiation, the virtual source-to-isocenter distance along the central axis of the useful beam.

(3) For nonisocentric x-ray equipment, the normal treatment distance shall be that specified by the manufacturer.

(Indiana State Department of Health; 410 IAC 5-6.1-73; filed Oct 29, 1993, 5:00 p.m.: 17 IR 363; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-6.1-74 "Patient" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 74. As used in this rule, "patient" means an individual subjected to examination, diagnosis, or treatment by a practitioner of the healing arts. *(Indiana State Department of Health; 410 IAC 5-6.1-74; filed Oct 29, 1993, 5:00 p.m.: 17 IR 363; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-75 "Phantom" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 75. As used in this rule, "phantom" means a device which has characteristics similar to specific human or animal tissue with respect to the attenuation and scattering of radiation x-rays. *(Indiana State Department of Health; 410 IAC 5-6.1-75; filed Oct 29, 1993, 5:00 p.m.: 17 IR 363; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-76 "Portable x-ray equipment" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 76. As used in this rule, "portable x-ray equipment" means x-ray equipment designed to be hand-carried. *(Indiana State Department of Health; 410 IAC 5-6.1-76; filed Oct 29, 1993, 5:00 p.m.: 17 IR 363; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-*

IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-6.1-77 "Position indicating device" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 77. As used in this rule, "position indicating device" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite SSD. It may also serve as a beam-limiting device. *(Indiana State Department of Health; 410 IAC 5-6.1-77; filed Oct 29, 1993, 5:00 p.m.: 17 IR 363; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-78 "Practitioner of the healing arts" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35; IC 25-10; IC 25-14; IC 25-19; IC 25-22.5

Sec. 78. As used in this rule, "practitioner of the healing arts" means one (1) of the following:
(1) A person licensed to practice medicine or osteopathic medicine by IC 25-22.5.
(2) A person licensed to practice dentistry by IC 25-14.
(3) A person licensed to practice chiropractic medicine by IC 25-10.
(4) A person licensed to practice podiatric medicine by IC 25-19.
(5) A person who is a corporate physician directly responsible for the health of Indiana employees and licensed to practice medicine in another state.
(Indiana State Department of Health; 410 IAC 5-6.1-78; filed Oct 29, 1993, 5:00 p.m.: 17 IR 364; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-6.1-79 "Primary dose monitoring system" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 79. As used in this rule, "primary dose monitoring system" means a system which will monitor the useful beam and automatically terminate irradiation when the preselected number of dose monitor units have been acquired. *(Indiana State Department of Health; 410 IAC 5-6.1-79; filed Oct 29, 1993, 5:00 p.m.: 17 IR 364; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-80 "Primary protective barrier" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 80. As used in this rule, "primary protective barrier" means a protective barrier of material which is placed in the useful radiation beam to reduce radiation exposure. The term does not include filters. *(Indiana State Department of Health; 410 IAC 5-6.1-80; filed Oct 29, 1993, 5:00 p.m.: 17 IR 364; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-81 "Protective apron" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 81. As used in this rule, "protective apron" means an apron made of radiation absorbing materials used as a secondary protective barrier. *(Indiana State Department of Health; 410 IAC 5-6.1-81; filed Oct 29, 1993, 5:00 p.m.: 17 IR 364; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-82 "Protective barrier" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 82. As used in this rule, "protective barrier" means a primary or secondary protective barrier composed of radiation absorbing material used to reduce radiation exposure. *(Indiana State Department of Health; 410 IAC 5-6.1-82; filed Oct 29, 1993, 5:00 p.m.: 17 IR 364; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-83 "Protective glove" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 83. As used in this rule, "protective glove" means a glove made of radiation absorbing materials used as a secondary protective barrier. *(Indiana State Department of Health; 410 IAC 5-6.1-83; filed Oct 29, 1993, 5:00 p.m.: 17 IR 364; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-84 "Radiation detector" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 84. As used in this rule, "radiation detector" means a device which, in the presence of radiation, provides a signal or other indication suitable for use in measuring incident radiation. *(Indiana State Department of Health; 410 IAC 5-6.1-84; filed Oct 29, 1993, 5:00 p.m.: 17 IR 364; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-85 "Radiation head" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 85. As used in this rule, "radiation head" means the structure from which the useful beam emerges. *(Indiana State Department of Health; 410 IAC 5-6.1-85; filed Oct 29, 1993, 5:00 p.m.: 17 IR 364; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-86 "Radiation therapy simulation system" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 86. As used in this rule, "radiation therapy simulation system" means a radiographic or fluoroscopic x-ray system used to target a patient for therapeutic radiation by determining the position and size of the therapeutic irradiation field. *(Indiana State Department of Health; 410 IAC 5-6.1-86; filed Oct 29, 1993, 5:00 p.m.: 17 IR 364; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR*

4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-6.1-87 "Radiographic imaging system" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 87. As used in this rule, "radiographic imaging system" means any x-ray system capable of producing a radiograph. *(Indiana State Department of Health; 410 IAC 5-6.1-87; filed Oct 29, 1993, 5:00 p.m.: 17 IR 364; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-88 "Rating" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 88. As used in this rule, "rating" means the operating limits specified by the manufacturer of x-ray equipment or a component thereof. *(Indiana State Department of Health; 410 IAC 5-6.1-88; filed Oct 29, 1993, 5:00 p.m.: 17 IR 364; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-89 "Scattered radiation" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 89. As used in this rule, "scattered radiation" means that radiation which has changed direction by virtue of its contact with matter after emerging from the radiation head. *(Indiana State Department of Health; 410 IAC 5-6.1-89; filed Oct 29, 1993, 5:00 p.m.: 17 IR 365; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-90 "Secondary dose monitoring system" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 90. As used in this rule, "secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary system. *(Indiana State Department of Health; 410 IAC 5-6.1-90; filed Oct 29, 1993, 5:00 p.m.: 17 IR 365; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-91 "Secondary protective barrier" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 91. As used in this rule, "secondary protective barrier" means a protective barrier sufficient to attenuate stray radiation as required, such as a protective apron, protective gloves, or a gonadal shield. *(Indiana State Department of Health; 410 IAC 5-6.1-91; filed Oct 29, 1993, 5:00 p.m.: 17 IR 365; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-92 "Shutter" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 92. As used in this rule, "shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly. *(Indiana State Department of Health; 410 IAC 5-6.1-92; filed Oct 29, 1993, 5:00 p.m.: 17 IR 365; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-93 "SID" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 93. As used in this rule, "SID" means source-image receptor distance, which is the distance from the source to the center of the input surface of the image receptor. *(Indiana State Department of Health; 410 IAC 5-6.1-93; filed Oct 29, 1993, 5:00 p.m.: 17 IR 365; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-94 "Source" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 94. As used in this rule, "source" means the focal spot of the x-ray tube. *(Indiana State Department of Health; 410 IAC 5-6.1-94; filed Oct 29, 1993, 5:00 p.m.: 17 IR 365; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-95 "Special purpose x-ray system" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 95. As used in this rule, "special purpose x-ray system" means a diagnostic x-ray system designed for use on specific body regions, for example, extremities, head or neck, thoracic, abdominal, or for specialized applications, for example, pantomographic, tomographic, or cystographic systems. Specifically excluded from this definition are intraoral dental and mammographic x-ray equipment. *(Indiana State Department of Health; 410 IAC 5-6.1-95; filed Oct 29, 1993, 5:00 p.m.: 17 IR 365; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-96 "Spot check" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 96. As used in this rule, "spot check" means a monthly procedure performed to assure that a previous calibration continues to be valid. *(Indiana State Department of Health; 410 IAC 5-6.1-96; filed Oct 29, 1993, 5:00 p.m.: 17 IR 365; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-97 "Spot film" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 97. As used in this rule, "spot film" means a radiograph made during a fluoroscopic procedure. *(Indiana State Department of Health; 410 IAC 5-6.1-97; filed Oct 29, 1993, 5:00 p.m.: 17 IR 365; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-98 "Spot film device" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 98. As used in this rule, "spot film device" means a device used to transport and/or position an image receptor between the x-ray source and a fluoroscopic image receptor or image intensifier to make a radiograph, including a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph. *(Indiana State Department of Health; 410 IAC 5-6.1-98; filed Oct 29, 1993, 5:00 p.m.: 17 IR 365; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-99 "SSD" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 99. As used in this rule, "SSD" means the distance between the source and the skin of the patient. *(Indiana State Department of Health; 410 IAC 5-6.1-99; filed Oct 29, 1993, 5:00 p.m.: 17 IR 365; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-100 "Stationary beam therapy" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 100. As used in this rule, "stationary beam therapy" means radiation therapy without relative displacement of the useful beam and the patient during irradiation. *(Indiana State Department of Health; 410 IAC 5-6.1-100; filed Oct 29, 1993, 5:00 p.m.: 17 IR 366; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-101 "Stationary x-ray equipment" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 101. As used in this rule, "stationary x-ray equipment" means x-ray equipment installed at a fixed location. *(Indiana State Department of Health; 410 IAC 5-6.1-101; filed Oct 29, 1993, 5:00 p.m.: 17 IR 366; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-102 "Target" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 102. As used in this rule, "target" means that part of a radiation head which by design intercepts a beam of accelerated particles with subsequent emission of other radiation. *(Indiana State Department of Health; 410 IAC 5-6.1-102; filed Oct 29, 1993, 5:00 p.m.: 17 IR 366; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-103 "Technique factors" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 103. As used in this rule, "technique factors" means the conditions of operation. They are as follows:

(1) For capacitor energy storage equipment, kVp and mAs.

(2) For field emission equipment rated for pulsed operation, kVp and the number of x-ray pulses.

(3) For all other equipment, kVp and mAs or kVp, mA, and exposure time in seconds.

(Indiana State Department of Health; 410 IAC 5-6.1-103; filed Oct 29, 1993, 5:00 p.m.: 17 IR 366; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-6.1-104 "Termination of irradiation" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 104. As used in this rule, "termination of irradiation" means cessation of x-ray exposure in a manner which requires that the x-ray control be reset before further exposures can be made at the control panel. *(Indiana State Department of Health; 410 IAC 5-6.1-104; filed Oct 29, 1993, 5:00 p.m.: 17 IR 366; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-105 "Traceable" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 105. As used in this rule, "traceable" means that a quantity or a measurement has been compared to a national standard through intermediate steps and that all comparisons have been documented. *(Indiana State Department of Health; 410 IAC 5-6.1-105; filed Oct 29, 1993, 5:00 p.m.: 17 IR 366; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-106 "Tube" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 106. As used in this rule, "tube" means an electron tube used to produce x-rays. *(Indiana State Department of Health; 410 IAC 5-6.1-106; filed Oct 29, 1993, 5:00 p.m.: 17 IR 366; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-107 "Tube housing assembly" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 107. As used in this rule, "tube housing assembly" means the housing with the tube installed which may include a high voltage and/or filament transformer and other appurtenances. *(Indiana State Department of Health; 410 IAC 5-6.1-107; filed Oct 29, 1993, 5:00 p.m.: 17 IR 366; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-108 "Tube rating chart" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 108. As used in this rule, "tube rating chart" means a set of curves which specify the limits of operation for the tube in terms of technique factors as rated by the manufacturer. *(Indiana State Department of Health; 410 IAC 5-6.1-108; filed Oct 29, 1993, 5:00 p.m.: 17 IR 366; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-109 "Useful beam" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 109. As used in this rule, "useful beam" means those x-rays emitted from the aperture of a beam-limiting device. *(Indiana State Department of Health; 410 IAC 5-6.1-109; filed Oct 29, 1993, 5:00 p.m.: 17 IR 366; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-110 "Veterinarian" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 110. As used in this rule, "veterinarian" means a person licensed to practice veterinary medicine under IC 15-5-1.1 *[IC 15-5 was repealed by P.L.2-2008, SECTION 83, effective July 1, 2008.]*. *(Indiana State Department of Health; 410 IAC 5-6.1-110; filed Oct 29, 1993, 5:00 p.m.: 17 IR 366; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-111 "Virtual source" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 111. As used in this rule, "virtual source" means a point from which radiation appears to originate. *(Indiana State Department of Health; 410 IAC 5-6.1-111; filed Oct 29, 1993, 5:00 p.m.: 17 IR 367; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-112 "Visible area" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 112. As used in this rule, "visible area" means that portion of the image receptor which x-rays are bombarding to produce a visible image. *(Indiana State Department of Health; 410 IAC 5-6.1-112; filed Oct 29, 1993, 5:00 p.m.: 17 IR 367; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-113 "Wedge filter" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 113. As used in this rule, "wedge filter" means a filter which can affect progressive, stepless attenuation of all or part of the useful beam. *(Indiana State Department of Health; 410 IAC 5-6.1-113; filed Oct 29, 1993, 5:00 p.m.: 17 IR 367; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-114 "x-ray" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 114. As used in this rule, "x-ray" means electromagnetic radiation of energy equal to or greater than one hundred twenty-four (124) electron volts produced by bombardment of a target with electrons in a vacuum. *(Indiana State Department of Health; 410 IAC 5-6.1-114; filed Oct 29, 1993, 5:00 p.m.: 17 IR 367; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-115 "x-ray control" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 115. As used in this rule, "x-ray control" means a device which controls input power to the x-ray high voltage generator or the tube, including devices such as timers, phototimers, automatic brightness stabilizers, and similar devices which control the technique factors of an x-ray exposure. *(Indiana State Department of Health; 410 IAC 5-6.1-115; filed Oct 29, 1993, 5:00 p.m.: 17 IR 367; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-116 "x-ray equipment" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 116. As used in this rule, "x-ray equipment" means an x-ray system, subsystem, or component thereof. *(Indiana State Department of Health; 410 IAC 5-6.1-116; filed Oct 29, 1993, 5:00 p.m.: 17 IR 367; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-117 "x-ray system" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 117. As used in this rule, "x-ray system" means an assemblage of components for the controlled production of x-rays. At a minimum, an x-ray system includes the following:

(1) An x-ray high voltage generator.
(2) An x-ray control.
(3) A tube housing assembly.
(4) A beam-limiting device.
(5) Necessary supporting structures.
(6) Appurtenances.

Included in an x-ray system are mobile x-ray equipment, portable x-ray equipment, particle accelerators, and stationary x-ray equipment. *(Indiana State Department of Health; 410 IAC 5-6.1-117; filed Oct 29, 1993, 5:00 p.m.: 17 IR 367; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-118 General requirements for operation of x-ray equipment

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 118. (a) All individuals associated with the operation of x-ray equipment shall comply with applicable sections of 410 IAC 5-4-2, 410 IAC 5-4-3, 410 IAC 5-4-10, and this rule.

(b) The registrant shall be responsible for directing the operation of those x-ray systems under his or her administrative control. The registrant or the registrant's agent shall comply with this section in the operation of such x-ray systems.

(c) At intervals prescribed in this rule, all new and existing facilities shall be surveyed by a diagnostic imaging physicist, radiation oncology physicist, health physicist, or x-ray machine inspector approved by the department. Such surveys shall also be performed after any change in the facility or equipment which might cause a significant increase in radiation hazard. The survey shall be done before the x-ray system is used for diagnostic purposes, and an evaluation report, including all violations of this rule, on a form acceptable to the commissioner must be completed by the physicist or inspector and a copy forwarded to the registrant and to the commissioner within sixty (60) days of completion of the survey. The cost of this evaluation must be negotiated between the physicist or inspector and the practitioner of the healing arts or registrant and will not be borne by the department.

(d) For each x-ray system, a notice of compliance with this rule, supplied by or approved by the commissioner, shall be prominently displayed on or near the x-ray control panel. This notice must indicate the date of full compliance and be signed by the physicist or inspector. For fluoroscopy systems, this notice may incorporate the entrance exposure posting requirement of section 119(k)(6) of this rule.

(e) For each x-ray facility, a notice of compliance with this rule, supplied by or approved by the commissioner, shall be prominently displayed in an area readily accessible to patients and visitors. This notice must indicate the date of full compliance and be signed by the physicist or inspector.

(f) At the intervals prescribed for facility inspections in this rule, the registrant shall be responsible for completing an x-ray machine registration application form. A diagnostic imaging physicist, radiation oncology physicist, health physicist, or x-ray machine inspector approved by the department shall be responsible for verifying that all information on the application is correct, and the form shall be submitted to the commissioner as part of the physicist's or inspector's evaluation report.

(g) On the effective date of this rule, in order to practice as a diagnostic imaging physicist, radiation oncology physicist, health physicist, or x-ray machine inspector in accordance with this rule, an individual must be approved by the department in accordance with subsection (h), (i), (j), or (k).

(h) In order to be approved to practice as a diagnostic imaging physicist, an individual must be certified by the ABR in diagnostic radiological physics or radiological physics or the ABMP in diagnostic imaging physics or shall possess equivalent qualifications as determined by the physicist review committee established in subsection (l). In determining equivalency in accordance with this section, the physicist review committee shall determine the following:

(1) The individual shall hold a bachelor's degree in physics or applied physics or physical science.

(2) The individual shall hold a master's or doctoral degree in physics or medical physics or a physical science with the equivalent of a physics minor.

(3) The individual shall have completed formal course work in the biological sciences.

(4) The individual shall have at least three (3) years of full-time active work experience in diagnostic or radiological physics under the direction of a diagnostic or radiological physicist certified by the ABR or ABMP or a radiologist certified by the ABR.

(5) The individual shall provide as references the names of a radiologist certified by the ABR and a diagnostic or radiological physicist certified by the ABR or ABMP, both of whom are familiar with the individual's training. At least one (1) of the two (2) references shall have directed the individual's work in accordance with subdivision (4).

In addition, the applicant must demonstrate to the physicist review committee that he or she is qualified to provide oversight for the establishment and conduct of a mammography quality assurance program required by section 127 of this rule. In determining qualifications in accordance with this subsection, the physicist review committee shall do the following:

(6) Determine that the individual has formal training or experience in evaluation of mammography systems, including performing, recording, and interpreting the results of required quality control checks.

(7) Determine that the individual has adequate testing equipment available to perform the quality control checks required by section 127 of this rule.

(8) Review a sample of a mammographic x-ray facility evaluation report prepared and submitted by the individual as part of their determination of his or her qualifications.

(i) On the effective date of this rule, any individual who has been approved previously by the department to practice as a qualified radiation therapy physicist is automatically approved to practice as a radiation oncology physicist. However, after the effective date of this rule, all other persons must be certified by the ABR in therapeutic radiological physics or radiological physics or the ABMP in radiation oncology physics or shall possess equivalent qualifications as determined by the physicist review committee established in subsection (l), in order to be approved to practice as a radiation oncology physicist. In determining equivalency in accordance with this subsection, the physicist review committee shall determine the following:

(1) The individual shall hold a bachelor's degree in physics or applied physics or a physical science.

(2) The individual shall hold a master's or doctoral degree in physics or medical physics or a physical science with the equivalent of a physics minor.

(3) The individual shall have completed formal course work in the biological sciences.

(4) The individual shall have at least three (3) years of full-time active work experience in radiation oncology physics, under the direction of a radiation oncology physicist or radiological physicist certified by the ABR or ABMP or a radiation oncology physician certified by the ABR.

(5) The individual shall provide as references the names of a radiation oncology physician certified by the ABR and a radiation oncology physicist certified by the ABR or ABMP, both of whom are familiar with the individual's training. At least one (1) of these references shall be from an individual who directed the individual's work in accordance with subdivision (4).

(j) On the effective date of this rule, any individual who has been approved previously by the department to practice as a qualified radiation or health physicist is automatically approved to practice as a health physicist. However, after the effective date of this rule, all other persons must be certified by the ABR, the ABMP, or the ABHP or shall possess equivalent qualifications as determined by the physicist review committee established in subsection (l), in order to be approved to practice as a health physicist. In determining equivalency in accordance with this subsection, the physicist review committee shall determine the following:

(1) The individual shall hold a bachelor's degree in health physics, radiological health, a physical science, engineering, or a biological science with a minor in a physical science or engineering.

(2) The individual shall have at least three (3) years of full-time active work experience in applied health physics. A master's degree in health physics or a closely related area may substitute for one (1) year of work experience required by this subsection. A doctoral degree in health physics or a closely related area may substitute for two (2) years of work experience required by this subsection.

