

120.773: continued

- (A) Deliver licensed material to a carrier for transport; or
- (B) Transport licensed material.

120.774: Transportation of Licensed Material

(A) Each licensee who transports licensed material outside the site of usage, as specified in the Agency license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the U.S. Department of Transportation regulations in 49 CFR parts 107, 171 through 180, and 390 through 397, appropriate to the mode of transport.

- (1) The licensee shall particularly note DOT regulations in the following areas:
  - (a) Packaging - 49 CFR Part 173: Subparts A and B and I.
  - (b) Marking and labeling - 49 CFR Part 172: Subpart D, §§ 172.400 through 172.407, §§ 172.436 through 172.441, and Subpart E.
  - (c) Placarding - 49 CFR Part 172: Subpart F, especially §§ 172.500 through 172.519, 172.556, and Appendices B and C.
  - (d) Accident reporting - 49 CFR Part 171: §§ 171.15 and 171.16.
  - (e) Shipping papers and emergency information - 49 CFR Part 172: Subparts C and G.
  - (f) Hazardous material employee training - 49 CFR Part 172: Subpart H.
  - (g) Security plans - 49 CFR Part 172: Subpart I.
  - (h) Hazardous material shipper/carrier registration - 49 CFR Part 107: Subpart G.
- (2) The licensee shall also note DOT regulations pertaining to the following modes of transportation:
  - (a) Rail - 49 CFR Part 174: Subparts A through D and K.
  - (b) Air - 49 CFR Part 175
  - (c) Vessel - 49 CFR Part 176: Subparts A through F and M.
  - (d) Public Highway - 49 CFR Part 177 and Parts 390 through 397.
- (3) Assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee in accordance with 105 CMR 120.242(E).

(B) If, for any reason, the regulations of the U.S. Department of Transportation are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of 49 CFR Parts 107, 171 through 180 and 390 through 397 appropriate to the mode of transport to the same extent as if the shipment was subject to the regulations. A request for modification, waiver, or exemption from those requirements, and any notification referred to in those requirements, must be filed with, or made to, the Director, Radiation Control Program.

120.775: Exemptions

(A) Any physician licensed by a State to dispense drugs in the practice of medicine is exempt from 105 CMR 120.774 with respect to transport by the physician of licensed material for use in the practice of medicine. However, any physician operating under 105 CMR 120.775 must be licensed under 10 CFR Part 35 or the equivalent Agreement State regulations.

(B) Common and contract carriers, freight forwarders, and warehouse workers 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), and the U.S. Postal Service are exempt from the requirements of 105 CMR 120.770 to the extent that they transport or store radioactive material in the regular course of their carriage for others or storage incident thereto. Common and contract carriers who are not subject to the requirements of the U.S. Department of Transportation or U.S. Postal Service are subject to 105 CMR 120.773 and other applicable requirements of 105 CMR 120.000.

(C) A licensee is exempt from all requirements of 105 CMR 120.770, with respect to shipment or carriage of the following low-level materials:

- (1) Natural material and ores containing naturally occurring radionuclides that are not intended to be processed for use of these radionuclides, provided the activity concentration of the material does not exceed ten times the values specified in 105 CMR 120.795: *Appendix A, Table A-2.*

120.125: General Requirements for the Issuance of Specific Licenses

- (A) A license application will be approved only if the Agency determines that:
- (1) the applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with 105 CMR 120.000 in such a manner as to minimize danger to public health and safety or property;
  - (2) the applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;
  - (3) the issuance of the license will not be inimical to the health and safety of the public; and,
  - (4) the applicant satisfies any applicable special requirements in 105 CMR **120.050 through 120.080**, 120.126, 120.127, 120.128, 120.300, 120.500, 120.620 120.800, 120.890 ~~or~~ **and** 120.900.

120.032: continued

(4) In the case of diagnostic x-ray system 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 Agency within 15 days following completion of the assembly. Such report shall suffice in lieu of any other by the assembler.

(B) 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 use shall meet the requirements of 105 CMR 120.000.

120.033: Out-of-state Radiation Machines

(A) Whenever any radiation machine is to be brought into the Commonwealth, for any temporary use, the person proposing to bring such machine into the Commonwealth shall give written notice to the Agency at least ten working days before such machine is to be used in the Commonwealth. The notice shall include:

- (1) The type of radiation machine;
- (2) The nature, duration, and scope of use;
- (3) The exact location(s) where the radiation machine is to be used; and,
- (4) States in which this machine is registered.

(B) The person referred to in 105 CMR 120.033 shall:

- (1) Comply with all applicable regulations of the Agency;
- (2) Register the radiation machine(s) with the Agency; and,
- (3) Submit payment of the required fee for registration.