(k) On the effective date of this rule, any individual who has been approved previously by the department to practice as a qualified x-ray machine physicist is automatically approved to practice as an x-ray machine inspector. However, after the effective date of this rule, all other persons must have a minimum of a bachelor's degree in a physical or biological science, health physics, or radiological health and a minimum of two (2) years of experience working with x-ray systems under the direct supervision of a

diagnostic imaging physicist, health physicist, or x-ray machine inspector, who has been approved by the department, in order to be approved to practice as an x-ray machine inspector.

(l) A physicist review committee is hereby created, which shall determine competency to practice as a diagnostic imaging physicist, radiation oncology physicist, health physicist, and x-ray machine inspector in accordance with subsection (h), (i), (j), or (k). The physicist review committee shall be composed of a diagnostic imaging physicist and a radiation oncology physicist, both certified by the ABR or ABMP, and a radiologist certified by the ABR. The diagnostic imaging physicist, the radiation oncology physicist, and the radiologist shall be appointed to the physicist review committee by the commissioner. Approval to practice as a diagnostic imaging physicist, radiation oncology physicist, health physicist, or x-ray machine inspector shall be based upon review of a completed application which demonstrates that the individual meets applicable education, training, and experience requirements of subsection (h), (i), (j), or (k).

(m) Approval to practice as a diagnostic imaging physicist, radiation oncology physicist, health physicist, or x-ray machine inspector may be revoked by the commissioner for failure to perform his or her duties as required by this rule. The commissioner may audit facility evaluations performed by a diagnostic imaging physicist, radiation oncology physicist, health physicist, or x-ray machine inspector. Any errors found as a result of such an audit shall be brought to the attention of the individual who performed the evaluation. If a subsequent audit indicates repetitive errors which have resulted in the issuance of unnecessary violation notices, or in violations not being reported to the commissioner, the commissioner may revoke that individual's approval to practice as a diagnostic imaging physicist, radiation oncology physicist, health physicist, or x-ray machine inspector.

(n) Department employees are exempt from the credentialing requirements of this section when they are conducting inspections or surveys of x-ray facilities for the commissioner.

(o) The radiation machine registration certificate issued by the commissioner in accordance with 410 IAC 5-2-6 shall be prominently displayed in an area readily accessible to patients and visitors.

(p) An x-ray system which does not comply with this rule shall not be operated for diagnostic or therapeutic purposes, if so directed by the commissioner.

(q) Individuals who will be operating the x-ray equipment shall be adequately instructed in proper operating procedures for such equipment. Diagnostic x-ray machines shall be operated only by a person who complies with applicable provisions of 410 IAC 5-11.

(r) In the vicinity of each x-ray control panel, a technique guide shall be provided for routine examinations performed utilizing that system.

(s) Written safety procedures and rules shall be available to each individual operating x-ray equipment, including any restrictions of operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures.

(t) Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. In addition to the patient being examined, others will be protected in the following manner:

(1) All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by five-tenths (0.5) mm lead equivalent.

(2) Staff and ancillary personnel shall be protected from direct scattered radiation by protective aprons or whole body protective barriers of not less than twenty-five hundredths (0.25) mm lead equivalent.

(3) Patients who cannot be removed from the room shall be protected from direct scattered radiation by whole body protective barriers of twenty-five hundredths (0.25) mm lead equivalent or shall be positioned so that portion of the body nearest to the tube head is at least two (2) meters from both the tube head and the nearest edge of the image receptor.

(u) Gonadal shielding of not less than twenty-five hundredths (0.25) mm lead equivalent shall be used for patients who have not passed the reproductive age during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

(v) Individuals shall not be exposed to the useful beam, except for healing arts purposes and such exposure has been authorized by a practitioner of the healing arts. This subsection specifically prohibits deliberate exposure for training, demonstration, or other nonhealing arts purposes.

(w) The following apply when a patient or film must be provided with auxiliary support during a radiation exposure:

(1) Mechanical holding devices shall be used when the technique permits. Written safety procedures established in accordance with subsection (s) shall list individual projections where holding devices cannot be utilized.

(2) Written safety procedures established in accordance with subsection (s) shall indicate the requirements for selecting a holder and the procedure the holder shall follow.

(3) The human holder shall be protected as required by subsection (t).

(4) No individual shall be used routinely to hold film or patients.

In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than five-tenths (0.5) mm lead equivalent material.

(x) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

(y) Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

(z) Any registrant proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the commissioner. When requesting such approval, that person shall submit all department required information. If any submitted information becomes invalid or outdated, the commissioner shall be immediately notified.

(aa) The registrant shall maintain the following information for each x-ray system for inspection by the commissioner:

(1) Maximum rating of technique factors.

(2) Model and serial numbers of all certified components.

(3) Aluminum equivalent filtration of the useful beam, including any routine variation.

(4) Records of surveys, calibrations, maintenance, and modifications performed on the x-ray systems for the following periods:

(A) For hospitals, medical facilities, and chiropractic facilities, twenty-four (24) months.

(B) For podiatric and veterinary facilities, forty-eight (48) months.

(C) For dental facilities, seventy-two (72) months.

(5) After the effective date of this rule, a scaled drawing of the room in which a stationary x-ray system is located, which indicates the use of areas adjacent to the room, and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall indicate either of the following:

(A) The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions.

(B) The type and thickness of materials or the lead equivalency of each wall, window, door, ceiling, and floor in the room.

(6) A copy of all correspondence with the commissioner regarding each x-ray machine, including a copy of all facility evaluation reports issued in compliance with this section.

(bb) Floor plans and equipment arrangements for all new diagnostic x-ray installations, or modifications of such installations, shall be evaluated with regard to shielding requirements prior to construction. A safety survey shall be performed prior to first use. Both evaluations shall be performed by a diagnostic imaging physicist or a health physicist approved by the department.

(cc) Floor plans and equipment arrangements for all new therapeutic x-ray installations, or modifications of such installations, shall be evaluated with regard to shielding requirements prior to construction. A safety survey shall be performed prior to first use. Both evaluations shall be performed by a radiation oncology physicist or a health physicist approved by the department.

(dd) A report of each plan review and safety survey conducted in compliance with subsection (bb) or (cc) shall be submitted to the registrant and the commissioner within twenty (20) working days of completing the plan review, and the registrant shall keep a copy of the report in its files for at least as long as the registrant uses that x-ray facility. *(Indiana State Department of Health; 410 IAC 5-6.1-118; filed Oct 29, 1993, 5:00 p.m.: 17 IR 367; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-119 Diagnostic x-ray systems

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 119. (a) Podiatric and veterinary x-ray facilities shall be evaluated at least once each twenty-four (24) months by a diagnostic imaging physicist or x-ray machine inspector approved by the department. Dental x-ray facilities shall be evaluated at least once each thirty-six (36) months by a diagnostic imaging physicist or x-ray machine inspector approved by the department.

Mammography facilities shall be evaluated at least once each twelve (12) months by a diagnostic imaging physicist approved by the department. All other diagnostic x-ray systems shall be evaluated at least once each twelve (12) months by a diagnostic imaging physicist or x-ray machine inspector approved by the department. Those x-ray facilities which have been evaluated within sixty (60) days after the end of the interval established in this section will be considered to be in compliance with this section as long as the evaluation occurs in the same calendar year as the date on which reevaluation is required. All diagnostic x-ray systems shall comply with this section.

(b) The x-ray control panel containing the main power switch shall bear the warning statement, legible and accessible to view, "WARNING: This x-ray system may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed.".

(c) For battery-powered generators, visual means shall be provided on the x-ray control panel to indicate whether the battery is charged adequately for proper operation.

(d) Leakage radiation from the diagnostic source assembly measured at a distance of one (1) meter in any direction from the source shall not exceed one hundred (100) mR in one (1) hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of one hundred (100) square cm with no linear dimension greater than twenty (20) cm.

(e) Radiation emitted by a component other than the diagnostic source assembly shall not exceed two (2) mR in one (1) hour at five (5) cm from any accessible surface of the component when it is operated in an assembled x-ray system under any condition for which it was designed. Compliance shall be determined by measurements averaged over an area of one hundred (100) square cm with no linear dimension greater than twenty (20) cm.

(f) The half-value layer of the useful beam for a given x-ray tube voltage shall be no less than the values shown as follows:

TABLE I

Design Operating Range	Measured Voltage	Half-Value Layer Aluminum Equivalent
Below 50 kVp	30 kVp	0.3 mm
	40 kVp	0.4 mm
	49 kVp	0.5 mm
50 to 70 kVp	50 kVp	1.2 mm
	60 kVp	1.3 mm
	70 kVp	1.5 mm
	71 kVp	2.1 mm
	80 kVp	2.3 mm
	90 kVp	2.5 mm
	100 kVp	2.7 mm
	110 kVp	3.0 mm
	120 kVp	3.2 mm
	130 kVp	3.5 mm
	140 kVp	3.8 mm
	150 kVp	4.1 mm

For a kVp not listed in Table I, linear interpolation shall be utilized to determine the minimum acceptable half-value layer. For capacitor energy storage x-ray systems, compliance shall be determined with the maximum charge per exposure assumed to be the kVp. The required minimum aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the source and the patient. The requirements of this subsection will be considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown as follows:

TABLE II

Total Filtration

Operating Voltage	Aluminum Equivalent
Below 50 kVp	0.5 mm
50 to 70 kVp	1.5 mm
Above 70 kVp	2.5 mm

In addition, there must be compliance with the following:

(1) Beryllium window tubes shall have a minimum of five-tenths (0.5) mm aluminum equivalent filtration permanently installed in the useful beam.

(2) For capacitor energy storage equipment, compliance with this subsection shall be determined with the maximum quantity of charge per exposure.

(3) For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filters and shall prevent an exposure unless the minimum filtration required by this subsection is in the useful beam for the kVp which has been selected.

(g) Where two (2) or more radiographic tubes are controlled by one (1) exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control and at or near the tube housing assembly which has been selected.

(h) The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless the tube housing movement is a designed function of the x-ray system.

(i) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated. For equipment having fixed technique factors, the requirement in this subsection may be met by placing permanent markings on such equipment. However, the markings shall be visible from the operator's position except in the case of spot films made by the fluoroscopist. *(Indiana State Department of Health; 410 IAC 5-6.1-119; filed Oct 29, 1993, 5:00 p.m.: 17 IR 371; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-120 Fluoroscopic x-ray systems

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 120. (a) Fluoroscopic x-ray systems shall be evaluated at least once each twelve (12) months by a diagnostic imaging physicist or x-ray machine inspector approved by the department and shall comply with applicable sections of this rule. Radiation therapy simulation systems are exempt from compliance with subsections (c) through (e), (g) through (l), and (p) if the following are met:

(1) Such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room when the system is producing x-rays.

(2) Systems which do not comply with subsection (p) are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. In such cases, procedures shall require that the timer be reset between examinations.

(b) The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID. An x-ray tube used for fluoroscopy shall not produce x-rays unless the primary protective barrier is in position to intercept the entire useful beam.

(c) Means shall be provided for stepless adjustment of the field size. In addition, the following requirements must be met:

(1) The minimum field size at the greatest SID shall be no greater than five (5) cm by five (5) cm.

(2) For equipment manufactured after February 25, 1978, when the angle between the image receptor and the beam axis of the x-ray beam is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

Compliance with this subsection shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(d) For image-intensified fluoroscopic equipment, neither the length nor the width of the x-ray field in the plane of the image

receptor shall exceed that of the visible area of the image receptor by more than three percent (3%) of the SID. The sum of the excess length and the excess width shall be no greater than four percent (4%) of the SID. In addition, the following requirements must be met:

(1) Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID or a visible area of greater than three hundred (300) square cm shall be provided with means for stepless adjustment of the x-ray field.

(2) All equipment with a fixed SID and a visible area of three hundred (300) square cm or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to one hundred twenty-five (125) square cm or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of five (5) cm by five (5) cm or less.

(3) For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(4) Compliance with this subsection shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. For rectangular x-ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

(e) Spot film devices which are certified components shall comply with the following additional requirements:

(1) Means shall be provided between the source and the patient for adjustment of the field size in the plane of the film to the size of that portion of the film which has been selected on the spot film selector. Such adjustment shall be automatically accomplished except when the field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option.

(2) It shall be possible to adjust the field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be no greater than five (5) cm by five (5) cm.

(3) The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two percent (2%) of the SID.

(4) For spot film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(f) X-ray production in the fluoroscopic mode shall be controlled by a dead-man switch. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure at any time, but means may be provided to permit completion of any single exposure of the series in process.

(g) The exposure measured at the point where the center of the useful beam enters the patient and at a kVp typical of clinical use of the x-ray system shall not exceed ten (10) roentgens per minute, except during recording of fluoroscopic images or when provided with optional high-level control. Compliance shall be determined in accordance with subsection (j).

(h) When equipment is provided with a high-level control, it shall not be operable at any combination of tube voltage and current which will result in an exposure rate in excess of five (5) roentgens per minute at the point where the center of the useful beam enters the patient unless the high-level control is activated. The high-level control shall be operable only through a dead-man switch. Additionally, a continuous signal audible to the fluoroscopist shall indicate when the high-level control is being employed. Compliance shall be determined in accordance with subsection (j).

(i) Certified systems which do not incorporate an automatic exposure control shall not be operable at any combination of tube voltage and current which will result in an exposure rate in excess of five (5) roentgens per minute, at the point where the center of beam enters the patient except during recording of fluoroscopic images or when the equipment is provided with an optional high-level control. Compliance shall be determined in accordance with subsection (j).

(j) Compliance with subsections (g) through (i) shall be determined as follows:

(1) Movable grids and compression devices shall be removed from the useful beam during the measurement.

(2) If the source is below the table, the exposure rate shall be measured one (1) cm above the table top or cradle.

(3) If the source is above the table, the exposure rate shall be measured at thirty (30) cm above the table top with the end of

the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(4) For C-arm type fluoroscopes, the exposure rate shall be measured thirty (30) cm from the input surface of the fluoroscopic imaging assembly.

(k) Periodic measurement of entrance exposure rate shall be performed in accordance with the following:

(1) Such measurements shall be made annually or after any maintenance of the system which might affect the exposure rate.

(2) Such measurements shall be made under conditions that satisfy the requirements of subsection (j).

(3) The kVp shall be the kVp typical of clinical use of the x-ray system.

(4) An x-ray system that incorporates automatic exposure control shall have sufficient material placed in the useful beam to produce a milliamperage typical of the use of the x-ray system.

(5) An x-ray system that does not incorporate an automatic exposure control shall utilize a milliamperage typical of the clinical use of the x-ray system.

(6) Results of such measurements shall be posted where any fluoroscopist has ready access to such results, and in the record required by section 118(aa)(5) of this rule. Such measurements shall be stated in roentgens per minute, and shall include the technique factors used in determining such results. The name of the person who performed the measurements and the date the measurements were performed shall be included with the results.

(l) The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed two (2) mR per hour at ten (10) cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate. The exposure rate shall be determined by measurements averaged over an area of one hundred (100) square cm with no linear dimension greater than twenty (20) cm. During such measurements, movable grids and compression devices shall be removed from the useful beam, and the attenuation block shall be positioned in the useful beam between the input surface of the fluoroscopic imaging assembly and a point ten (10) cm from the point of measurement of the entrance exposure rate. Exceptions to the measurement shall be as follows:

(1) If the source is below the table top, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned thirty (30) cm above the table top.

(2) If the source is above the table top and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the table top as possible, but no closer than thirty (30) cm.

(m) During fluoroscopy and cinefluorography, kV and mA shall be continuously indicated.

(n) The SSD shall be no less than:

(1) thirty-eight (38) cm on stationary fluoroscopes installed after June 25, 1978;

(2) thirty-five and five-tenths (35.5) cm on stationary fluoroscopes which were in operation prior to June 25, 1978;

(3) thirty (30) cm on all mobile fluoroscopes; or

(4) twenty (20) cm for image intensified fluoroscopes used in specific surgical applications.

(o) For image intensified fluoroscopes used in specific surgical applications, written safety procedures must be provided which state precautionary measures to be adhered to during use of such equipment.

(p) Means shall be provided to preset the cumulative ontime of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed five (5) minutes without resetting. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative ontime. Such signal shall continue to sound while x-rays are produced until the timing device is reset.

(q) Mobile fluoroscopes shall provide intensified imaging.

(r) Scattered radiation shall be controlled in accordance with the following:

(1) Fluoroscopic table designs, when combined with procedures utilized, shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be no less than twenty-five hundredths (0.25) mm lead equivalent.

(2) Equipment configuration, when combined with procedures, shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the table top, unless that individual:

(A) is at least one hundred twenty (120) cm from the center of the useful beam; or

(B) the radiation has passed through not less than twenty-five hundredths (0.25) mm lead equivalent material, including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency

provided by the protective apron referred to in section 118(t)(2) of this rule.

(3) The commissioner may grant an exemption to subdivision (2) where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for protective barriers is practical, the commissioner shall not permit such exemption.

(Indiana State Department of Health; 410 IAC 5-6.1-120; filed Oct 29, 1993, 5:00 p.m.: 17 IR 372; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-6.1-121 General purpose radiographic systems

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 121. (a) All general purpose radiographic systems, except extraoral dental x-ray systems, shall be evaluated at least each twelve (12) months by a diagnostic imaging physicist or x-ray machine inspector approved by the department. Extraoral dental x-ray systems must be evaluated at intervals not to exceed thirty-six (36) months by a diagnostic imaging physicist or x-ray machine inspector approved by the department. General purpose radiographic systems shall comply with all applicable portions of this section.

(b) The useful beam shall be limited to the area of clinical interest.

(c) General purpose stationary x-ray systems and mobile x-ray systems shall comply with the following requirements:

(1) There shall be a means for stepless adjustment of the field size.

(2) A method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed two percent (2%) of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

(3) The commissioner may grant an exemption to subdivisions (1) and (2) for noncertified x-ray systems, provided the registrant applies for such an exemption in writing. An application for such exemption shall demonstrate that it is impractical to comply with subdivisions (1) and (2) and that the protection afforded through compliance with subdivisions (1) and (2) will be assured through alternate methods.

(4) Any light localizer used to define the x-ray field shall provide an average illumination of not less than ten (10) foot-candles at one hundred (100) cm or at the maximum SID, whichever is less.

(d) Stationary general purpose x-ray systems shall also comply with the following requirements:

(1) A method shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor:

(A) to align the center of the x-ray field with respect to the center of the image receptor to within two percent (2%) of the SID;

(B) to indicate the SID to within two percent (2%).

(2) The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted.

(3) The field size dimension and SID shall be indicated, in inches or cm, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within two percent (2%) of the SID when the beam axis is perpendicular to the plane of the image receptor.

(e) Radiographic equipment having only one (1) image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor. Additionally, such equipment shall be provided with a means to align the center of the x-ray field with the center of the image receptor to within two percent (2%) of the SID or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(f) A timer shall be provided to terminate the exposure at:

(1) a preset time interval;

(2) a preset product of current and time;

(3) a preset number of pulses; or

(4) a preset radiation exposure to the image receptor.

It shall not be possible to make an exposure when the timer is set to the zero (0) or off position, if either is provided.

(g) An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated at any time, except for exposures of one-half (1/2) second duration or less, or during serial radiography when means are provided or permit completion of any single exposure of a series in process. The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated. X-ray controls shall be located as follows:

(1) Stationary x-ray systems shall have the x-ray control permanently mounted in a protected area so that the operator must remain in that protected area during the entire exposure.

(2) Mobile and portable x-ray systems which are used for greater than one (1) week in the same location, such as a room or a suite, shall comply with subdivision (1).

(3) Mobile and portable x-ray systems which are used for greater than one (1) hour and less than one (1) week at the same location, such as a room or a suite, shall comply with subdivision (1) or be provided with a protective barrier six and five-tenths (6.5) feet high placed at least six (6) feet from the tube housing assembly and at least six (6) feet from the patient.

(4) Mobile and portable x-ray systems which are used to make an exposure of a patient at the use location shall comply with subdivision (3) or be provided with a method of x-ray control which will permit the operator to be at least twelve (12) feet from the tube housing assembly during an exposure.