(C) A pre-operational inspection may be required at the discretion of the Director of the Radiation Control Program.

(D) If, for a specific case, the ten working day period is not practical, notification to the Agency by telephone and hardcopy, permission to proceed sooner may be granted.

120.040: Notification to Fire Department

The user shall notify the local fire department of the presence on his premises of any radioactive material that may present special fire-fighting problems or require special precautionary measures in case of fire or other natural catastrophe, and he shall establish effective liaison with the fire department in regards to this matter.

120.100: LICENSING OF RADIOACTIVE MATERIAL

120.101: Purpose and Scope

(A) 105 CMR 120.100, 120.500 and 120.770, provide for the licensing of radioactive material. No person shall manufacture, produce, receive, possess, use, transfer, own, or acquire radioactive material except as authorized pursuant to 105 CMR 120.100, 120.500 or 120.770, or as otherwise provided in 105 CMR 120.000.

(B) In addition to the requirements of 105 CMR 120.100, all licensees are subject to the requirements of 105 CMR 120.000, 120.200, 120.750, and 120.770. Furthermore, licensees engaged in industrial radiographic operations are subject to the requirements of 105 CMR 120.300; licensees using radionuclides in the healing arts are subject to the requirements of 105 CMR 120.500, licensees engaged in land disposal of radioactive material are subject to the requirements of 105 CMR 120.801 through 120.885, and licensees engaged in wireline and subsurface tracer studies are subject to the requirements of 105 CMR 120.900.



105 CMR: DEPARTMENT OF PUBLIC HEALTH

120.001: GENERAL PROVISIONS

120.002: Purpose and Scope

Except as otherwise specifically provided, 105 CMR 120.000 apply to all persons who receive, possess, use, transfer, own, or acquire any source of radiation; provided, however, that nothing in 105 CMR 120.000 shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission (NRC). Regulation by the Commonwealth of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the State and the NRC and to 10 CFR Part 150 of the NRC's regulations.

120.003: Regulatory Authority

The authority for the Department of Public Health to promulgate 105 CMR 120.000 is found in: M.G.L. c. 111, §§ 3, 5M, 5N, 5O, 5P.

120.004: Citation

105 CMR 120.000 shall be known and may be cited as the Massachusetts Regulations for the Control of Radiation (MRCR).

120.005: Definitions

As used in 105 CMR 120.000, these terms have the definitions set forth in 105 CMR 120.005. Additional definitions used only in a certain Section will be found in that Section.

105 CMR 120.000 means all Sections of the Massachusetts Regulations for the Control of Radiation.

A<sub>1</sub> means the maximum activity of special form radioactive material permitted in a Type A package. A<sub>2</sub> means the maximum activity of radioactive material, other than special form radioactive material, permitted in a Type A package. These values are either listed in 120.795: *Table I*, or may be derived in accordance with the procedure prescribed in 120.795: *Appendix A*.

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

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. For purposes of this definition, "particle accelerator" is an equivalent term.

Accelerator-produced Material means any material made radioactive by a particle accelerator.

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

Adult means an individual 18 or more years of age.

Agency means the Radiation Control Program of the Massachusetts Department of Public Health.

Agreement State means any State with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into an effective agreement under § 274b of the Atomic Energy Act of 1954, as amended (St. 1973, c. 689).

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

120.005: continued

Airborne Radioactivity Area means a room, enclosure, or area in which airborne radioactive materials exist in concentrations:

- (a) In excess of the derived air concentrations (DACs) specified in 105 CMR 120.200: *Appendix B, Table I*; or
- (b) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6% of the annual limit on intake (ALI) or 12 DAC-hours.

Airline Respirator (*see Supplied-air Respirator (SAR)*).

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

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

As Low as is Reasonably Achievable (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in 105 CMR 120.000 as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of ionizing radiation and licensed or registered sources of radiation in the public interest.

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

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

Background Radiation means radiation from cosmic sources; non-technologically enhanced naturally occurring radioactive material, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee or registrant. "Background radiation" does not include sources of radiation from radioactive materials regulated by the Agency.

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

Bioassay means the determination of kinds, quantities, or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement (*in vivo* counting), or by analysis and evaluation of materials excreted or removed from the human body. For purposes of 105 CMR 120.000, Radiobioassay is an equivalent term.

Brachytherapy means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

Byproduct Material means:

- (1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;



## 120.005: continued

- (2) (a) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or
- (b) Any material that:
  - 1. Has been made radioactive by use of a particle accelerator; and
  - 2. Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and
- (3) Any discrete source of naturally occurring radioactive material, other than source material, that:
  - (a) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and
  - (b) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

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. The method observed by the licensee or registrant for determining calendar quarters shall only be changed at the beginning of a 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.