(h) The following apply when an automatic exposure control is provided:

(1) Indication shall be made on the x-ray control panel when the mode of operation is selected.

(2) If the x-ray tube voltage is fifty (50) kVp or greater, the exposure time for field emission equipment rated for pulsed operation shall be no greater than the time interval equal to two (2) pulses.

(3) The exposure time for all equipment other than that specified in subdivision (2) shall be no greater than one-sixtieth (1/60) second or the time interval required to deliver five (5) mAs, whichever is greater.

(4) Either the product of peak x-ray tube voltage, current, and exposure time shall be no more than sixty (60) kWs per exposure or the product of x-ray tube current and exposure time shall be no more than six hundred (600) mAs per exposure, except when the x-ray tube voltage is less than fifty (50) kVp, in which case the product of x-ray tube current and exposure time shall be no more than two thousand (2,000) mAs per exposure.

(5) A visible signal shall indicate when an exposure has been terminated as required by subdivision (4). Manual resetting shall be required before further automatically timed exposures can be made.

(i) With a timer setting of five-tenths (0.5) second or less, the average exposure time (T_{avg}) shall be no less than five (5) times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}). A minimum of four (4) timer tests must be performed to determine T_{avg}, T_{max}, and T_{min}. This requirement is expressed mathematically as:

$$T_{avg} \geq 5\ (T_{max} - T_{min})$$

(j) All mobile or portable radiographic systems shall be provided with means to limit the SSD to no less than thirty (30) cm.

(k) The coefficient of variation of exposure shall not exceed ten-hundredths (0.10) when all technique factors are held constant. This requirement shall be deemed to have been met if, when four (4) exposures are made at identical technique factors, the value of the average exposure (E_{avg}) is no less than five (5) times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}). This requirement is expressed mathematically as:

$$E_{avg} \geq 5\ (E_{max} - E_{min})$$

(l) For capacitor energy storage equipment in standby status, radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed two (2) mR per hour at five (5) cm from any accessible surface of the diagnostic source assembly with the beam-limiting device fully open.

(m) General purpose x-ray systems incorporating one (1) or more certified components shall be required to comply with the following additional requirements which relate to those certified components:

(1) When such equipment is operated on an adequate power supply as specified by the manufacturer in accordance with applicable federal standards, the estimated coefficient of variation shall be no greater than five-hundredths (0.05) for any specific combination of selected technique factors.

(2) When such equipment allows a choice of x-ray tube current settings and is operated on a power supply specified by the manufacturer in accordance with applicable federal standards, for any tube potential (kVp) within forty percent (40%) to one hundred percent (100%) of the maximum kVp rating, the absolute value of the difference between the ratio of average exposure in mR to the indicated mAs obtained at any two (2) consecutive tube current settings, shall not differ by more than ten-hundredths (0.10) of the absolute value of their sum. A minimum of four (4) measurements per tube current setting are

required to determine each average exposure. This requirement is expressed mathematically as:

$$|X_1 - X_2| \leq 0.10\,|X_1 + X_2|$$

Where: X_1 and X_2 = The ratios of average exposure to mAs obtained at each of two (2) consecutive tube current settings

(3) Deviation of technique factors from indicated values shall not exceed ten percent (10%) or the limits specified for that system by its manufacturer, whichever is greater.

(4) The following apply for general purpose stationary and mobile x-ray systems:

(A) There shall be means for stepless adjustment of the field size. The minimum field size at an SID of one hundred (100) cm shall be no greater than five (5) cm by five (5) cm.

(B) When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than one hundred sixty (160) lux or fifteen (15) foot-candles at one hundred (100) cm or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from compliance with this clause.

(C) The edge of the light field at one hundred (100) cm or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of at least four (4) for beam-limiting devices used on stationary equipment and a contrast ratio of at least three (3) for beam-limiting devices used on mobile x-ray equipment. Compliance shall be determined utilizing a measuring instrument aperture of one (1) mm diameter.

(5) Beam limitation for portable x-ray systems shall comply with subsection (d) and subdivision (4).

(6) Stationary general purpose x-ray systems equipped with a tube housing assembly, an x-ray control, and, if so equipped, a table, all of which are certified in accordance with 21 CFR 1020.30(C), shall comply with the following:

(A) Means shall be provided for positive beam limitation which will, at the SID for which the device is designed, either cause automatic adjustment of the x-ray field in the plane of the image receptor to the image receptor size within five (5) seconds after insertion of the image receptor or, if adjustment is accomplished automatically in a time interval greater than five (5) seconds or is manual, will prevent production of x-rays until such adjustment is completed. For the SID at which the device is not intended to operate, the device shall prevent the production of x-rays.

(B) The field size in the plane of the image receptor, whether automatically or manually adjusted, shall be such that neither the length nor the width of the x-ray field differs from that of the image receptor by greater than three percent (3%) of the SID. The sum of the absolute values for the field size length and width differences shall be no more than four percent (4%) of the SID when the beam axis is perpendicular to the plane of the image receptor.

(C) The radiographic system shall be capable of operation, at the discretion of the operator, so that the field size at the image receptor can be adjusted to a size smaller than the image receptor. The minimum field size at a distance of one hundred (100) cm shall be no greater than five (5) cm by five (5) cm. Return to positive beam limitation as specified in clauses (A) and (B) shall occur upon a change in image receptor.

(D) Positive beam limitation may be bypassed:

(i) when radiography is conducted without use of the cassette tray or permanently mounted vertical cassette holder;

(ii) or when either the beam axis or table angulation is not within ten (10) degrees of horizontal or vertical during any part of the exposure; or

(iii) during stereoscopic radiography.

If a bypass mode is provided, return to positive beam limitation shall be automatic.

(E) Capability may be provided to override positive beam limitation in the event of system failure or when it is necessary to perform special procedures which cannot be performed in the positive mode. However, if such capability is provided, it shall be necessary to use a key to override the positive mode and it shall be impossible to remove the key while the positive mode is overridden.

(n) Except for dental panoramic systems, termination of exposure shall cause automatic resetting of the timer to its initial setting or to the zero (0) position. *(Indiana State Department of Health; 410 IAC 5-6.1-121; filed Oct 29, 1993, 5:00 p.m.: 17 IR 374; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-122 Special purpose x-ray systems

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 122. (a) In addition to compliance with sections 118, 119, and 121 of this rule, special purpose x-ray systems and associated facilities shall comply with this section. Special purpose x-ray facilities must be evaluated at intervals not to exceed twelve (12) months by a diagnostic imaging physicist or x-ray machine inspector approved by the department.

(b) Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent (2%) of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(c) Means shall be provided to align the center of the x-ray field with the center of the image receptor to within two percent (2%) of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. This subsection may be met if the system complies with section 121(c) of this rule. This subsection may also be met if means for alignment are provided, with either of the following:

(1) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the system is designed, with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed.

(2) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the system is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

(Indiana State Department of Health; 410 IAC 5-6.1-122; filed Oct 29, 1993, 5:00 p.m.: 17 IR 377; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-6.1-123 Intraoral dental radiographic systems

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 123. (a) In addition to compliance with sections 118 and 119 of this rule, intraoral dental x-ray equipment and associated facilities shall comply with this section. Extraoral dental radiographic systems are exempt from this section, but must comply with section 121 of this rule. Intraoral dental x-ray facilities must be evaluated at intervals not to exceed thirty-six (36) months by a diagnostic imaging physicist or x-ray machine inspector approved by the department.

(b) X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the SSD to no less than eighteen (18) cm if the system is capable of operation above fifty (50) kVp or no less than ten (10) cm, if the system is not capable of operation above fifty (50) kVp.

(c) Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:

(1) if the minimum SSD is eighteen (18) cm or more, the x-ray field, at the minimum SSD, shall be containable in a circle of diameter seven (7) cm or less; or

(2) if the minimum SSD is less than eighteen (18) cm, the x-ray field, at the minimum SSD, shall be containable in a circle of diameter six (6) cm or less.

(d) Means shall be provided to terminate exposure at:

(1) a preset time interval;

(2) a preset product of current and time;

(3) a preset number of pulses; or

(4) a preset radiation exposure to the image receptor.

It shall not be possible to make an exposure when the timer is set to the zero (0) or off position if either is provided. With a timer setting of five-tenths (0.5) seconds or less, the average exposure period (T_{avg}) shall be no less than five (5) times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when four (4) timer tests are performed. This requirement is expressed mathematically as:

$$T_{avg} \geq 5\ (T_{max} - T_{min})$$

(e) An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half (1/2) second or less. The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated. X-ray controls shall be located as follows:

(1) Stationary x-ray systems installed after June 25, 1978, shall have the x-ray control permanently mounted in a protected area so that the operator must remain in that protected area during the entire exposure.

(2) Mobile and portable x-ray systems which are used for greater than one (1) week in the same location, such as a room or suite, shall comply with subdivision (1).

(3) Mobile and portable x-ray systems which are used for greater than one (1) hour and less than one (1) week at the same location, such as a room or a suite, shall comply with subdivision (1) or be provided with a protective barrier six and five-tenths (6.5) feet high placed at least six (6) feet from the tube housing assembly and at least six (6) feet from the patient.

(4) Mobile and portable x-ray systems which are used to make an exposure of a patient at the use location shall comply with subdivision (3) or be provided with a method of x-ray control which will permit the operator to be at least twelve (12) feet from the tube housing assembly during an exposure.

(f) The coefficient of variation of exposure shall not exceed ten-hundredths (0.10) when all technique factors are held constant. This requirement shall be deemed to have been met if, when four (4) exposures are made at identical technique factors, the value of the average exposure (E_{avg}) is no less than five (5) times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}). This requirement is expressed mathematically as:

$$E_{avg} \geq 5\ (E_{max} - E_{min})$$

(g) Patient and film holding devices shall be used when the techniques permit.

(h) The tube housing and the position indicating device shall not be hand held during an exposure.

(i) The x-ray system shall be operated in such a manner that the useful beam at the patient's skin complies with subsection (c).

(j) Dental fluoroscopy shall be conducted only with image intensification.

(k) Diagnostic x-ray systems incorporating one (1) or more certified components shall be required to comply with the following additional requirements which relate to those certified components:

(1) When such equipment is operated on an adequate power supply as specified by the manufacturer in accordance with applicable federal standards, the coefficient of variation of exposure shall be no greater than five-hundredths (0.05) for any specific combination of selected technique factors.

(2) When such equipment allows a choice of x-ray tube current settings and is operated on a power supply specified by the manufacturer in accordance with applicable federal standards, for any tube potential (kVp) within forty percent (40%) to one hundred percent (100%) of the maximum kVp rating, the absolute value of the difference between the ratio of average exposure in mR to the indicated mAs obtained at any two (2) consecutive tube current settings, shall not differ by more than ten-hundredths (0.10) of the absolute value of their sum. A minimum of four (4) measurements per tube current setting are required to determine each average exposure. This requirement is expressed mathematically as:

$$|X_1 - X_2| \leq 0.10\ |X_1 + X_2|$$

Where: X_1 and X_2 = The ratios of average exposure to mAs obtained at each of two (2) consecutive tube current settings

(3) Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.

(4) Termination of exposure shall cause automatic resetting of the timer to its initial setting or to the zero (0) position.

(5) All dental x-ray systems manufactured on or after December 1, 1980, shall have a half-value layer of not less than one and five-tenths (1.5) mm aluminum equivalent. Systems operating above seventy (70) kVp are subject to the filtration requirements of section 119(f) of this rule.

(Indiana State Department of Health; 410 IAC 5-6.1-123; filed Oct 29, 1993, 5:00 p.m.: 17 IR 377; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-6.1-124 Therapeutic x-ray systems operating at less than one MeV

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 124. (a) This section and 410 IAC 5-9, excluding 410 IAC 5-9-8(a), 410 IAC 5-9-10(a), 410 IAC 5-9-10(c), and 410 IAC 5-9-10(d), shall apply to medical facilities using therapeutic x-ray systems capable of operating at less than one (1) MeV.

(b) When the tube is operated at its leakage technique factors, leakage radiation shall not exceed the following:

(1) For contact therapy systems, one hundred (100) mR per hour at five (5) cm from the surface of the tube housing assembly.

(2) For systems capable of operating from zero (0) to one hundred fifty (150) kVp which are manufactured prior to June 25, 1978, one (1) roentgen per hour at one (1) meter from the source.

(3) For systems capable of operating from zero (0) to one hundred fifty (150) kVp which were manufactured on or after June 25, 1978, one hundred (100) mR per hour at one (1) meter from the source.

(4) For systems capable of operating from greater than one hundred fifty (150) to five hundred (500) kVp, one (1) roentgen per hour at one (1) meter from the source.

(5) For systems capable of operating in excess of five hundred (500) kVp, no more than one-tenth of one percent (0.1%) of the useful beam at one (1) meter from the source.

(c) Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or a higher degree of protection as required for the tube housing assembly.

(d) Removable beam-limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than one percent (1%) of the original x-ray beam at the maximum kilovoltage and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the patient.

(e) Adjustable beam-limiting devices installed after June 25, 1978, shall comply with subsection (d). Adjustable beam-limiting devices installed before June 25, 1978, shall, for the portion of the x-ray beam to be blocked by such devices, transmit no more than five percent (5%) of the useful beam at the maximum kilovoltage and maximum treatment filter.

(f) The filter system shall be such that filters cannot be accidentally displaced from the useful beam at any possible tube orientation. Each filter shall be marked to identify its thickness and material of which it is constructed. For wedge filters, the wedge angle shall appear on the wedge or wedge tray. The radiation at five (5) cm from the filter insertion slot opening shall not exceed thirty (30) roentgens per hour at any operating condition.

(g) The tube housing assembly shall be capable of immobilization for stationary treatment. It shall be marked so that it is possible to determine the location of the focal spot to within five (5) mm. The marking shall be readily accessible for use during calibration procedures.

(h) Contact therapy system tube housing assemblies shall have a removable shield of at least five-tenths (0.5) mm lead equivalency at one hundred (100) kVp which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

(i) Therapeutic x-ray systems capable of operating at greater than one hundred fifty (150) kVp, which were manufactured after June 25, 1978, shall be provided with a beam monitor system having the following capabilities:

(1) The system shall have the radiation detector of the monitoring system interlocked to prevent incorrect positioning.

(2) The system shall not allow irradiation until a value for exposure has been selected at the x-ray control panel.

(3) The system shall independently terminate irradiation when the selected exposure has been reached.

(4) The system shall be so designed that the dose administered to a patient prior to any system malfunction or power failure can be accurately determined.

(5) The system shall have a display at the x-ray control panel from which the dose at a reference point in the soft tissue can be calculated. This display must be intentionally reset to the zero (0) position.

(6) The system shall have a display at the x-ray control panel which does not have scale multiplying factors and utilizes a design such that increasing dose is displayed by increasing numbers.

(j) A timer shall be provided with a display at the x-ray control panel. The timer shall have a preset time selector and an elapsed time indicator. The timer shall be a cumulative timer which activates with the production of radiation and retains its readings after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to the zero (0) position. The timer shall terminate irradiation when a preselected time has elapsed if any dose monitoring system present has not previously terminated irradiation. The timer shall permit accurate

presetting and determination of exposure times as short as one (1) second. The timer shall not permit an exposure if set at the zero (0) position. When irradiation is controlled by a shutter mechanism, the timer shall not activate until the shutter is opened.

(k) The x-ray control panel shall be fitted with a device to terminate exposure at any time. In addition to displays required by other provisions of this section, the x-ray control panel shall indicate the following:

(1) When electrical power is available at the x-ray control panel.

(2) If activation of the x-ray tube is possible.

(3) When x-rays are being produced.

(4) kV and x-ray tube current.

For x-ray equipment manufactured after June 25, 1978, the x-ray control panel shall display specific filters in the beam.

(l) When an x-ray control panel may energize more than one (1) x-ray tube, it shall be possible to activate only one (1) x-ray tube at a time. The x-ray control panel shall identify which x-ray tube is energized, and the tube housing assembly shall also indicate when that tube is energized.

(m) There shall be means of determining the SSD to within one (1) cm.

(n) Unless it is possible to bring the x-ray output to the prescribed exposure parameters within five (5) seconds, the beam shall be automatically attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. After the system is at operating parameters, the shutter shall be controlled electrically by the operator from the x-ray control panel. The x-ray control panel shall indicate the shutter position.

(o) Each x-ray system equipped with a beryllium or other low filtration window shall be clearly labeled as such upon the tube housing assembly and at the x-ray control panel.

(p) Facilities which will house therapeutic x-ray systems capable of operating at fifty (50) kVp or more shall comply with the following:

(1) Provision shall be made for verbal communication between the patient and the operator at the x-ray control panel. However, where treatment requirements or excessive noise levels make verbal communication impractical, other effective methods of communication shall be utilized.

(2) Windows, mirrors, closed circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the x-ray control panel.

(3) When the primary viewing system is electronic, an alternate viewing system shall be available for use in the event of failure of the primary viewing system. The alternate viewing system may also be electronic. In the event of failure of both viewing systems, the therapeutic x-ray system shall not be used to irradiate patients until one (1) of the viewing systems is again fully operational.

(q) Facilities which will house therapeutic x-ray systems capable of operating at one hundred fifty (150) kVp or more shall comply with subsection (o) and the following:

(1) All protective barriers shall be fixed, except for entrance doors or beam interceptors.

(2) The x-ray control panel shall be located outside the treatment room.

(3) Interlocks shall be provided such that all treatment room entrances must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to continue irradiation without closing all entrance doors and manually reinitiating irradiation at the x-ray control panel.

(4) When any door referred to in subdivision (3) is opened while the x-ray tube is activated, the exposure one (1) meter from the source shall be reduced to less than one hundred (100) mR per hour.

(r) Registrants shall have all new therapeutic x-ray facilities, and existing facilities not previously surveyed, surveyed by a radiation oncology physicist approved by the department. Such surveys shall also be performed after any change in the facility or equipment which might cause a significant increase in radiation hazard. The survey shall be done before the therapeutic x-ray system is used for therapeutic purposes, and an evaluation report, including all violations of this rule on a form acceptable to the commissioner, must be completed by the radiation oncology physicist and a copy forwarded to the registrant and to the commissioner within thirty (30) days of receipt of the completion of the survey. The survey and report shall indicate all locations where the dose equivalent rate exceeds the limits specified in this rule.

(s) The registrant shall establish procedures to check all timer calculations by an independent method or by a second individual before administering thirty percent (30%) of the prescribed total dose, to assure that the given dose agrees with the manual or computer generated dose calculation, and with the written order of a practitioner of the healing arts. Additionally, the registrant shall verify that the correct beam filtration and cone factors are used and documented.

(t) Calibration of therapeutic x-ray systems subject to this section shall be performed before the system is first used for irradiation of an individual and thereafter at time intervals not to exceed twelve (12) months. Calibrations shall be also be performed after any change which might significantly alter the beam energy, spatial distribution, or other output characteristics of the therapy beam. Calibration shall be performed by a radiation oncology physicist approved by the department, who is physically present at the facility. Radiation measurements conducted during calibrations required by this subsection shall be performed using a dosimetry system which complies with the following:

(1) The dosimetry system shall have an air-kerma or exposure calibration factor traceable to the National Institute for Standards and Technology.

(2) The dosimetry system shall have been calibrated within the previous two (2) years and after any servicing that may have affected its calibration. The system shall have been calibrated in such a fashion that an uncertainty can be stated for the radiation output measured by the system. The dosimetry system shall have had constancy checks performed on the system as specified by a radiation oncology physicist. Calibration shall be in sufficient detail that the dose at a reference point in soft tissue may be calculated with a maximum uncertainty of five percent (5%).

(3) Calibration of each therapy beam shall include, but not be limited to, the output, half-value layer, and cone factors. Records of calibration measurements and dosimetry system calibrations conducted in accordance with this subsection shall be maintained by the registrant for at least five (5) years after completion of such calibration.

(u) An independent check of the output of a therapeutic x-ray system shall be performed annually. The check shall be performed by either of the following:

(1) A radiation oncology physicist approved by the department, other than the one who performed the annual output calibration, using a dosimetry system other than the one that was used during said annual calibration. The dosimetry system must also comply with subsection (t).