Chelating Agent means amine polycarboxylic acids, hydroxy-carboxylic acids, gluconic acid, and polycarboxylic acids.

CMR means Code of Massachusetts Regulations.

Collective Dose means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

Commissioner means the Commissioner, Massachusetts Department of Public Health.

Committed Dose Equivalent ( $H_{T,50}$ ) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

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

Confirmatory Action Letters means letters, confirming a licensee's, registrant's, or vendor's agreement to take certain actions to remove significant concerns about health and safety, safeguards, or the environment.

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

120.005: continued

Constraint (Dose Constraint) means a value above which specified licensee actions are required.

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

Curie means a unit of quantity of activity. One curie (Ci) is that quantity of radioactive material which decays at the rate of  $3.7 \times 10^{10}$  disintegrations or transformations per second (dps or tps). Commonly used submultiples of the curie are the millicurie and the microcurie. One millicurie (mCi) =  $1 \times 10^{-3}$  curie =  $3.7 \times 10^7$  tps. One microcurie ( $\mu$ Ci) =  $1 \times 10^{-6}$  curie =  $3.7 \times 10^4$  tps. One nanocurie (nCi) =  $1 \times 10^{-9}$  curie =  $3.7 \times 10^1$  tps. One picocurie (pCi) =  $1 \times 10^{-12}$  curie =  $10^{-2}$  tps.

Cyclotron means a particle accelerator in which the charged particles travel in an outward spiral or circular path. A cyclotron accelerates charged particles at energies usually in excess of ten megaelectron volts and is commonly used for production of short half-life radionuclides for medical use. (See 105 CMR 120.005: Accelerator).

Decommission means to remove safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and/or termination of license.

Deep Dose Equivalent ( $H_d$ ) means the dose equivalent at a tissue depth of one centimeter (1000 mg/cm<sup>2</sup>) and applies to external whole body exposure.

Demand Respirator means an atmosphere-supplying respirator that admits breathing air to the face piece only when a negative pressure is created inside the facepiece by inhalation.

Department means the Department of Public Health.

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.

Discrete Source means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, industrial, or research activities.

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

Distinguishable from Background means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

Dose is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of 105 CMR 120.000, Radiation Dose is an equivalent term.

Dose Equivalent ( $H_T$ ) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

Dose Limits means the permissible upper bounds of radiation doses established in accordance with 105 CMR 120.000. For purposes of 105 CMR 120.000, Limits is an equivalent term.



120.005: continued

Ionizing Radiation (See Radiation).

Irradiation means the exposure of a living being or matter to ionizing radiation.

Kilovolt (kV) [Kilo Electron Volt (keV)] means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of 1,000 volts in a vacuum. [Note: current convention is to use kV for photons and keV for electrons.]

Lead Equivalent means the thickness of the material in question affording the same attenuation, under specified conditions, as lead.

Leakage Radiation means radiation emanating from the diagnostic or therapeutic source assembly except for:

- (1) The useful beam; and,
- (2) Radiation produced when the exposure switch or timer is not activated.

Lens Dose Equivalent (LDE) means the external exposure to the lens of the eye as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm<sup>2</sup>).

License means a license issued by the Agency in accordance with the regulations adopted by the Agency.

Licensed (or Registered) Material means radioactive material received, possessed, used, transferred or disposed of under a general or specific license [or registration] issued by the Agency.

Licensee means any person who is licensed by the Agency in accordance with 105 CMR 120.000 and M.G.L. c. 111, §§ 3, 5M, 5N, 5O and 5P.

Licensing State means any State which has been finally designated as such by the Conference of Radiation Control Program Directors, Inc., which reviews state regulations to establish equivalency with the Suggested State Regulations and ascertains whether a State has an effective program for control of natural occurring or accelerator produced radioactive material (NARM). The Conference will designate as Licensing States those states with regulations for control of radiation relating to, and an effective program for, the regulatory control of NARM.

Limits (See Dose limits).

Loose-fitting Facepiece means a respiratory inlet covering that is designed to form a partial seal with the face.

Lost or Missing Source of Radiation means licensed (or registered) source of radiation whose location is unknown. This definition includes, but is not limited to, licensed (or registered) material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

Major Processor means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding four 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 105 CMR 120.772.

Manifest means a detailed record of the characteristics and quantities of packaged waste as presented for transportation, treatment, storage, or disposal which usually accompanies waste transfers for these purposes.

Member of the Public means an individual except when that individual is receiving an occupational dose.

Minor means an individual less than 18 years of age.



120.005: continued

Monitoring means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of 105 CMR 120.000, Radiation Monitoring and Radiation Protection Monitoring are equivalent terms.