(2) A thermoluminescence dosimetry service capable of measuring doses with an accuracy of five percent (5%) or less.

(v) Output spot checks shall be performed on therapeutic x-ray systems during spot checks conducted in accordance with subsection (t), and thereafter at intervals not to exceed one (1) month, by a radiation oncology physicist approved by the department. Output spot check procedures shall be in writing and shall have been developed by a radiation oncology physicist approved by the department. Output spot check procedures shall specify:

(1) which tests or measurements are to be performed;

(2) the frequency the tests or measurements are to be performed;

(3) the acceptable tolerance for each parameter measured compared to the value for that parameter as determined in the last calibration conducted in accordance with subsection (t); and

(4) the action to be taken if a tolerance has been exceeded for any test or measurement required by the written output spot check procedures.

If an output spot check conducted in accordance with this subsection indicates a variance of more than five percent (5%) in output per timer unit compared to the value determined in the last spot check conducted under this subsection, the radiation oncology physicist shall calibrate the therapeutic x-ray system. Records of each output spot check measurement conducted in accordance with this subsection shall be maintained by the registrant for a minimum of five (5) years from the date the output calibration was performed.

(w) The registrant shall perform weekly output constancy checks on each of their therapeutic x-ray systems in accordance with written output constancy check procedures developed by a radiation oncology physicist approved by the department. The output constancy check procedures shall specify:

(1) the tests or measurements to be performed;

(2) the acceptable tolerance for each parameter measured compared to the value for that parameter as determined in the last calibration conducted in accordance with subsection (t); and

(3) the action to be taken if a tolerance has been exceeded for a test or measurement required by the written output constancy check procedures.

At least monthly, a radiation oncology physicist approved by the department shall review the results of all required output constancy checks performed since his or her last such review. If an output constancy check conducted in accordance with this subsection indicates a variance of more than five percent (5%) in output per timer unit compared to the value determined in the last calibration conducted in accordance with subsection (t), the registrant shall repair the therapeutic x-ray system or undertake other corrective action before the equipment is again used to irradiate patients. The registrant shall also perform an output constancy check to

determine whether or not the therapeutic x-ray system is again in compliance with this subsection prior to utilizing the equipment to irradiate patients. A record of each output constancy check performed in accordance with this subsection, and any repairs or corrective action undertaken in compliance with this subsection, shall be maintained by the registrant for a minimum of two (2) years from the date the output constancy check, repair, or corrective action was performed.

(x) The registrant shall perform checks on treatment planning computers and dose calculation algorithms in accordance with written quality assurance procedures developed by a radiation oncology physicist approved by the department. At a minimum, the written quality assurance procedures shall require that the registrant do the following:

(1) Ensure that any computer software changes, including beam data files, have been correctly implemented without corrupting beam data.

(2) Verify that all users of treatment planning computers have been trained in the use of the computers.

(y) The registrant shall establish and maintain a written quality management plan to assure that radiation from an x-ray therapy system is administered as ordered by a practitioner of the healing arts. At a minimum, a quality management plan must assure all of the following:

(1) Prior to administration, a written order for therapeutic radiation must be prepared by a practitioner of the healing arts. The order shall specify, at a minimum, the following:

(A) The patient's name.

(B) The anatomical treatment site or sites.

(C) For each treatment site, the following:

(i) Beam energy.

(ii) HVL.

(iii) The dose per fraction.

(iv) The number of fractions.

(v) The total dose.

If, in the opinion of a practitioner of the healing arts, any delay could jeopardize the health of a patient, the practitioner may verbally order therapeutic radiation, as long as the practitioner prepares a written order in accordance with this subdivision, to confirm his or her verbal orders, within seventy-two (72) hours of issuing the verbal order.

(2) Treatment plans and related calculations for radiation are in accordance with the written order of a practitioner of the healing arts.

(3) Each administration of therapeutic radiation is in accordance with a written order of a practitioner of the healing arts.

(4) Any deviation from the written order of a practitioner of the healing arts in excess of ten percent (10%) of the daily prescribed dose is identified, evaluated, and the findings communicated to the practitioner of the healing arts.

(z) The registrant shall review the radiation oncology chart of patients subjected to irradiation from a therapeutic x-ray system in accordance with written quality assurance procedures developed by a radiation oncology physicist approved by the department. At a minimum, the written quality assurance procedures shall require the following:

(1) The documented timer settings used for each field is *[sic., are]* in conformance with the calculations.

(2) The therapeutic x-ray system operator initials the treatment documentation for each patient he or she treats, each day.

(3) The daily radiation dose and the cumulative radiation dose are recorded.

(4) Each written order for therapy treatment is being followed.

(5) The total prescribed dose for each treatment site is appropriately indicated.

(aa) The registrant shall submit a written report to the commissioner of any misadministration within fifteen (15) days of discovery of the misadministration. The report shall:

(1) state the name and address of the registrant;

(2) state the name of the practitioner of the healing arts who prescribed the x-ray therapy at issue;

(3) state the name of the individual who was improperly irradiated or the name of that individual's parent or guardian, if applicable;

(4) briefly describe the nature of the misadministration and any resultant effect on the individual who was improperly irradiated;

(5) describe the actions taken by the registrant to prevent a recurrence of similar misadministrations; and

(6) state what information has been presented to the individual who was improperly irradiated, or to that individual's parent or guardian, if applicable.

A copy of the report shall be maintained by the registrant for at least five (5) years after the date of the misadministration.

(bb) If possible, within twenty-four (24) hours of discovery of a misadministration, the registrant shall notify the individual who has been improperly irradiated, or that individual's parent or guardian, if applicable, about the misadministration, unless, in the opinion of a practitioner of the healing arts, such notification would be harmful to that individual. Also, within twenty-four (24) hours of discovery of a misadministration, the registrant shall notify the referring practitioner of the healing arts about the misadministration. At a minimum, the notification shall briefly describe the nature of the misadministration and any resultant effect on the individual who was improperly irradiated.

(cc) Therapeutic x-ray systems shall not be left unattended unless the system or the treatment room door is secured against unauthorized use.

(dd) When a patient must be held in position for radiation therapy, mechanical supports or restraining devices shall be used.

(ee) The tube housing assembly shall not be held by hand during operation unless the system is designed to require holding and the kVp of the system does not exceed fifty (50) kVp. In such cases, the holder shall wear protective gloves and an apron of not less than five-tenths (0.5) mm lead equivalency at one hundred (100) kVp.

(ff) No individual other than the patient shall be in the treatment room during exposures from therapeutic x-ray systems unless such individual is shielded by protective barriers sufficient to reduce their exposure to no more than that allowed by 410 IAC 5-4-2. No individual other than the patient shall be in the treatment room during exposures from therapeutic x-ray systems operating above one hundred fifty (150) kVp.

(gg) A therapeutic x-ray system shall not be used to administer radiation therapy unless it complies with subsections (t), (v), and (w). *(Indiana State Department of Health; 410 IAC 5-6.1-124; filed Oct 29, 1993, 5:00 p.m.: 17 IR 379; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-125 Therapeutic x-ray or electron systems operating at one MeV or more

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 125. (a) This section and 410 IAC 5-9, excluding 410 IAC 5-9-8(a), 410 IAC 5-9-10(a), 410 IAC 5-9-10(c), and 410 IAC 5-9-10(d), shall apply to medical facilities using therapeutic x-ray or electron systems capable of operating at one (1) MeV or more.

(b) Therapeutic x-ray or electron systems manufactured after January 1, 1985, shall comply with the following:

(1) The absorbed dose due to leakage radiation, when measured at any point in the patient plane, shall not exceed one-tenth of one percent (0.1%) for x-ray leakage or five-hundredths percent (0.05%) for neutron leakage of the maximum absorbed dose of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the isocenter or normal treatment distance.

(2) For each therapeutic x-ray or electron system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in subdivision (1) for operating conditions producing maximum leakage radiation. Radiation measurements excluding neutrons shall be averaged over an area of one hundred (100) square cm or less. Neutron measurements shall be averaged over an area of two hundred (200) square cm or less. Records on leakage radiation measurements shall be maintained for inspection by the commissioner.

(c) Therapeutic x-ray or electron systems manufactured on or before January 1, 1985, shall comply with the following:

(1) The absorbed dose due to leakage radiation at any point in the patient plane shall not exceed one-tenth of one percent (0.1%) of the maximum absorbed dose of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the isocenter or normal treatment distance for x-ray leakage.

(2) For each system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in subdivision (1) for operating conditions producing maximum leakage radiation. Radiation measurements shall be averaged over an area of one hundred (100) square cm or less. Records on leakage radiation measurements shall be maintained for inspection by the commissioner.

(d) Adjustable or interchangeable beam-limiting devices shall be provided. Such devices shall transmit no more than two percent (2%) of the useful beam, excluding its neutron component, at the normal treatment distance for the portion of the useful beam which is to be attenuated by the beam-limiting device.

(e) Each filter which is removable from the system shall be clearly marked with an identification number. Documentation shall

be available at the control panel describing each filter. For wedge filters, the wedge angle shall be indicated on the wedge or wedge tray. If the absorbed dose rate data required by subsection (t) relates exclusively to operation with a field-flattening or beam-scattering filter in place, such filter shall not be removable by hand.

(f) Those therapeutic x-ray or electron systems manufactured after January 1, 1985, which utilize a system of wedge filters, interchangeable field-flattening filters, or interchangeable beam-scattering filters shall comply with the following:

(1) Irradiation shall not be possible until a selection of a filter or filter code has been made at the x-ray control panel.

(2) An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position.

(3) An interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the x-ray control panel.

(g) The registrant shall determine, or obtain from the manufacturer, data sufficient to assure that the following requirements are met:

(1) The absorbed dose resulting from x-rays in a useful electron beam at a point on the central axis of the beam ten (10) cm greater than the practical range of the electrons shall not exceed the values stated in the table in this subdivision. Linear interpolation shall be used for values not stated.

TABLE III

Maximum Energy of Electron Beam	X-Ray Absorbed Dose as a Fraction of Maximum Dose
1 MeV	0.03
15 MeV	0.05
35 MeV	0.10
50 MeV	0.20

Compliance shall be determined using the following:

(A) A measurement within a phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam.

(B) A phantom having cross sectional dimensions which exceed the measurement radiation field by at least five (5) cm and of depth sufficient to perform the required measurement.

(2) The absorbed dose at a surface located at the normal treatment distance, at the point of intersection of that surface with the central axis of the useful beam during x-ray irradiation, shall not exceed the limits stated in the table in this subdivision. Linear interpolation shall be used for values not stated.

TABLE IV

Maximum Photon Energy	Absorbed Dose at the Surface as a Fraction of the Maximum Dose
1 MeV	0.80
2 MeV	0.70
5 MeV	0.60
15 MeV	0.50
35 MeV	0.40
50 MeV	0.20

Compliance shall be determined by measurements made as follows:

(A) Within a phantom using an instrument which will allow extrapolation to the surface absorbed dose.

(B) Using a phantom having size and placement which complies with subdivision (1).

(C) After removal of all beam-modifying devices which can be removed by hand, except for beam-scattering or beam-flattening filters.

(h) All therapeutic x-ray or electron systems shall be provided with one (1) or more dose monitoring chambers, in accordance with the following:

(1) Therapeutic x-ray or electron systems manufactured after January 1, 1985, shall be provided with at least two (2) dose monitoring chambers. The dose monitoring chambers shall be incorporated into two (2) separate dose monitoring systems.

(2) Therapeutic x-ray or electron systems manufactured on or before January 1, 1985, shall be provided with at least one (1) dose monitoring chamber. The dose monitoring chamber shall be incorporated into the primary dose monitoring system.

(i) Each dose monitoring chamber shall be removable only by use of tools and shall be interlocked to prevent incorrect positioning. Each dose monitoring chamber shall form part of a dose monitoring system from which readings of the absorbed dose at a reference point in the treatment volume can be calculated in dose monitor units. Each dose monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation. Each dose monitoring system shall have a legible display located at the control panel.

(j) Therapeutic x-ray or electron systems manufactured after January 1, 1985, shall comply with this subsection. The design of each dose monitoring system shall assure that malfunctioning of one (1) system shall not cause incorrect functioning of the second system. The failure of any element common to both monitoring systems which could affect the correct function of both systems shall terminate irradiation. Each dose monitoring system display shall:

(1) maintain a reading until intentionally reset to the zero (0) position;

(2) have only one (1) scale and no scale multiplying factors;

(3) utilize a design such that increasing dose is displayed by increasing numbers; and

(4) be such that, in the event a dose monitoring system fails, the dose monitor units delivered may be accurately determined. In the event of a power failure, the dose monitoring information displayed at the control panel at the time of the power failure shall be retrievable from at least one (1) dose monitoring system.

(k) For therapeutic x-ray or electron systems manufactured after January 1, 1985, which are inherently capable of producing useful beams with asymmetry exceeding five percent (5%), the asymmetry of the radiation beam in two (2) orthogonal directions shall be monitored before the beam passes through the beam-limiting device. Monitoring devices, indicators, and controls shall be provided so that if the difference in dose rate between one (1) region and another region symmetrically displaced from the central axis of the beam exceeds five percent (5%) of the central axis dose rate, this condition is indicated at the control panel. If the difference exceeds ten percent (10%), the controls shall automatically terminate irradiation.

(l) Irradiation shall not be possible until selection of the number of dose monitor units to be delivered has been made at the control panel. The preselected number of dose monitor units shall be displayed at the control panel until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the dosimeter display to the zero (0) position before subsequent treatment can be initiated.

(m) During stationary beam therapy, the primary dose monitoring system shall terminate irradiation when the preselected number of dose monitor units have been detected by that system. If original design of the equipment included a second dose monitoring system, that system shall be capable of terminating irradiation when the system detects that the preselected number of dose monitoring units set at the control panel indicate either fifteen percent (15%), or greater, or forty (40) dose monitor units, or greater, above the preselected number of dose monitor units set at the control panel. For therapeutic x-ray or electron systems manufactured after January 1, 1985, which are used for stationary beam therapy:

(1) a second dose monitoring system shall be incorporated which can terminate irradiation when fifteen percent (15%), or greater, or forty (40) dose monitor units, or greater, above the number selected at the x-ray control panel has been detected by the second dose monitoring system; and

(2) the control panel shall indicate which dose monitoring system has terminated irradiation.

(n) It shall be possible to interrupt irradiation and gantry rotation at any time at the control panel. Following an interruption, it shall be possible for the operator to commence irradiation without reselecting operating conditions. If any change is made of a preselected value during an interruption, irradiation and gantry rotation shall be automatically terminated.

(o) A timer that has a display shall be provided at the control panel. The timer shall have a preset time selector and an elapsed time indicator. The timer shall be a cumulative timer that activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated, it shall be necessary to reset the elapsed time indicator to the zero (0) position before irradiation can be initiated. The timer shall terminate irradiation when a preselected time has elapsed if the dose monitoring systems have not previously terminated irradiation.

(p) Equipment capable of both x-ray therapy and electron therapy shall comply with the following additional requirements:

(1) Irradiation shall not be possible until the type of radiation to be utilized has been selected at the control panel. The type of radiation selected shall be displayed at the control panel before and during irradiation.

(2) An interlock system shall be provided to ensure that the equipment can emit only that type of radiation which has been selected.
(3) An interlock system shall be provided to prevent irradiation if operating conditions selected in the treatment room do not agree with the operating conditions selected at the control panel.
(4) When electron applicators are fitted, an interlock system shall prevent irradiation with x-rays except to obtain a port film.
(5) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted.
(q) Equipment capable of generating radiation beams of different energies shall comply with the following:
(1) Irradiation shall not be possible until an energy value has been selected at the control panel. The energy value selected shall be displayed at the control panel before and during irradiation.
(2) An interlock system shall be provided to prevent irradiation if operating conditions selected in the treatment room do not agree with the operating conditions selected at the control panel.
(3) For therapy systems manufactured after January 1, 1985, except systems that employ a straight through waveguide design, an interlock system shall be provided to terminate irradiation if the bending magnet current for the energy selected varies by more than ten percent (10%) of its normal value.
(r) Equipment capable of both stationary beam therapy and moving beam therapy shall comply with the following:
(1) Irradiation shall not be possible until either stationary beam therapy or moving beam therapy has been selected at the control panel. The mode of treatment selected shall be displayed at the x-ray control panel.
(2) An interlock system shall be provided to ensure that the equipment can operate only in the mode selected.
(3) An interlock system shall be provided to prevent irradiation if any operation selected to be carried out in the treatment room does not agree with the operation selected at the control panel.
(4) For therapy systems manufactured after January 1, 1985, an interlock system shall be provided to terminate irradiation if the gantry moves during stationary beam therapy, or if the gantry ceases rotation before the preselected arc is swept, unless the stoppage is preplanned.
(5) Moving beam therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement.
(6) Therapy systems manufactured after January 1, 1985, shall also comply with the following:
(A) An interlock system shall be provided to terminate irradiation if the gantry speed, dose rate, or dose rate per degree varies by more than twenty percent (20%) of the preselected value.
(B) For moving beam therapy wherein irradiation is terminated based on the arc swept, the dose monitor units shall differ by less than five percent (5%) from the value calculated for the absorbed dose per unit angle.
(C) For moving beam therapy wherein the dose monitor system terminates irradiation, the termination shall be in accordance with subsection (m).

(s) For therapy systems manufactured after January 1, 1985, a system shall be provided from which readings of the absorbed dose rate at a reference point in the treatment volume can be calculated. The dose monitoring chambers specified in subsection (h) may form part of this system. The dose monitor unit rate shall be displayed at the control panel.

(t) The registrant shall determine, or shall obtain from the manufacturer, the location of the target or the virtual source of x-rays with reference to an accessible point on the radiation head. If the equipment is capable of electron therapy, the registrant shall also determine, or shall obtain from the manufacturer, the location of the electron window with reference to an accessible point on the radiation head.

(u) Capability shall be provided for radiation safety interlocks to be checked for proper operation.

(v) Facilities which will house therapeutic x-ray or electron systems capable of operating at more than one (1) MeV shall comply with 410 IAC 5-4 and the following:
(1) All protective barriers shall be fixed except for entrance doors or beam interceptors.
(2) The control panel shall be located outside the treatment room.
(3) Windows, mirrors, closed circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be located so the operator can observe the patient from the control panel.
(4) When the primary viewing system is electronic, either an alternate viewing system shall be available for use in the event of failure of the primary viewing system, or the therapeutic x-ray or electron system shall not be used when the primary viewing system is not fully functional. Alternate viewing systems may also be electronic. In the event of failure of both

viewing systems, the therapeutic x-ray or electron system shall not be used to irradiate patients until one (1) of the viewing systems is again fully operational.

(5) Provision shall be made for verbal communication between the patient and the operator at the control panel. However, where treatment requirements or excessive noise levels make verbal communication impractical, other effective methods of communication shall be utilized.

(6) Each treatment room entrance shall be provided with a readily observable warning light near the outside of the entrance. The warning light shall indicate when irradiation is in progress in the treatment room.

(7) Interlocks shall be provided such that all treatment room entrances must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to continue irradiation without closing all entrance doors and manually reinitiating irradiation at the control panel.

(w) Registrants shall have all new therapeutic x-ray or electron facilities, and existing facilities not previously surveyed, surveyed by a radiation oncology physicist approved by the department. Such surveys shall also be performed after any change in the facility or equipment which might cause a significant increase in radiation hazard. The registrant shall obtain a written report of the survey from the radiation oncology physicist, and a copy of the report shall be transmitted by the registrant to the commissioner within thirty (30) days of receipt of the report of the survey. The survey and report shall indicate all locations where the dose equivalent rate exceeds the limits specified in this rule.

(x) The registrant shall establish procedures to check all monitor unit calculations by an independent method or by a second individual before administering thirty percent (30%) of the prescribed total dose to assure that the dose to a single point on the central axis, or to a point of special interest, agrees with the manual or computer generated dose calculation and with the written order of a practitioner of the healing arts. Additionally, the registrant shall verify that the correct central axis depth-dose values, field size factors, off-axis ratios, and beam modifying factors are used and documented.

(y) Calibration of therapeutic x-ray or electron systems subject to this section shall be performed in accordance with an established calibration protocol acceptable to the commissioner, such as the protocol established by the American Association of Physicists in Medicine. The calibrations shall be performed before the system is first used for irradiation of an individual, and thereafter at time intervals not to exceed twelve (12) months. Calibrations shall also be performed after any change which might significantly alter the dose monitor unit, beam energy, spatial distribution, or other characteristics of the therapy beam. Calibration shall be performed by a radiation oncology physicist approved by the department, who is physically present at the facility. Radiation measurements conducted during calibrations required by this subsection shall be performed using a dosimetry system which complies with the following:

(1) The dosimetry system shall have an air-kerma calibration factor for cobalt 60 gamma rays traceable to the National Institute for Standards and Technology.

(2) The dosimetry system shall have been calibrated within the previous two (2) years and after any servicing that may have affected its calibration. The system shall have been calibrated in such a fashion that an uncertainty can be stated for the radiation output measured by the system. The dosimetry system shall have had constancy checks performed on the system as specified by a radiation oncology physicist approved by the department. Calibration shall be in sufficient detail that the dose at a reference point in soft tissue may be calculated with a maximum uncertainty of five percent (5%).

(3) Calibration of each therapy beam shall include, but not be limited to, the following determinations:

(A) Verification that the equipment is operating in compliance with the design specifications concerning the radiographic isocenter, light-radiation field congruency, laser alignment, optical distance indicator, field size indicators, variation in the axis of rotation for the table, collimator, gantry, and beam flatness and symmetry at specified depths for various gantry angles.

(B) Verification of beam energy, output factors, off-axis ratios, dose-depth values, and isodose data for each beam.

(C) Verification of transmission data for all beam modification devices such as wedges, blocking trays, compensators, and custom blocks.

(D) Verification that existing depth-dose data and isodose charts applicable to the equipment continues to be valid or are updated to existing machine conditions.

Records of calibration measurements and dosimetry system calibrations conducted in accordance with this subsection shall be maintained by the registrant for at least five (5) years after completion of such calibration.

(z) An independent check of the output of each therapeutic beam shall be performed annually. The check shall be performed by either of the following:

(1) A radiation oncology physicist approved by the department, other than the one who performed the annual output calibration, using a dosimetry system other than the one that was used during the annual calibration. The dosimetry system must also comply with subsection (y).

(2) A thermoluminescence dosimetry service capable of measuring doses with an accuracy of five percent (5%) or less.

(aa) Output spot checks shall be performed on therapeutic x-ray or electron systems during spot checks conducted in accordance with subsection (y), and thereafter at intervals not to exceed one (1) month by a radiation oncology physicist approved by the department. Output spot check procedures shall be in writing and shall have been developed by a radiation oncology physicist approved by the department. Output spot check procedures shall specify which tests or measurements to be performed, the frequency the tests or measurements are to be performed, the acceptable tolerance for each parameter measured compared to the value for that parameter as determined in the last calibration conducted in accordance with subsection (y), and the action to be taken if a tolerance has been exceeded for any test or measurement required by the written output spot check procedures. Written output spot check procedures are required for at least the following parameters:

(1) Output per monitor unit.

(2) Light-radiation field congruency.

(3) Laser alignment.

(4) Optical distance indicators.

(5) Field size indicators.

If an output spot check conducted in accordance with this subsection indicates a variance of more than five percent (5%) in output per monitor unit compared to the value determined in the last spot check conducted in this subsection, the radiation oncology physicist shall calibrate the therapeutic x-ray system. Records of each output calibration measurement conducted in accordance with this subsection shall be maintained by the registrant for a minimum of five (5) years from the date the output calibration was performed.

(bb) The registrant shall perform weekly output constancy checks on each of their therapeutic x-ray or electron systems in accordance with written output constancy check procedures developed by a radiation oncology physicist approved by the department. The output constancy check procedures shall specify the following:

(1) The tests or measurements to be performed.

(2) The acceptable tolerance for each parameter measured compared to the value for that parameter as determined in the last calibration conducted in accordance with subsection (y).

(3) The action to be taken if a tolerance has been exceeded for a test or measurement required by the written output constancy check procedures.

At least monthly, a radiation oncology physicist approved by the department shall review the results of all required output constancy checks performed since his or her last such review. If an output constancy check conducted in accordance with this subsection indicates a variance of more than five percent (5%) in output per monitor unit compared to the value determined in the last calibration conducted in accordance with subsection (y), the registrant shall repair the therapeutic x-ray or electron system or undertake other corrective action before the equipment is again used to irradiate patients. The registrant shall also perform an output constancy check to determine whether or not the therapeutic x-ray or electron system is again in compliance with this subsection prior to utilizing the equipment to irradiate patients. A record of each output constancy check performed in accordance with this subsection, and any repairs or corrective action undertaken in compliance with this subsection, shall be maintained by the registrant for a minimum of two (2) years from the date the output constancy check, repair, or corrective action was performed.

(cc) The registrant shall perform checks on treatment planning computers and dose calculation algorithms in accordance with quality assurance procedures developed by a radiation oncology physicist approved by the department. At a minimum, the quality assurance procedures shall require that the registrant do the following:

(1) Verify that the output for external beam programs, including irregular fields, agree with measured beam data for test cases.

(2) Ensure that any computer hardware changes have been correctly installed.

(3) Ensure that any computer software changes, including beam data files, have been correctly implemented without corrupting beam data.

(4) Verify that all users of treatment planning computers have been trained in the use of the computers.

(dd) The registrant shall establish and maintain a written quality management plan to assure that radiation from an x-ray or electron therapy system is administered as ordered by a practitioner of the healing arts. At a minimum, the quality management plan must assure the following:

(1) Prior to administration, a written order for therapeutic radiation must be prepared by a practitioner of the healing arts. Said order shall specify, at a minimum, the following:

(A) The patient's name.

(B) The anatomical treatment site or sites.

(C) For each treatment site, treatment mode, and beam energy, the following:

(i) The dose per fraction.

(ii) The number of fractions.

(iii) The total dose.

If, in the opinion of a practitioner of the healing arts, any delay could jeopardize the health of a patient, said practitioner may verbally order therapeutic radiation, as long as the practitioner prepares a written order in accordance with this subdivision, to confirm his or her verbal orders within seventy-two (72) hours of issuing the verbal order.

(2) Treatment plans and related calculations for radiation are in accordance with the written order of a practitioner of the healing arts.

(3) That each administration of therapeutic radiation is in accordance with a written order of a practitioner of the healing arts.

(4) That deviations from the written order of a licensed practitioner of the healing arts in excess of ten percent (10%) of the daily prescribed dose is identified, evaluated, and the findings communicated to the practitioner of the healing arts.

(ee) The registrant shall review the radiation oncology chart of patients subjected to irradiation from a therapeutic x-ray or electron system in accordance with written quality assurance procedures developed by a radiation oncology physicist approved by the department. At a minimum, the written quality assurance procedures must require the following:

(1) That the documented monitor units used for each field is *[sic., are]* in conformance with calculations.

(2) That the therapeutic x-ray or electron system operator initials the treatment documentation for each patient he or she treats, each day.

(3) The daily radiation dose and the cumulative radiation dose is *[sic., are]* recorded.

(4) Each written order for therapy treatment is being followed.

(5) The total prescribed dose for each treatment site is appropriately indicated.

(ff) The registrant shall submit a written report to the commissioner of any misadministration within fifteen (15) days of discovery of the misadministration. The report shall contain the following:

(1) State the name and address of the registrant.

(2) State the name of the practitioner of the healing arts who prescribed the x-ray or electron therapy at issue.

(3) State the name of the individual who was improperly irradiated, or the name of that individual's parent or guardian, if applicable.

(4) Briefly describe the nature of the misadministration and any resultant effect on the individual who was improperly irradiated.

(5) Describe the actions taken by the registrant to prevent a recurrence of similar misadministrations.

(6) State what information has been presented to the individual who was improperly irradiated, or to that individual's parent or guardian, if applicable.

A copy of the report shall be maintained by the registrant for at least five (5) years after the date of the misadministration.

(gg) If possible, within twenty-four (24) hours of discovery of a misadministration, the registrant shall notify the individual who has been improperly irradiated, or that individual's parent or guardian, if applicable, about the misadministration, unless, in the opinion of a practitioner of the healing arts, such notification would be harmful to that individual. Also, within twenty-four (24) hours of discovery of a misadministration, the registrant shall notify the referring practitioner of the healing arts about the misadministration. At a minimum, the notifications shall briefly describe the nature of the misadministration and any resultant effect on the individual who was improperly irradiated.

(hh) A therapeutic x-ray system shall not be used to administer radiation therapy unless it complies with subsections (u), (y), (z), and (aa) through (cc). *(Indiana State Department of Health; 410 IAC 5-6.1-125; filed Oct 29, 1993, 5:00 p.m.: 17 IR 383; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-126 Veterinary medicine radiographic systems

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 126. (a) No person other than a veterinarian shall direct or order the application of radiation to any animal, nor shall any person other than a veterinarian, or a person working under the direct supervision of a veterinarian, apply radiation to animals. Such direction or order to apply radiation shall be in the course of the veterinarian's professional practice or in the interest of science and shall comply with all applicable sections of this rule.

(b) Veterinary x-ray facilities shall comply with applicable provisions of sections 118, 120, and 123 of this rule and this section. All veterinary x-ray facilities must be evaluated at intervals not to exceed twenty-four (24) months by a diagnostic imaging physicist or x-ray machine inspector approved by the department.

(c) The protective tube housing shall be of diagnostic type.

(d) Light beam diaphragms shall be provided for collimating the useful beam to the area of clinical interest. Cones may be used only if it can be demonstrated that the x-ray tube and cassette can be fixed such that the primary beam is limited to the cassette. Diaphragms and cones shall provide the same degree of protection as is required of the housing.

(e) The total filtration permanently in the useful beam shall not be less than five-tenths (0.5) mm aluminum equivalent for machines operating up to fifty (50) kVp, one and five-tenths (1.5) mm aluminum equivalent for machines operating from fifty (50) to seventy (70) kVp, and two and five-tenths (2.5) mm aluminum equivalent for machines operating above seventy (70) kVp.

(f) A device shall be provided to terminate the exposure after a preset time or exposure. It shall not be possible to make an exposure when the timer is set to the zero (0) or off position if either is provided.

(g) A dead-man switch shall be provided, together with an electrical cord of sufficient length, so that the operator can stand out of the useful beam and at least six (6) feet from the animal during x-ray exposures.

(h) All radiographic areas shall be provided with sufficient protective barriers that the radiation limits specified in 410 IAC 5-4-2, 410 IAC 5-4-5(a), and 410 IAC 5-4-6 are not exceeded.

(i) The operator shall stand away from the useful beam and the animal as far as reasonably possible during the radiographic exposures.

(j) No individual other than the operator shall be in the x-ray room while exposures are being made unless such individual's assistance is required to ensure a successful radiographic procedure.

(k) When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and a protective apron, and the individual shall be so positioned that no part of his or her body will be struck by the useful beam. The exposure of any individual who must hold an animal during radiography shall be monitored via a personnel dosimetry program. *(Indiana State Department of Health; 410 IAC 5-6.1-126; filed Oct 29, 1993, 5:00 p.m.: 17 IR 389; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-6.1-127 Mammographic x-ray equipment

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 127. (a) Mammographic x-ray facilities shall comply with applicable provisions of sections 118 and 119 of this rule and this section. All mammographic x-ray facilities must be evaluated at least once every twelve (12) months by a diagnostic imaging physicist approved by the department.

(b) The registrant shall assure that the results of all mammography procedures are interpreted by a physician certified by the ABR, the American Osteopathic Board of Radiology, or by a physician accredited by the ACR through their mammography accreditation program.

(c) The registrant shall assure that the physician does the following:

(1) Has successfully completed or taught a minimum of forty (40) hours of postgraduate instruction in mammography interpretation.

(2) Has successfully completed or taught a minimum of fifteen (15) hours of postgraduate work in mammography

interpretation every thirty-six (36) months.

(3) Reads the results of ten (10) or more screening or diagnostic mammographic exams per week.

(4) Prepares and signs a written report on his or her interpretation of the results of each mammography procedure.

(5) Provides a copy of the written report and the original images or films to the registrant for inclusion in the patient's medical record.

(6) Provides a written statement to the patient, either through the referring physician or his or her designee, or, if a referring physician is not available, directly to the patient. The statement shall be written in terms easily understood by a lay person and must describe the test results and the importance of the mammogram to ongoing health, as well as that person's responsibility to share with any new physician or supplier of their next mammogram the date and place of their previous mammography procedure. If the results of the mammogram are positive, the statement must describe the next step that should be taken by the patient. The statement must also record the following:

(A) The date of the mammography procedure.

(B) The name of the facility providing the mammography procedure.

(C) The physician to whom the person wants a copy of the statement to be sent, if any.

The statement must further indicate that the original images or films are being provided to the mammography facility for inclusion in the individual's medical record.

(d) The registrant shall assure that a physician qualified in accordance with subsection (c)(1) through (c)(3) documents at least annually that he or she:

(1) has checked the procedure manual and has observed at least monthly the performance of the operator of the mammographic x-ray equipment and has determined that both are adequate; and

(2) has verified that safe operating procedures are used and that all applicable requirements of this rule are being met.

(e) The registrant shall assure that all operators of mammographic x-ray equipment:

(1) have a general diagnostic x-ray machine operator's certificate in accordance with 410 IAC 5-11;

(2) have passed the advanced examination in mammography administered by the ARRT or have successfully completed ten (10) hours of specialized training in mammographic positioning, compression, and technique factor setting prior to performing mammograms; and

(3) successfully complete ten (10) hours of specialized training in mammographic positioning, compression, and technique factor setting at least every twenty-four (24) months thereafter.

(f) The registrant must have an orientation program for operators of mammographic x-ray equipment based on a procedure manual that is available to all members of the staff.

(g) All x-ray equipment used to perform mammography shall be specifically designed for mammography.

(h) Target-filter combinations shall comply with the following:

(1) For film/screen mammography, the target shall be constructed of molybdenum, with molybdenum filtration and a beryllium window. Tungsten targets with special filters such as palladium or rhodium are also acceptable, but only if the x-ray equipment has been accredited by the ACR.

(2) For xeroradiography, the target shall be constructed of tungsten with aluminum filtration.

(i) The x-ray equipment shall be capable of use with antiscatter grids.

(j) An x-ray control shall be incorporated such that an exposure can be terminated at any time except for exposures of one-half (1/2) second or less. The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated. The x-ray control panel shall have labeled control settings or meters to show all physical factors used for exposure, such as focal spot, kVp, mA, mAs, time, and automatic exposure control. The x-ray equipment must be operable only from a shielded position.

(k) A mark on the visible exterior surface of the source assembly shall indicate the location of the focal spot. The SID shall be no less than fifty (50) cm.

(l) For film/screen equipment, the half-value layer shall be no less than three-tenths (0.3) mm aluminum equivalent at a measured tube voltage of thirty (30) kVp with the compression device in the useful x-ray beam. Otherwise, the half-value layer shall be no less than that specified in section 119(f), Table I of this rule.

(m) For xeroradiography equipment, the half-value layer shall be no less than one (1.0) mm aluminum equivalent at the clinically employed kVp.

(n) A compression device shall be provided. For film/screen systems, the compression device shall be of the flat plate type,

parallel to the image receptor.

(o) Mammographic x-ray equipment shall be provided with a means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID, except the edge of the image receptor designed to be adjacent to the chest wall, in which case the x-ray field may not extend beyond this edge by more than two percent (2%) of the SID.

(p) For mammographic x-ray equipment equipped with a beam-limiting device and a light localizer, the light field shall be aligned with the radiation field within two percent (2%) of the SID.

(q) For all mammographic x-ray equipment:

(1) the kVp shall be accurate within two (2) kV, plus or minus; and

(2) the coefficient of variation shall be no greater than five-hundredths (0.05) for each kVp tested.

Compliance shall be based on determination of the coefficient of variation and the average of at least four (4) consecutive measurements for the kVp at which the x-ray equipment is normally used. Compliance may be based on single measurements for other kVps over the range of use. However, if any single measurement is out of compliance, an average and coefficient of variation shall be determined at that kVp for comparison to subdivisions (1) and (2).

(r) Mammographic x-ray equipment shall have automatic exposure control, including the following:

(1) The coefficient of variation for automatic exposure control reproducibility shall be no greater than five-hundredths (0.05). Determination of compliance shall be based on at least four (4) consecutive measurements of exposure or optical density obtained at a fixed kVp and attenuator thickness.

(2) Mammographic x-ray equipment shall:

(A) be capable of maintaining constant film density to within plus or minus three-tenths (0.3) of the average optical density over the kVp range used for thicknesses of approximately two (2) cm, four (4) cm, and six (6) cm of acrylic or BR-12; or

(B) have kVp/thickness density control correction charts.

(s) The coefficient of variation for exposure timer reproducibility shall be no greater than five-hundredths (0.05). Compliance shall be based on at least four (4) consecutive measurements.

(t) The coefficient of variation for exposure shall be no greater than five-hundredths (0.05) when all technique factors are held constant. Determination of compliance shall be based on at least four (4) consecutive measurements.

(u) When mammographic x-ray equipment allows a choice of tube current settings and is operated on a power supply specified by the manufacturer in accordance with applicable federal standards, for any tube potential (kVp) within forty percent (40%) to one hundred percent (100%) of the maximum kVp rating, the absolute value of the difference between the ratio of average exposure in mR to the indicated mAs obtained at any two (2) consecutive tube current settings shall not differ by more than ten-hundredths (0.10) of the absolute value of their sum. A minimum of four (4) measurements per tube current setting are required to determine each average exposure. This requirement is expressed mathematically as:

$$|X_1 - X_2| \leq 0.10\,|X_1 + X_2|$$

Where: X_1 and X_2 = The ratios of average exposure to mAs obtained at each of two (2) consecutive tube current settings

(v) For a cranio-caudal view of a four and five-tenths (4.5) cm compressed breast with fifty percent (50%) glandular tissue, the average glandular dose shall not exceed the following:

(1) For a film/screen without grid, one-tenth (0.1) centigray (0.1 rad) per projection.

(2) For a film/screen with grid, three-tenths (0.3) centigray (0.3 rad) per projection.

(3) For xeroradiography, four-tenths (0.4) centigray (0.4 rad) per projection.

(w) There shall be a quality assurance program specific to mammography, covering all components of the x-ray equipment, from the x-ray generator to the image developer, to ensure consistently high quality images with minimum patient exposure. The quality assurance program shall be reviewed at least annually. Establishment and conduct of the quality assurance program shall be the responsibility of the registrant under the direction of a physician and a diagnostic imaging physicist approved by the department. The diagnostic imaging physicist must do the following:

(1) Conduct, or train others to conduct, equipment performance monitoring.

(2) Analyze the monitoring results to determine if there are any problems requiring correction.

(3) Serve as the liaison between the facility and service engineer.

(x) All quality assurance records shall be maintained for at least three (3) years and shall be readily available for inspection by the commissioner.

(y) The registrant shall assure that monitoring is conducted at least once each twelve (12) months at each mammographic x-ray facility as part of a quality assurance program. The monitoring shall be conducted by a diagnostic imaging physicist approved by the department in accordance with Table V and the following:

TABLE V

Parameter	Frequency	Individual Responsible
Darkroom cleanliness	daily	mammographer
Processor performance	daily	mammographer
Screen cleanliness	weekly	mammographer
View boxes and viewing conditions	weekly	mammographer
Image quality (phantom images)	monthly	mammographer
Repeat analysis	quarterly	mammographer
Analysis of fixer retention in film	quarterly	mammographer
Darkroom fog	semiannually	mammographer
Screen-film contact	semiannually	mammographer
Compression	semiannually	mammographer
AEC density control function	annually	diagnostic imaging physicist
Star pattern focal spot size test	annually	diagnostic imaging physicist
Uniformity of screen speed	annually	diagnostic imaging physicist
Assembly physical evaluation	annually	diagnostic imaging physicist

(1) Processor performance shall be monitored daily before the first patient examination.

(2) Image quality shall be evaluated utilizing the RMI Model 156 ACR mammography accreditation phantom (or other image quality phantom approved in advance by the commissioner) each time mammographic x-ray equipment is moved, altered in any major way (such as replacement of parts), and at least monthly between movements or alterations. Image quality shall be evaluated by obtaining a test image at the settings normally used for a four and five-tenths (4.5) cm compressed breast with fifty percent (50%) glandular tissue. A file of such images shall be maintained for review by the physician and the diagnostic imaging physicist for comparison with earlier images. Image quality of the RMI Model 156 phantom shall comply with the following:

(A) Fibrils of seventy-five hundredths (0.75) mm, eighty-nine hundredths (0.89) mm, one and twelve-hundredths (1.12) mm, and one and fifty-six hundredths (1.56) mm shall be visualized.

(B) Masses of seventy-five hundredths (0.75) mm, one (1) mm, and two (2) mm shall be visualized.

(C) Speck groups of thirty-two hundredths (0.32) mm, forty-hundredths (0.40) mm, and fifty-hundredths (0.50) mm shall be fully visualized.

If the results fall outside the acceptable range, the test must be repeated. If the results continue to be unacceptable, the cause of the problem must be identified and corrected before further examinations are conducted.

(Indiana State Department of Health; 410 IAC 5-6.1-127; filed Oct 29, 1993, 5:00 p.m.: 17 IR 389; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-6.1-128 Mammography inspection for calendar year 1993

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 128. Notwithstanding section 122(a) of this rule, all x-ray facilities providing mammographic x-ray services shall be inspected in accordance with this rule, on or after the effective date of this rule and before January 1, 1994. However, any x-ray

facility providing mammographic x-ray services, which was inspected on or after January 1, 1993, and before the effective date of this rule by a person qualified in accordance with section 118(h) of this rule, shall be considered in compliance with this section. *(Indiana State Department of Health; 410 IAC 5-6.1-128; filed Oct 29, 1993, 5:00 p.m.: 17 IR 392; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

Rule 7. Sealed Radioactive Sources in the Healing Arts

410 IAC 5-7-1 Scope of rule

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 1. The provisions of 410 IAC 5-7 apply to all licensees or registrants who use sealed sources in the healing arts and are in addition to, and not in substitution for, other applicable provisions of 410 IAC 5. *(Indiana State Department of Health; Rule HRH-2, PT G, Sec G.1; filed May 26, 1978, 3:30 pm: 1 IR 221; filed Feb 29, 1984, 10:10 am: 7 IR 966; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-7-1.1 Definitions

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 1.1. As used in 410 IAC 5-7, the following definitions apply:

"Brachytherapy" means a method of radiation therapy in which an encapsulated source or group of sources is utilized to deliver beta or gamma radiation at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

"Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body. *(Indiana State Department of Health; 410 IAC 5-7-1.1; filed Feb 29, 1984, 10:10 am: 7 IR 966; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-7-2 Interstitial, intracavitary, and superficial applications

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 2. (a) Accountability, Storage and Transit.

(1) Except as otherwise specifically authorized by the board, each licensee shall provide accountability of sealed sources and shall keep a record of the issue and return of all sealed sources to their place of storage.

(2) Each licensee or registrant shall conduct a physical inventory at intervals not to exceed 6 months to account for all sources and devices received and possessed. Records of the inventories shall be maintained for inspection by the board and shall include the quantities and kinds of radioactive material, location of sources and devices, and the date of the inventory.[1/]

[1/] The U.S. Nuclear Regulatory Commission requires these inventories to be done on a quarterly basis.

(3) Each licensee shall follow the radiation safety and handling instructions approved by the board, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state and furnished by the manufacturer on the label attached to the source, device, or permanent container thereof, or in the leaflet or brochure which accompanies the source or device, and maintain such instruction in a legible and conveniently available form.

(4) Each licensee or registrant shall assure that needles or standard medical applicator cells containing cobalt-60 as wire, radium-226, or cesium-137 are not opened while in the licensee's or registrant's possession unless specifically authorized by a license or permit issued by the board.

(b) Testing Sealed Sources for Leakage and Contamination.

(1) All sealed sources, containing more than 100 microcuries of radioactive material with a half-life greater than 30 days, or

10 microcuries of radium-226, shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as are approved by the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state and described by the manufacturer on the label attached to the source, device or permanent container thereof, or in the leaflet or brochure which accompanies the source or device. Each source or device shall be so tested prior to its first use unless the supplier furnishes a certificate that the source or device has been so tested within 6 months prior to the transfer.
(2) Leak tests shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample or, in the case of radium, the escape of radon at the rate of 0.001 microcurie per 24 hours. The test sample shall be taken from the source or from the surfaces of the device in which the source is permanently or semipermanently mounted or stored on which one might expect contamination to accumulate. Any test conducted pursuant to 410 IAC 5-7-2(b)(1) which reveals the presence of 0.005 microcurie or more of removable contamination or, in the case of radium, the escape of radon at the rate of 0.001 microcurie or more per 24 hours shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with applicable provisions of 410 IAC 5-4. A report shall be filed with the board within 5 days of the source withdrawal describing the equipment involved, the test results, and the corrective action taken.
(3) Leak test results shall be recorded in units of microcuries and maintained for inspection by the board.
(c) Radiation Surveys.
(1) The maximum radiation level at a distance of one meter from the patient in whom brachytherapy sources have been inserted shall be determined by measurement or calculation. This radiation level shall be entered on the patient's chart and other signs as required under 410 IAC 5-7-2(d).
(2) The radiation levels in the patient's room and the surrounding area shall be determined, recorded, and maintained for inspection by the board.
(3) The licensee or registrant shall assure that patients treated with the cobalt-60, cesium-137, iridium-192 or radium-226 implants remain hospitalized until a source count and radiation survey of the patient confirm that all implants have been removed.
(d) Signs and Records.
(1) In addition to the requirements of 410 IAC 5-4-11, the bed, cubicle, or room of the hospital brachytherapy patient shall be marked with a sign indicating the presence of brachytherapy sources. This sign shall incorporate the radiation symbol and specify the radionuclide, the activity, date, and the individual(s) to contact for radiation safety instructions. The sign is not required provided the exception in 410 IAC 5-4-12(b) is met.
(2) The following information shall be included in the patient's chart:
(i) The radionuclide administered, number of sources, activity in millicuries and time and date of administration;
(ii) The exposure rate at 1 meter, the time the determination was made, and the name of the individual who made the determination;
(iii) The radiation symbol; and
(iv) The precautionary instructions necessary to assure that the exposure of individuals does not exceed that permitted under 410 IAC 5-4-2.

(Indiana State Department of Health; Rule HRH-2, PT G, Sec G.2; filed May 26, 1978, 3:30 pm: 1 IR 221; filed Feb 29, 1984, 10:10 am: 7 IR 966; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-7-3 Teletherapy

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 3. (a) Equipment.
(1) The housing shall be so constructed that, at 1 meter from the source, the maximum exposure rate does not exceed 10 milliroentgens per hour when the beam control mechanism is in the "off" position. The average exposure rate measured at a representative number of points about the housing, each 1 meter from the source, shall not exceed 2 milliroentgens per hour.
(2) For teletherapy equipment installed after the effective date of 410 IAC 5, the leakage radiation measured at 1 meter from

the source when the beam control mechanism is in the "on" position shall not exceed 0.1 percent of the useful beam exposure rate.

(3) Adjustable or removable beam-defining diaphragms shall allow transmission of not more than 5 percent of the useful beam.

(4) The beam control mechanism shall be of a positive design capable of acting in any orientation of the housing for which it is designed to be used. In addition to an automatic closing device, the mechanism shall be designed so that it can be manually returned to the "off" position with a minimum risk of exposure.

(5) The closing device shall be so designed as to return automatically to the "off" position in the event of any breakdown or interruption of the activating force and shall stay in the "off" position until activated from the control panel.

(6) When any door to the treatment room is opened, the beam control mechanism shall automatically and rapidly restore the unit to the "off" position and cause it to remain there until the unit is reactivated from the control panel.

(7) There shall be at the housing and at the control panel a warning device that plainly indicates whether the beam is "on" or "off."

(8) The equipment shall be provided with a locking device to prevent unauthorized use.

(9) The control panel shall be provided with a timer that automatically terminates the exposure after a preset time.

(10) Provision shall be made to permit continuous observation of patients during irradiation.

(b) Operation. No individual shall be in the treatment room during irradiation unless that individual is the patient. Mechanical restraining or supporting devices shall be used for positioning the patient, if necessary.

(c) Testing for Leakage and Contamination. Teletherapy sources shall be tested for leakage and contamination in accordance with the procedures described in 410 IAC 5-7-2(b). Tests of leakage may be made by wiping accessible surfaces of the housing port or collimator while the source is in the "off" position and measuring these wipes for transferred contamination.

(d) Calibration and Physical Decay Determinations.

(1) Calibration measurements shall be performed by a qualified radiation therapy physicist on each teletherapy unit:

(i) Prior to the first use of the unit for treating humans;

(ii) Prior to treating humans;

(A) Whenever spot-check measurements indicate that the output value differs by more than 5 percent from the value obtained at the last calibration corrected mathematically for physical decay;

(B) Following replacement of the radiation source or following reinstallation of the teletherapy unit in a new location; and

(C) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(iii) At intervals not exceeding 1 year.

(2) Calibration measurement shall include determination of:

(i) The exposure rate or dose rate to an accuracy within 3 percent for the range of field sizes and for the range of distances or for the axis distance, used in radiation therapy;

(ii) The congruence between the radiation field and the field indicated by the light beam localizing device;

(iii) The uniformity of the radiation field and its dependence upon the orientation of the useful beam;

(iv) Timer accuracy; and

(v) The accuracy of all distance measuring devices used for treating humans.

(3) The exposure rate or dose rate values shall be corrected mathematically for physical decay at intervals not exceeding 1 month.

(4) Calibration measurements and physical decay corrections shall be performed by a qualified radiation therapy physicist in accordance with 410 IAC 5-7-3(g).

(e) Spot-Check Measurements

(1) Spot-check measurements shall be performed on each teletherapy unit at intervals not exceeding 1 month.

(2) Spot-check measurements shall include determination of:

(i) Timer accuracy;

(ii) The congruence between the radiation field and the field indicated by the light beam localizing device;

(iii) The accuracy of all distance measuring devices used for treating humans;

(iv) The exposure rate, dose rate or a quantity related in a known manner to these rates for one typical set of operating

conditions; and

(v) The difference between the measurements made in 410 IAC 5-7-3(e)(2)(iv) and the anticipated output expressed as a percentage of the anticipated output. The anticipated output is the value obtained at the last calibration corrected mathematically for physical decay.

(3) Spot-check measurements shall be performed in accordance with procedures established by a qualified radiation therapy physicist in accordance with 410 IAC 5-7-3(g)(1). A qualified radiation therapy physicist need not actually perform the spot-check measurements. If a qualified radiation therapy physicist does not perform the spot-check measurements, the results of the spot-check measurements shall be reviewed by a qualified radiation therapy physicist within 15 days.

(f) Dosimetry System Calibration

(1) Calibration measurements shall be performed using a dosimetry system that has been calibrated by the National Bureau of Standards or by a Regional Calibration Laboratory accredited by the American Association of Physicists of Medicine. The dosimetry system shall have been calibrated within the previous 2 years and after any servicing that may have affected system calibration.

(2) Spot-check measurements shall be performed using a dosimetry system that has been calibrated in accordance with 410 IAC 5-7-3(f)(1). Alternatively, a dosimetry system used solely for spot-check measurements may be calibrated by direct intercomparison with a system that has been calibrated in accordance with 410 IAC 5-7-3(f)(1). This alternative calibration method shall have been performed within the previous 1 year and after each servicing that may have affected system calibration. Dosimetry systems calibrated by the alternative method shall not be used for teletherapy calibration measurements.

(g) Records. The licensee or registrant shall maintain, for inspection by the board, records of the measurements, tests, corrective actions, and instrument calibrations.

(1) Records of teletherapy calibration measurements and calibration of the instruments used to make these measurements shall be preserved for 5 years after completion of the teletherapy calibration.

(2) Records of spot-check measurements and corrective actions and calibration of instruments used to make spot-check measurements shall be preserved for 2 years after completion of the spot-check measurements and corrective actions.

(Indiana State Department of Health; Rule HRH-2, PT G, Sec G.3; filed May 26, 1978, 3:30 pm: 1 IR 222; filed Feb 29, 1984, 10:10 am: 7 IR 968; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

Rule 8. Radiation Safety Requirements for Analytical X-Ray Equipment

410 IAC 5-8-1 Scope of rule

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 1. 410 IAC 5-8 provides special requirements for analytical x-ray equipment. The requirements of 410 IAC 5-8 are in addition to, and not in substitution for, applicable requirements in other parts of 410 IAC 5. *(Indiana State Department of Health; Rule HRH-2, PT H, Sec H.1; filed May 26, 1978, 3:30 pm: 1 IR 222; filed Feb 29, 1984, 10:10 am: 7 IR 969; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-8-2 Definitions

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 2. As used in 410 IAC 5-8, the following definitions apply:

"Analytical x-ray equipment" means equipment used for x-ray diffraction or fluorescence analysis.

"Analytical x-ray system" means a group of components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials.

"Fail-safe characteristics" mean a design feature which causes beam port shutters to close, or otherwise prevents emergence

of the primary beam, upon the failure of a safety or warning device.

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

"Normal operating procedures" mean step-by-step instructions necessary to accomplish the analysis. These procedures shall include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant, and data-recording procedures which are related to radiation safety.

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

"Primary beam" means radiation which passes through an aperture of the source housing by a direct path from the x-ray tube or a radioactive source located in the radiation source housing. *(Indiana State Department of Health; Rule HRH-2, PT H, Sec H.2; filed May 26, 1978, 3:30 pm: 1 IR 223; filed Feb 29, 1984, 10:10 am: 7 IR 970; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-8-3 Equipment requirements

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 3. (a) Safety Device. A device which prevents the entry of any portion of an individual's body into the primary x-ray beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configurations. A registrant (or licensee) may apply to the board for an exemption from the requirement of a safety device. Such application shall include:

(1) A description of the various safety devices that have been evaluated;

(2) The reason each of these devices cannot be used; and

(3) A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

(b) Warning Devices.

(1) Open-beam configurations shall be provided with a readily discernible indication of:

(i) X-ray tube status (ON-OFF) located near the radiation source housing, if the primary beam is controlled in this manner; and/or

(ii) Shutter status (OPEN-CLOSED) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

(2) Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after June 25, 1978, warning devices shall have fail-safe characteristics.

(c) Ports. Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening.

(d) Labeling. All analytical x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

(1) "CAUTION–HIGH INTENSITY X-RAY BEAM," or words having a similar intent, on the x-ray source housing; and

(2) "CAUTION RADIATION–THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words having a similar intent, near any switch that energizes an x-ray tube if the radiation source is an x-ray tube; or

(3) "CAUTION–RADIOACTIVE MATERIAL," or words having a similar intent, on the source housing in accordance with 410 IAC 5-4-11 if the radiation source is a radionuclide.

(e) Shutters. On open-beam configurations installed after June 25, 1978, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

(f) Warning Lights. An easily visible warning light labeled with the words "X-RAY, ON," or words having a similar intent, shall be located:

(1) Near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized; or

(2) In the case of a radioactive source, near any switch that opens a housing shutter, and shall be illuminated only when the shutter is open.

(3) On equipment installed after June 25, 1978, warning lights shall have fail-safe characteristics.

(g) Radiation Source Housing. Each radiation source housing shall be subject to the following requirements:

(1) Each x-ray tube housing shall be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing or if the housing is disassembled.

(2) Each radioactive source housing or port cover or each x-ray tube housing shall be so constructed that, with all shutters closed, the radiation measured at a distance of 5 cm from its surface is not capable of producing a dose in excess of 2.5 millirems in one hour. For systems utilizing x-ray tubes, this limit shall be met at any specified tube rating.

(3) If radioactive sources are used, corresponding dose limits shall not exceed 2 mrem per hour.

(h) Generator Cabinet. Each x-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of 5 cm from its surface such that it is not capable of producing a dose in excess of 0.25 mrem in one hour. *(Indiana State Department of Health; Rule HRH-2, PT H, Sec H.3; filed May 26, 1978, 3:30 pm: 1 IR 223; filed Feb 29, 1984, 10:10 am: 7 IR 970; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-8-4 Area requirements; surveys; posting

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 4. (a) Radiation Levels. The local components of an analytical x-ray system shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in 410 IAC 5-4-6. For systems utilizing x-ray tubes, these levels shall be met at any specified tube rating.

(b) Surveys

(1) Radiation surveys, as required by 410 IAC 5-4-9, of all analytical x-ray systems sufficient to show compliance with paragraph 410 IAC 5-8-4(a) shall be performed:

(i) Upon installation of the equipment, and at least once every 12 months thereafter;

(ii) Following any change in the initial arrangement, number or type of local components in the system;

(iii) Following any maintenance requiring the disassembly or removal of a local component in the system;

(iv) During the performance of maintenance and alignment procedures if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed;

(v) Any time a visual inspection of the local components in the system reveals an abnormal condition; and

(vi) Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in 410 IAC 5-4-2.

(2) Radiation survey measurements shall not be required if a registrant (or licensee) can demonstrate compliance to the satisfaction of the board with 410 IAC 5-8-4 in some other manner.

(c) Posting. Each area or room containing analytical x-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION–X-RAY EQUIPMENT," or words having a similar intent in accordance with 410 IAC 5-4-11. *(Indiana State Department of Health; Rule HRH-2, PT H, Sec H.4; filed May 26, 1978, 3:30 pm: 1 IR 224; filed Feb 29, 1984, 10:10 am: 7 IR 971; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-8-5 Operation requirements

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 5. (a) Procedures. Normal operating procedures shall be written and available to all analytical x-ray equipment workers. No person shall be permitted to operate analytical x-ray equipment in any manner other than that specified in the procedures unless such person has obtained written approval of the radiation safety officer.

(b) Bypassing. No person shall bypass a safety device unless such person has obtained the approval of the radiation safety officer. Such approval shall be for a specified period of time. When a safety device has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING," or words having a similar intent, shall be placed on the radiation source housing.

(c) Repair or Modification of X-Ray Tube Systems. Except as specified in 410 IAC 5-8-5(b), no operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

(d) Radioactive Source Replacement, Testing or Repair. Radioactive source housings shall be opened for source replacement, leak testing or other maintenance or repair procedures only by individuals authorized to specifically conduct such procedures under a license issued by the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state. *(Indiana State Department of Health; Rule HRH-2, PT H, Sec H.5; filed May 26, 1978, 3:30 pm: 1 IR 224; filed Feb 29, 1984, 10:10 am: 7 IR 971; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-8-6 Personnel requirements; instruction; monitoring

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 6. (a) Instruction. No person shall be permitted to operate or maintain analytical x-ray equipment unless such person has received instruction in and demonstrated competence as to:

(1) Identification of radiation hazards associated with the use of the equipment;
(2) Significance of the various radiation warning, safety devices, and interlocks incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;
(3) Proper operating procedures for the equipment;
(4) Recognition of symptoms of an acute localized exposure; and
(5) Proper procedures for reporting an actual or suspected exposure.

(b) Personnel Monitoring.

(1) Finger or wrist dosimetric devices shall be provided to and shall be used by:
  (i) Analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and
  (ii) Personnel maintaining analytical x-ray equipment if the maintenance procedures require the presence of a primary x-ray beam when any local component in the analytical x-ray system is disassembled or removed.
(2) Reported dose values shall not be used for the purpose of determining compliance with 410 IAC 5-4-2 unless evaluated by a qualified radiation health physicist.

(Indiana State Department of Health; Rule HRH-2, PT H, Sec H.6; filed May 26, 1978, 3:30 pm: 1 IR 224; filed Feb 29, 1984, 10:10 am: 7 IR 972; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

Rule 9. Radiation Safety Requirements for Particle Accelerators

410 IAC 5-9-1 Scope of rule

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 1. (a) 410 IAC 5-9 establishes procedures for the registration and the use of particle accelerators. Particle accelerations utilized only for medical applications are subject to all provisions of 410 IAC 5-9 with the exception of 410 IAC 5-9-8(a), 410 IAC 5-9-10(a), (c), and (d).

(b) In addition to the requirements of 410 IAC 5-9, all registrants (or licensees) are subject to the requirements of 410 IAC

5-1, 410 IAC 5-2, 410 IAC 5-4, and 410 IAC 5-10. Registrants engaged in industrial radiographic operations are subject to the requirements of 410 IAC 5-5 and registrants engaged in the healing arts are subject to the requirements of 410 IAC 5-6 *[410 IAC 5-6 was repealed filed Oct 29, 1993, 5:00 p.m.: 17 IR 392. See 410 IAC 5-6.1.]* and/or 410 IAC 5-7. Registrants engaged in the production of radioactive material are subject to the requirements of 410 IAC 5-3. *(Indiana State Department of Health; Rule HRH-2, PT I, Sec I.1; filed May 26, 1978, 3:30 pm: 1 IR 224; filed Feb 29, 1984, 10:10 am: 7 IR 972; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-9-2 Registration required

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 2. No person shall receive, use, transfer, own or acquire a particle accelerator except as authorized in a registration issued pursuant to 410 IAC 5-2. *(Indiana State Department of Health; Rule HRH-2, PT I, Sec I.2; filed May 26, 1978, 3:30 pm: 1 IR 225; filed Feb 29, 1984, 10:10 am: 7 IR 973; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-9-2.5 Issuance of registration

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 2.5. In addition to 410 IAC 5-2, a registration application for use of a particle accelerator will be approved only if the board determines that:

(a) The registrant is qualified by reason of training and experience to use the accelerator in question for the purpose requested in accordance with 410 IAC 5-9 and 410 IAC 5-4 and 410 IAC 5-10 in such a manner as to minimize danger to public health and safety or property.

(b) The registrant's proposed or existing equipment, facilities, operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property.

(c) The issuance of the registration will not be inimical to the health and safety of the public, and the registrant satisfies any applicable special requirement in 410 IAC 5-9-3.

(d) The registrant has appointed a radiation safety officer;

(e) The registrant and/or the applicant's staff has substantial experience in the use of particle accelerators and training sufficient for application to its intended uses.

(f) The registrant has established a radiation safety committee to approve, in advance, proposals for uses of particle accelerators, whenever deemed necessary by the board.

(g) The registrant has an adequate training program for operators of particle accelerators. *(Indiana State Department of Health; 410 IAC 5-9-2.5; filed Feb 29, 1984, 10:10 am: 7 IR 973; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-9-3 Human uses; special provisions for registration

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 3. In addition to the requirements set forth in 410 IAC 5-2, a registration for use of a particle accelerator in the healing arts will be issued only if:

(a) Whenever deemed necessary by the board, the registrant has appointed a medical committee of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of a particle accelerator. Membership of the committee should include physicians expert in internal medicine, hematology, therapeutic radiology, and a person experienced in depth-dose

calculations and protection against radiation;

(b) The individuals designated by the registrant as the users have substantial training and experience in deep therapy techniques or in the use of particle accelerators to treat humans; and

(c) The individual designated by the registrant as the user is a physician. *(Indiana State Department of Health; Rule HRH-2, PT I, Sec I.3; filed May 26, 1978, 3:30 pm: 1 IR 225; filed Feb 29, 1984, 10:10 am: 7 IR 973; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-9-4 General radiation safety requirements *(Repealed)*

Sec. 4. *(Repealed by Indiana State Department of Health; filed Feb 29, 1984, 10:10 am: 7 IR 829)*

410 IAC 5-9-5 Limitations on operation; termination

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 5. (a) No registrant shall permit any individual to act as an operator of a particle accelerator until such individual:

(1) Has been instructed in radiation safety and shall have demonstrated an understanding thereof;

(2) Has received copies of and instructions in 410 IAC 5-9 and, the applicable requirements of 410 IAC 5-4 and 410 IAC 5-10, and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof; and

(3) Has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed.

(b) The radiation safety committee or the radiation safety officer shall have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to protect health and minimize danger to public health and safety or property. *(Indiana State Department of Health; Rule HRH-2, PT I, Sec I.5; filed May 26, 1978, 3:30 pm: 1 IR 225; filed Feb 29, 1984, 10:10 am: 7 IR 974; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-9-6 Installation consultant and survey; shielding

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 6. (a) A qualified radiation or health physicist shall be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation.

(b) Each particle accelerator installation shall be provided with such primary and/or secondary barriers as are necessary to assure compliance with 410 IAC 5-4-2 and 410 IAC 5-4-6. *(Indiana State Department of Health; Rule HRH-2, PT I, Sec I.6; filed May 26, 1978, 3:30 pm: 1 IR 225; filed Feb 29, 1984, 10:10 am: 7 IR 974; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-9-7 Controls and interlock devices

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 7. (a) Instrumentation, readouts, and controls on the particle accelerator control console shall be clearly identified and easily discernible.

(b) All entrances into a target room or other high radiation area shall be provided with a safety interlock that shuts down the machine under conditions of barrier penetration.

(c) Each safety interlock shall be on a circuit which shall allow it to operate independently of all other safety interlocks.

(d) All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents operation of the accelerator.

(e) When a safety interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the safety interlock has been tripped, and lastly at the main control console.

(f) A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. Such a cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control without resetting the cutoff switch. *(Indiana State Department of Health; Rule HRH-2, PT I, Sec I.7; filed May 26, 1978, 3:30 pm: 1 IR 225; filed Feb 29, 1984, 10:10 am: 7 IR 974; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-9-8 Warning devices

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 8. (a) Each location designated as a high radiation area, and each entrance to such location shall be equipped with easily observable warning lights that operate when, and only when, radiation is being produced.

(b) Except in facilities designed for human exposure, each high radiation area shall have an audible warning device which shall be activated for 15 seconds prior to the possible creation of such high radiation area. Such warning device shall be clearly discernible in all high radiation areas and adjacent radiation areas.

(c) Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be identified in accordance with 410 IAC 5-4-11. *(Indiana State Department of Health; Rule HRH-2, PT I, Sec I.8; filed May 26, 1978, 3:30 pm: 1 IR 226; filed Feb 29, 1984, 10:10 am: 7 IR 975; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-9-9 Operating and emergency procedures

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 9. (a) Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.

(b) The safety interlock system shall not be used to turn off the accelerator beam except in an emergency.

(c) All safety and warning devices, including interlocks, shall be checked for proper operation at intervals not to exceed three months. Results of such tests shall be maintained at the accelerator for inspection by the board.

(d) Electrical circuit diagrams of the accelerator and the associated safety interlock systems shall be kept current and maintained for inspection by the board and shall be available to the operator at each accelerator facility.

(e) If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:

(1) Authorized by the radiation safety committee and/or radiation safety officer;

(2) Recorded in a permanent log and a notice posted at the accelerator control console; and

(3) Terminated as soon as possible.

(f) A copy of the current operating and the emergency procedures shall be maintained at the accelerator control panel. *(Indiana State Department of Health; Rule HRH-2, PT I, Sec I.9; filed May 26, 1978, 3:30 pm: 1 IR 226; filed Feb 29, 1984, 10:10 am: 7 IR 975; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-9-10 Monitoring systems

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 10. (a) There shall be available at each particle accelerator facility appropriate portable monitoring equipment which is operable and has been appropriately calibrated for the radiations being produced at the facility. Such equipment shall be tested for proper operation daily and calibrated at intervals not to exceed one year and after each servicing and repair.

(b) A radiation protection survey shall be performed and documented by, a qualified radiation or health physicist when changes have been made in shielding operation, equipment or occupancy of adjacent areas.

(c) Radiation levels in all high radiation areas shall be continuously monitored. The monitoring system shall be electrically independent of the accelerator control and safety interlock systems and capable of providing a readout at the control panel.

(d) All area monitors shall be calibrated at intervals not to exceed 1 year and after each servicing and repair.

(e) Whenever applicable, periodic surveys shall be made to determine the amount of airborne particulate radioactivity present.

(f) Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination.

(g) All area surveys shall be made in accordance with the written procedures established by a qualified radiation or health physicist or the radiation safety officer.

(h) Records of all radiation protection surveys, calibrations and instrumentation tests shall be maintained at the accelerator facility for inspection by the board. *(Indiana State Department of Health; Rule HRH-2, PT I, Sec I.10; filed May 26, 1978, 3:30 pm: 1 IR 226; filed Feb 29, 1984, 10:10 am: 7 IR 975; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-9-11 Ventilation systems

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 11. (a) Ventilation systems shall be provided to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to airborne radioactive material in excess of those limits specified in 410 IAC 5-4-27, Table I.

(b) A registrant, as required by 410 IAC 5-4-7, shall not vent, release or otherwise discharge airborne radioactive material to an unrestricted area which exceeds the limits specified in 410 IAC 5-4-27, Table II, except as authorized pursuant to 410 IAC 5-4-17 or 410 IAC 5-4-7(b). For purposes of 410 IAC 5-9-11, concentrations may be averaged over a period not greater than one year. Every effort should be made to maintain releases of radioactive material to unrestricted areas as far below these limits as is reasonably achievable. *(Indiana State Department of Health; Rule HRH-2, PT I, Sec I.11; filed May 26, 1978, 3:30 pm: 1 IR 226; filed Feb 29, 1984, 10:10 am: 7 IR 976; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

Rule 10. Notices, Instructions and Reports to Workers; Inspections

410 IAC 5-10-1 Scope of rule

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 1. 410 IAC 5-10 establishes requirements for notices, instructions and reports by licensees or registrants to individuals engaged in activities under a license or registration and options available to such individuals in connection with board inspections of licensees or registrants to ascertain compliance with the provisions of IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]* and 410 IAC 5, orders and licenses issued thereunder regarding radiological working conditions. 410 IAC 5-10 apply *[sic.]* to all persons who receive, possess, use, own or transfer sources of radiation licensed by or registered with the board pursuant to 410 IAC 5-2 and 410 IAC 5-3. *(Indiana State Department of Health; Rule HRH-2, PT J, Sec J.1; filed May 26, 1978, 3:30 pm: 1 IR 227; filed Feb 29, 1984, 10:10 am: 7 IR 976; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10-2 Posting of documents for workers' examination

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 2. (a) Each licensee or registrant shall post current copies of the following documents:

(1) 410 IAC 5-10 and 410 IAC 5-4;

(2) The license, certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto;

(3) The operating procedures applicable to work under the license or registration;

(4) Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to 410 IAC 5-1, and any response from the licensee or registrant.

(b) If posting of a document specified in 410 IAC 5-10-2(a)(1), (2), or (3) is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

(c) Board form X "Notice to Employees" shall be posted by each licensee or registrant wherever individuals work in or frequent any portion of a restricted area.

(d) Documents, notices or forms posted pursuant to this section shall appear in a sufficient number of places to permit individuals engaged in work 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.

(e) Board documents posted pursuant to 410 IAC 5-10-2(a)(4) shall be posted within 5 working days after receipt of the documents from the board; the licensee's or registrant's response, if any, shall be posted within 5 working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later. *(Indiana State Department of Health; Rule HRH-2, PT J, Sec J.11; filed May 26, 1978, 3:30 pm: 1 IR 227; filed Feb 29, 1984, 10:10 am: 7 IR 976; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10-3 Instructions to workers

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 3. (a) All individuals working in or frequenting any portion of a restricted area:

(1) Shall be kept informed of the storage, transfer, or use of sources of radiation in such portions of the restricted area;

(2) Shall be instructed in the health protection problems associated with exposure to such radiation or radioactive material, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

(3) Shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of board rules and licenses for the protection of personnel from exposures to radiation or radioactive material occurring in such areas;

(4) Shall be instructed of their responsibility to report promptly to the licensee or registrant any condition which may constitute, lead to or cause a violation of board rules and licenses or unnecessary exposure to sources of radiation;

(5) Shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to sources of radiation; and

(6) Shall be advised as to the radiation exposure reports which workers shall be furnished pursuant to 410 IAC 5-10-4.

(b) The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area. *(Indiana State Department of Health; Rule HRH-2, PT J, Sec J.12; filed May 26, 1978, 3:30 pm: 1 IR 227; filed Feb 29, 1984, 10:10 am: 7 IR 977; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10-4 Reports furnished to individual workers

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 4. (a) 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 410 IAC 5-10-4. The information reported shall include data and results obtained pursuant to board rules, orders or license conditions, as shown in records maintained by the licensee or registrant pursuant to 410 IAC 5-4-21. Each notification and report shall:

(1) Be in writing;

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

(3) Include the individual's exposure information; and

(4) Contain the following statement:

"This report is furnished to you under the provisions of 410 IAC 5-10. You should preserve this report for further reference."

(b) Each licensee or registrant shall advise each worker annually of the worker's exposure to radiation or radioactive material as shown in records maintained by the licensee or registrant pursuant to 410 IAC 5-4-21(a) and (c).

(c) Each licensee or registrant shall furnish to each worker a report of the worker's exposure to radiation or radioactive material upon termination of employment. Such report shall be furnished within 30 days from the termination of employment or within 30 days after the exposure of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover each calendar quarter in which the worker's activities involved exposure to sources of radiation licensed by or radiation machines registered with the board and shall include the dates and locations of work under the license or registration in which the worker participated.

(d) When a licensee or registrant is required pursuant to 410 IAC 5-4-24 to report to the board any exposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on his exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the board.

(e) At the request of a worker who is terminating employment in a given calendar quarter with the licensee or registrant in work involving radiation dose or of a worker who, while employed by another person, is terminating assignment to work involving radiation dose in the licensee's or registrant's facility in that calendar quarter, each licensee or registrant shall provide to each such worker or to the worker's designee at termination, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during that specifically identified calendar quarter or fraction thereof, or provide a written estimate of that dose if the finally determined personnel monitoring results are not available at that time. Estimated doses shall be clearly indicated as such. *(Indiana State Department of Health; Rule HRH-2, PT J, Sec J.13; filed May 26, 1978, 3:30 pm: 1 IR 227; filed Feb 29, 1984, 10:10 am: 7 IR 977; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10-5 Inspections by board; representatives of licensee, registrant, or workers

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 5. (a) Each licensee or registrant shall afford to the board at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to 410 IAC 5.

(b) During an inspection, board inspectors may consult privately with workers as specified in 410 IAC 5-10-6. The licensee or registrant may accompany board inspectors during other phases of an inspection.

(c) If at the time of inspection an individual has been authorized by the workers to represent them during board inspections, the licensee or registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

(d) Each workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in 410 IAC 5-10-3.

(e) Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

(f) With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany board inspectors during the inspection of physical working conditions.

(g) Notwithstanding the other provisions of this section, board inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an agency of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area. *(Indiana State Department of Health; Rule HRH-2, PT J, Sec J.14; filed May 26, 1978, 3:30 pm: 1 IR 228; filed Feb 29, 1984, 10:10 am: 7 IR 978; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10-6 Inspectors consulting with workers

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 6. (a) Board inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of board rules and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

(b) During the course of an inspection any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or caused any violation of IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*, 410 IAC 5, or license condition, or any unnecessary exposure of an individual to sources of radiation under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of 410 IAC 5-10-7(a).

(c) The provisions of 410 IAC 5-10-6(b) shall not be interpreted as authorization to disregard instructions pursuant to 410 IAC 5-10-3. *(Indiana State Department of Health; Rule HRH-2, PT J, Sec J.15; filed May 26, 1978, 3:30 pm: 1 IR 228; filed Feb 29, 1984, 10:10 am: 7 IR 978; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10-7 Request for inspection by workers

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 7. (a) Any worker or representative of workers who believes that a violation of IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*, 410 IAC 5 or license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the division of industrial hygiene and radiological health. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the division of industrial hygiene and radiological health no later than at the time of inspection.

(b) If upon receipt of such notice the director, division of industrial hygiene and radiological health, determines that the complaint meets the requirements set forth in 410 IAC 5-10-7(a), and that there are reasonable grounds to believe that the alleged violation exists or has occurred, he shall cause an inspection to be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspections pursuant to this section need not be limited to matters referred to in the complaint.

(c) No licensee or registrant or contractor or subcontractor of the licensee or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under 410 IAC 5 or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of himself or others of any option afforded by 410 IAC 5-10. *(Indiana State Department of Health; Rule HRH-2, PT J, Sec J.16; filed May 26, 1978, 3:30 pm: 1 IR 228; filed Feb 29, 1984, 10:10 am: 7 IR 979; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10-8 Inspection not warranted; informal review; notice

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 8. (a) If the division of industrial hygiene and radiological health determines, with respect to a complaint under 410 IAC 5-10-7, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the division of industrial hygiene and radiological health shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the board who will provide the licensee or registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the board who will provide the complainant with a copy of such statement by certified mail. Upon the request of the complainant, the board may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written or oral views presented, the board shall affirm, modify or reverse the determination of the division of industrial hygiene and radiological health and furnish the complainant and the licensee or registrant a written notification of his decision and the reason therefore.

(b) If the division of industrial hygiene and radiological health determines that an inspection is not warranted because the requirements of 410 IAC 5-10-7(a) have not been met, he shall notify the complainant in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of 410 IAC 5-10-7(a). *(Indiana State Department of Health; Rule HRH-2, PT J, Sec J.17; filed May 26, 1978, 3:30 pm: 1 IR 229; filed Feb 29, 1984, 10:10 am: 7 IR 979; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

Rule 10.1. Wireline Service Operations and Subsurface Tracer Studies; Safety Standards

410 IAC 5-10.1-1 Scope of rule

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 1. 410 IAC 5-10.1 establishs *[sic.]* radiation safety requirements for persons using sources of radiation for wireline service operations including mineral logging, radioactive markers, and subsurface tracer studies. The requirements of this section are in addition to, and not in substitution for, the requirements of 410 IAC 5-1, 410 IAC 5-2, 410 IAC 5-3, 410 IAC 5-4, and 410 IAC 5-10. *(Indiana State Department of Health; 410 IAC 5-10.1-1; filed Feb 29, 1984, 10:10 am: 7 IR 980; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10.1-2 Applicability of rule

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 2. 410 IAC 5 applies to all licensees or registrants who use sources of radiation for wireline service operations including

mineral logging, radioactive markers or subsurface tracer studies. *(Indiana State Department of Health; 410 IAC 5-10.1-2; filed Feb 29, 1984, 10:10 am: 7 IR 980; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10.1-3 Definitions

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 3. As used in 410 IAC 5-10.1 the following definitions apply:

"Field station" means a facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary jobsites.

"Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.

"Logging supervisor" means the individual who provides personal supervision of the utilization of sources of radiation at the well site.

"Logging tool" means a device used subsurface to perform well-logging.

"Mineral logging" means any logging performed for the purpose of mineral exploration other than oil or gas.

"Personal supervision" means guidance and instruction by the supervisor who is physically present at the jobsite and watching the performance of the operation in such proximity that contact can be maintained and immediate assistance given as required.

"Radioactive marker" means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.

"Source holder" means a housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source in well-logging operations.

"Subsurface tracer study" means the release of a substance tagged with radioactive material for the purpose of tracing the movement or position of the tagged substance in the well-bore or adjacent formation.

"Temporary jobsite" means a location to which radioactive materials have been dispatched to perform wireline service operations or subsurface tracer studies.

"Well-bore" means a drilled hole in which wireline service operations and subsurface tracer studies are performed.

"Well-logging" means the lowering and raising of measuring devices or tools which may contain sources of radiation into well-bores or cavities for the purpose of obtaining information about the well and/or adjacent formations.

"Wireline" means a cable containing one or more electrical conductors which is used to lower and raise logging tools in the well-bore.

"Wireline service operation" means any evaluation or mechanical service which is performed in the well-bore using devices on a wireline. *(Indiana State Department of Health; 410 IAC 5-10.1-3; filed Feb 29, 1984, 10:10 am: 7 IR 980; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10.1-4 Prohibition

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 4. No licensee shall perform wireline service operations with a sealed source(s) unless, prior to commencement of the operation, the licensee has a written agreement with the well operator, well owner, drilling contractor or land owner that:

(a) In the event a sealed source is lodged downhole, a reasonable effort at recovery will be made; and

(b) In the event a decision is made to abandon the sealed source downhole, the requirements of 410 IAC 5-10.1-25(c) shall be met. *(Indiana State Department of Health; 410 IAC 5-10.1-4; filed Feb 29, 1984, 10:10 am: 7 IR 981; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10.1-5 Transportation and dose limit requirements

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 5. Sources of radiation shall be used, stored, and transported in such a manner that the transportation requirements of 410 IAC 5-3 and the dose limitation requirements of 410 IAC 5-4 are met. *(Indiana State Department of Health; 410 IAC 5-10.1-5; filed Feb 29, 1984, 10:10 am: 7 IR 981; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10.1-6 Storage precautions

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 6. (a) Each source of radiation, except accelerators, shall be provided with a storage and/or transport container. The container shall be provided with a lock, or tamper seal for calibration sources, to prevent unauthorized removal of, or exposure to, the source of radiation.

(b) Sources of radiation shall be stored in a manner which will minimize danger from explosion and/or fire. *(Indiana State Department of Health; 410 IAC 5-10.1-6; filed Feb 29, 1984, 10:10 am: 7 IR 981; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10.1-7 Transport precautions

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 7. Transport Precautions. Transport containers shall be physically secured to the transporting vehicle to prevent accidential *[sic.]* loss, tampering or unauthorized removal. *(Indiana State Department of Health; 410 IAC 5-10.1-7; filed Feb 29, 1984, 10:10 am: 7 IR 981; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10.1-8 Survey instruments

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 8. (a) The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments at each field station to make physical radiation surveys as required by this part and by 410 IAC 5-4-9. Instrumentation shall be capable of measuring 0.1 milliroentgen per hour through at least 20 milliroentgens per hour.

(b) Each radiation survey instrument shall be calibrated:

(1) At intervals not to exceed 6 months and after each instrument servicing;

(2) At energies and radiation levels appropriate for use; and

(3) So that accuracy within plus or minus 20 percent of the true radiation level can be demonstrated on each scale.

(c) Calibration records shall be maintained for a period of 2 years for inspection by the board. *(Indiana State Department of Health; 410 IAC 5-10.1-8; filed Feb 29, 1984, 10:10 am: 7 IR 981; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10.1-9 Leak testing of sealed sources

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 9. (a) Requirements. Each licensee using sealed sources of radioactive material shall have the sources tested for leakage. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the board for 6 months after the next required leak test is performed or until transfer or disposal of the sealed source.

(b) Method of Testing. Tests for leakage shall be performed only by persons specifically authorized to perform such tests by the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state. The test sample shall be taken from the surface of the source, source holder or from the surface of the device in which the source is stored or mounted and on which one might expect contamination to accumulate. The test sample shall be analyzed for radioactive contamination, and the analysis shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample.

(c) Interval of Testing. Each sealed source of radioactive material shall be tested at intervals not to exceed 6 months. In the absence of a certificate from a transferor indicating that a test has been made prior to the transfer, the sealed source shall not be put into use until tested. If for any reason, it is suspected that a sealed source may be leaking, it shall be removed from service immediately and tested for leakage as soon as practical.

(d) Leaking or Contaminated Sources. If the test reveals the presence of 0.005 microcurie or more of leakage or contamination, the licensee shall immediately withdraw the source from use and shall cause it to be decontaminated, repaired or disposed of in accordance with 410 IAC 5. A report describing the equipment involved, the test results, and the corrective action taken shall be filed with the board.

(e) Exemptions. The following sources are exempted from the periodic leak test requirements of 410 IAC 5-10.1-9(a) through (d):

(1) Hydrogen-3 sources;
(2) Sources of radioactive material with a half-life of 30 days or less;
(3) Sealed sources of radioactive material in gaseous form;
(4) Sources of beta- and/or gamma-emitting radioactive material with an activity of 100 microcuries or less; and
(5) Sources of alpha-emitting radioactive material with an activity of 10 microcuries or less.

(Indiana State Department of Health; 410 IAC 5-10.1-9; filed Feb 29, 1984, 10:10 am: 7 IR 981; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-10.1-10 Quarterly inventory

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 10. Each licensee or registrant shall conduct a quarterly physical inventory to account for all sources of radiation. Records of inventories shall be maintained for 2 years from the date of the inventory for inspection by the board and shall include the quantities and kinds of sources of radiation, the location where sources of radiation are assigned, the date of the inventory, and the name of the individual conducting the inventory. *(Indiana State Department of Health; 410 IAC 5-10.1-10; filed Feb 29, 1984, 10:10 am: 7 IR 982; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10.1-11 Utilization records

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 11. Each licensee or registrant shall maintain current records, which shall be kept available for inspection by the board for 2 years from the date of the recorded event, showing the following information for each source of radiation:

(a) Make, model number, and a serial number or a description of each source of radiation used;

(b) The identity of the well-logging supervisor or field unit to whom assigned;

(c) Locations where used and dates of use; and

(d) In the case of tracer materials and radioactive markers, the utilization record shall indicate the radionuclide and activity used in a particular well. *(Indiana State Department of Health; 410 IAC 5-10.1-11; filed Feb 29, 1984, 10:10 am: 7 IR 982; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10.1-12 Sealed sources used in downhole operations

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 12. Design, Performance, and Certification Criteria for Sealed Sources Used in Downhole Operations.

(a) Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations and manufactured one year after the effective date of 410 IAC 5 shall be certified by the manufacturer or other testing organization acceptable to the board to meet the following minimum criteria:

(1) Be of doubly encapsulated construction;

(2) Contain radioactive material whose chemical and physical forms are as insoluble and nondispersible as practical; and

(3) Has been individually pressure tested to at least 24,656 pounds per square inch absolute (170 MN/m^2) without failure.

(b) For sealed sources, except those containing radioactive material in gaseous form, acquired one year after the effective date of 410 IAC 5, in the absence of a certificate from a transferor certifying that an individual sealed source meets the requirements of 410 IAC 5-10.1-12(a), the sealed source shall not be put into use until such determinations and testing have been performed.

(c) Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations two years after the effective date of 410 IAC 5 shall be certified by the manufacturer, or other testing organization acceptable to the board, as meeting the sealed source performance requirements for oil well-logging as contained in the American National Standard N542, "Sealed Radioactive Sources, Classification" in effect on the effective date of 410 IAC 5.

(d) Certification documents shall be maintained for inspection by the board for a period of 2 years after source disposal. If the source is abandoned downhole, the certification documents shall be maintained until the board authorizes disposition. *(Indiana State Department of Health; 410 IAC 5-10.1-12; filed Feb 29, 1984, 10:10 am: 7 IR 982; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10.1-13 Labels

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 13. (a) Each source, source holder or logging tool containing radioactive material shall bear a durable, legible, and clearly visible marking or label, which has, as a minimum, the standard radiation caution symbol, without the conventional color requirement, and the following wording:

DANGER[1/]
RADIOACTIVE

This labeling shall be on the smallest component transported as a separate piece of equipment.

(b) Each transport container shall have permanently attached to it a durable, legible, and clearly visible label which has, as a minimum, the standard radiation caution symbol and the following wording:

DANGER[1/]
RADIOACTIVE
NOTIFY CIVIL AUTHORITIES
(OR NAME OF COMPANY)

[1/] or CAUTION

(Indiana State Department of Health; 410 IAC 5-10.1-13; filed Feb 29, 1984, 10:10 am: 7 IR 982; readopted filed Nov 15, 2001,

1:30 p.m.: 25 IR 1270; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 5-10.1-14 Inspection and maintenance

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 14. (a) Each licensee or registrant shall conduct, at intervals not to exceed 6 months, a program of inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools to assure proper labeling and physical condition. Records of inspection and maintenance shall be maintained for a period of 2 years for inspection by the board.

(b) If any inspection conducted pursuant to 410 IAC 5-10.1-14(a) reveals damage to labeling or components critical to radiation safety, the device shall be removed from service until repairs have been made.

(c) The repair, opening, or modification of any sealed source shall be performed only by persons specifically authorized to do so by the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state. *(Indiana State Department of Health; 410 IAC 5-10.1-14; filed Feb 29, 1984, 10:10 am: 7 IR 983; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10.1-15 Training and testing of personnel

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 15. (a) No licensee or registrant shall permit any individual to act as a logging supervisor as defined in this part until such individual has:

(1) Received, in a course recognized by the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state instruction in the subjects outlined in 410 IAC 5-10.1-26 and demonstrated an understanding thereof;

(2) Read and received instruction in the requirements contained in 410 IAC 5-10.1 and the applicable sections of 410 IAC 5-1, 410 IAC 5-4, and 410 IAC 5-10 or their equivalent, conditions of appropriate license or certificate of registration, and the licensee's or registrant's operating and emergency procedures, and demonstrated an understanding thereof; and

(3) Demonstrated competence to use sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.

(b) No licensee or registrant shall permit any individual to assist in the handling of sources of radiation until such individual has:

(1) Read or received instruction in the licensee's or registrant's operating and emergency procedures and demonstrated an understanding thereof; and

(2) Demonstrated competence to use, under the personal supervision of the logging supervisor, the sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.

(c) The licensee or registrant shall maintain employee training records for inspection by the board for 2 years following termination of employment. *(Indiana State Department of Health; 410 IAC 5-10.1-15; filed Feb 29, 1984, 10:10 am: 7 IR 983; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10.1-16 Operating and emergency procedures

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 16. The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:

(a) Handling and use of sources of radiation to be employed so that no individual is likely to be exposed to radiation doses

in excess of the standards established in 410 IAC 5-4;

(b) Methods and occasions for conducting radiation surveys;

(c) Methods and occasions for locking and securing sources of radiation;

(d) Personnel monitoring and the use of personnel monitoring equipment;

(e) Transportation to temporary jobsites and field stations, including the packaging and placing of sources of radiation in vehicles, placarding of vehicles, and securing sources of radiation during transportation;

(f) Minimizing exposure of individuals in the event of an accident;

(g) Procedure for notifying proper personnel in the event of an accident;

(h) Maintenance of records;

(i) Inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools;

(j) Procedure to be followed in the event a sealed source is lodged downhole; and

(k) Procedures to be used for picking up, receiving, and opening packages containing radioactive material. *(Indiana State Department of Health; 410 IAC 5-10.1-16; filed Feb 29, 1984, 10:10 am: 7 IR 983; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10.1-17 Personnel monitoring

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 17. (a) No licensee or registrant shall permit any individual to act as a logging supervisor or to assist in the handling of sources of radiation unless each such individual wears either a film badge or a thermoluminescent dosimeter (TLD). Each film badge or TLD shall be assigned to and worn by only one individual.

(b) Personnel monitoring records shall be maintained for inspection until the board authorizes disposition. *(Indiana State Department of Health; 410 IAC 5-10.1-17; filed Feb 29, 1984, 10:10 am: 7 IR 984; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10.1-18 Security during operations

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 18. During each logging or tracer application, the logging supervisor or other designated employee shall maintain direct surveillance of the operation to protect against unauthorized and/or unnecessary entry into a restricted area, as defined in 410 IAC 5-1. *(Indiana State Department of Health; 410 IAC 5-10.1-18; filed Feb 29, 1984, 10:10 am: 7 IR 984; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10.1-19 Handling tools

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 19. The licensee shall provide and require the use of tools that will assure remote handling of sealed sources other than low-activity calibration sources. *(Indiana State Department of Health; 410 IAC 5-10.1-19; filed Feb 29, 1984, 10:10 am: 7 IR 984; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10.1-20 Subsurface tracer studies

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 20. (a) Protective gloves and other appropriate protective clothing and equipment shall be used by all personnel handling radioactive tracer material. Precautions shall be taken to avoid ingestion or inhalation of radioactive material.

(b) No licensee shall cause the injection of radioactive material into potable aquifers without prior written authorization from the board. *(Indiana State Department of Health; 410 IAC 5-10.1-20; filed Feb 29, 1984, 10:10 am: 7 IR 984; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10.1-21 Particle accelerators

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 21. No licensee or registrant shall permit above-ground testing of particle accelerators, designed for use in well-logging, which results in the production of radiation, except in areas or facilities controlled or shielded so that the requirements of 410 IAC 5-4-2 and 410 IAC 5-4-6 as applicable, are met. *(Indiana State Department of Health; 410 IAC 5-10.1-21; filed Feb 29, 1984, 10:10 am: 7 IR 984; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10.1-22 Surveys; records

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 22. (a) Radiation surveys and/or calculations shall be made and recorded for each area where radioactive materials are stored.

(b) Radiation surveys and/or calculations shall be made and recorded for the radiation levels in occupied positions and on the exterior of each vehicle used to transport radioactive material. Such surveys and/or calculations shall include each source of radiation or combination of sources to be transported in the vehicle.

(c) After removal of the sealed source from the logging tool and before departing the jobsite, the logging tool detector shall be energized, or a survey meter used, to assure that the logging tool is free of contamination.

(d) Radiation surveys shall be made and recorded at the jobsite or well-head for each tracer operation, except those using hydrogen-3, carbon-14, and sulfur-35. These surveys shall include measurements of radiation levels before and after the operation.

(e) Records required pursuant to 410 IAC 5-10.1-22(a) through (d) shall include the dates, the identification of individual(s) making the survey, the identification of survey instrument(s) used, and an exact description of the location of the survey. Records of these surveys shall be maintained for inspection by the board for 2 years after completion of the survey. *(Indiana State Department of Health; 410 IAC 5-10.1-22; filed Feb 29, 1984, 10:10 am: 7 IR 984; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10.1-23 Recordkeeping at field stations

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 23. Each licensee or registrant shall maintain, for inspection by the board, the following documents and records for the specific devices and sources used at the field station:

(a) Appropriate license, certificate of registration or equivalent document;

(b) Operating and emergency procedures;

(c) Applicable regulations;
(d) Records of the latest survey instrument calibrations pursuant to 410 IAC 5-10.1-22;
(e) Records of the latest leak test results pursuant to 410 IAC 5-10.1-9;
(f) Quarterly inventories required pursuant to 410 IAC 5-10.1-10;
(g) Utilization records required pursuant to 410 IAC 5-10.1-11;
(h) Records of inspection and maintenance required pursuant to 410 IAC 5-10.1-14; and
(i) Survey records required pursuant to 410 IAC 5-10.1-22. *(Indiana State Department of Health; 410 IAC 5-10.1-23; filed Feb 29, 1984, 10:10 am: 7 IR 985; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10.1-24 Recordkeeping at temporary jobsites
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 24. Each licensee or registrant conducting operations at a temporary jobsite shall have the following documents and records available at that site for inspection by the board:
(a) Operating and emergency procedures;
(b) Survey records required pursuant to 410 IAC 5-10.1-22 for the period of operation at the site;
(c) Evidence of current calibration for the radiation survey instruments in use at the site; and
(d) When operating in the state under reciprocity, a copy of the appropriate license, certificate of registration or equivalent document(s). *(Indiana State Department of Health; 410 IAC 5-10.1-24; filed Feb 29, 1984, 10:10 am: 7 IR 985; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10.1-25 Notification of incidents, abandonment, and lost sources
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 25. (a) Notification of incidents and sources lost in other than downhole logging operations shall be made in accordance with appropriate provisions of 410 IAC 5-4.
(b) Whenever a sealed source or device containing radioactive material is lodged downhole, the licensee shall:
(1) Monitor at the surface for the presence of radioactive contamination with a radiation survey instrument or logging tool during logging tool recovery operations; and
(2) Notify the board immediately by telephone if radioactive contamination is detected at the surface or if the source appears to be damaged.
(c) When it becomes apparent that efforts to recover the radioactive source will not be successful, the licensee shall:
(1) Advise the well-operator of 410 IAC 5 and an appropriate method of abandonment, which shall include:
(i) The immobilization and sealing in place of the radioactive source with a cement plug;
(ii) The setting of a whipstock or other deflection device; and
(iii) The mounting of a permanent identification plaque, at the surface of the well, containing the appropriate information required by 410 IAC 5-10.1-25(d).
(2) Notify the board by telephone, giving the circumstances of the loss, and request approval of the proposed abandonment procedures; and
(3) File a written report with the board within 30 days of the abandonment, setting forth the following information:
(i) Date of occurrence and a brief description of attempts to recover the source;
(ii) A description of the radioactive source involved, including radionuclide, quantity, and chemical and physical form;
(iii) Surface location and identification of well;
(iv) Results of efforts to immobilize and set the source in place;
(v) Depth of the radioactive source;

(vi) Depth of the top of the cement plug;
(vii) Depth of the well; and
(viii) Information contained on the permanent identification plaque.

(d) Whenever a sealed source containing radioactive material is abandoned downhole, the licensee shall provide a permanent plaque[2/] for posting the well or well-bore. This plaque shall:

(1) Be constructed of long-lasting material, such as stainless steel or monel; and

(2) Contain the following information engraved on its face:
(i) The word "CAUTION";
(ii) The radiation symbol without the conventional color requirement;
(iii) The date of abandonment;
(iv) The name of the well-operator or well owner;
(v) The well name and well identification number(s) or other designation;
(vi) The sealed source(s) by radionuclide and quantity of activity;
(vii) The source depth and the depth to the top of the plug; and
(viii) An appropriate warning, depending on the specific circumstances of each abandonment.[3/]

[2/] An example of a suggested plaque is shown in 410 IAC 5-10.1-27.

[3/] Appropriate warnings may include: (a) "Do not drill below plug back depth"; (b) "Do not enlarge casing"; or (c) "Do not re-enter the hole", followed by the words, "before contacting the Indiana state board of health."

(e) The licensee shall immediately notify the board by telephone and subsequently by confirming letter if the licensee knows or has reason to believe that radioactive material has been lost in or to an underground potable water source. Such notice shall designate the well location and shall describe the magnitude and extent of loss of radioactive material, assess the consequences of such loss, and explain efforts planned or being taken to mitigate these consequences. *(Indiana State Department of Health; 410 IAC 5-10.1-25; filed Feb 29, 1984, 10:10 am: 7 IR 985; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 5-10.1-26 Training courses for logging supervisors; scope

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 26.

SUBJECTS TO BE INCLUDED
IN TRAINING COURSES
FOR LOGGING SUPERVISORS

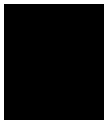
I. Fundamentals of Radiation Safety
A. Characteristics of radiation
B. Units of radiation dose and quantity of radioactivity
C. Significance of radiation dose
1. Radiation protection standards
2. Biological effects of radiation dose
D. Levels of radiation from sources of radiation
E. Methods of minimizing radiation dose
1. Working time
2. Working distances
3. Shielding
II. Radiation Detection Instrumentation to be Used
A. Use of radiation survey instruments
1. Operation
2. Calibration
3. Limitations

B. Survey techniques
C. Use of personnel monitoring equipment
III. Equipment to be Used
A. Handling equipment
B. Sources of radiation
C. Storage and control of equipment
D. Operation and control of equipment
IV. The Requirements of Pertinent Federal and State Rules
V. The Licensee's or Registrant's Written Operating and Emergency Procedures
VI. The Licensee's or Registrant's Record Keeping Procedures *(Indiana State Department of Health; 410 IAC 5-10.1-26; filed Feb 29, 1984, 10:10 am: 7 IR 986; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

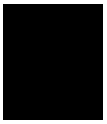
410 IAC 5-10.1-27 Plaque on wells containing abandoned sealed sources
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 27. Example of Plaque for Identifying Wells Containing Sealed Sources Containing Radioactive Material Abandoned Downhole

[COMPANY NAME]
[WELL IDENTIFICATION]



CAUTION



ONE 2 CURIE CS-137 RADIOACTIVE SOURCE ABANDONED
3-3-75 AT 8400 FT. PLUG BACK DEPTH 8200 FT.
DO NOT RE-ENTER THIS WELL BEFORE CONTACTING
INDIANA STATE BOARD OF HEALTH

The size of the plaque should be convenient for use on active or inactive wells; e.g., a 7-inch square. Letter size of the word "CAUTION" should be approximately twice the letter size of the rest of the information; e.g., 1/2-inch and 1/4-inch letter size, respectively. *(Indiana State Department of Health; 410 IAC 5-10.1-27; filed Feb 29, 1984, 10:10 am: 7 IR 986; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

Rule 11. Diagnostic Radiation Machine Operators; Certification *(Repealed)*

(Repealed by Indiana State Department of Health; filed Nov 27, 2006, 1:48 p.m.: 20061227-IR-410050190FRA)

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