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

Nationally Tracked Source means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in 105 CMR 120.298: *Appendix D*. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

Natural Radioactivity means radioactivity of naturally occurring nuclides.

Negative Pressure Respirator (Tight Fitting) means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

Non-ionizing Radiation (See Radiation).

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

Nuclear Regulatory Commission (NRC) means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

Occupational Dose means the dose received by an individual in the course of employment in which the individual's assigned duties for the licensee or registrant involve exposure to sources of radiation, whether or not the sources of radiation are in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received: from background radiation, or from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 105 CMR 120.527, or from voluntary participation in medical research program, or as a member of the public.

Package means the packaging together with its radioactive contents as presented for transport.

Particle Accelerator (See Accelerator).

Patient means an individual subjected to healing arts examination, diagnosis, or treatment

Person means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency of the commonwealth other than the Department, any political subdivision of the commonwealth, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing, but not including federal government agencies.

Personnel Monitoring Equipment (See Individual Monitoring Devices).

Phantom means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

105 CMR: DEPARTMENT OF PUBLIC HEALTH

120.006: continued

- (a) That the exemption of the prime contractor or subcontractor is authorized by law; and
- (b) 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.

120.007: Prohibited Uses

(A) A hand-held fluoroscopic screen shall not be used with x-ray equipment unless it has been listed in the Registry of Sealed Source and Devices or accepted for certification by the U.S. Food and Drug Administration, Center for Devices and Radiological Health.

(B) A Shoe-fitting fluoroscopic device shall not be used.

120.008: Impounding

Sources of radiation shall be subject to impounding pursuant to M.G.L. c. 111, §§ 50 and 5P.

120.009: Records

(A) 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 105 CMR 120.000.

(B) Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward the following records to the Agency:

- (1) Records of disposal of licensed material made under 105 CMR 120.252 (including burials authorized before January 28, 1981), 105 CMR 120.253, 120.254, 120.255; and,
- (2) Records required by 105 CMR 120.263(B)(4).

(C) If licensed activities are transferred or assigned in accordance with 105 CMR 120.131(B), each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

- (1) Records of disposal of licensed material made under 105 CMR 120.252 (including burials authorized before January 28, 1981), 105 CMR 120.253, 120.254, 120.255; and,
- (2) Records required by 105 CMR 120.263(B)(4).

(D) Prior to license termination, each licensee shall forward the records required by 105 CMR 120.125(C)(1)(g) to the Agency.

120.010: Inspections

(A) Each licensee and registrant shall afford the Agency 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 Agency for inspection, upon reasonable notice, records maintained pursuant to 105 CMR 120.000.

120.011: Tests

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

- (A) Sources of radiation;



120.014: continued

**TABLE II**  
**MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE**  
**EQUIVALENT FOR MONOENERGETIC NEUTRONS**

| Neutron Energy<br>(MeV) | Quality Factor*<br>(Q) | Fluence per Unit Dose Equivalent**<br>(neutrons cm <sup>-2</sup> rem <sup>-1</sup> ) | Fluence per Unit Dose Equivalent**<br>(neutrons cm <sup>-2</sup> Sv <sup>-1</sup> ) |
|-------------------------|------------------------|--|---|
| $1.0 \times 10^{-7}$    | 2                      | $980 \times 10^6$  | $980 \times 10^8$   |
| $1.0 \times 10^{-6}$    | 2                      | $810 \times 10^6$  | $810 \times 10^8$   |
| $1.0 \times 10^{-5}$    | 2                      | $810 \times 10^6$  | $810 \times 10^8$   |
| $1.0 \times 10^{-4}$    | 2                      | $840 \times 10^6$  | $840 \times 10^8$   |
| $1.0 \times 10^{-3}$    | 2                      | $980 \times 10^6$  | $980 \times 10^8$   |
| $1.0 \times 10^{-2}$    | 2.5                    | $1010 \times 10^6$   | $1010 \times 10^8$  |
| $1.0 \times 10^{-1}$    | 7.5                    | $170 \times 10^6$  | $170 \times 10^8$   |
| $5.0 \times 10^{-1}$    | 11                     | $39 \times 10^6$   | $39 \times 10^8$  |
| 1                       | 11                     | $27 \times 10^6$   | $27 \times 10^8$  |
| 2.5                     | 9                      | $29 \times 10^6$   | $29 \times 10^8$  |
| 5                       | 8                      | $23 \times 10^6$   | $23 \times 10^8$  |
| 7                       | 7                      | $24 \times 10^6$   | $24 \times 10^8$  |
| 10                      | 6.5                    | $24 \times 10^6$   | $24 \times 10^8$  |
| 14                      | 7.5                    | $17 \times 10^6$   | $17 \times 10^8$  |
| 20                      | 8                      | $16 \times 10^6$   | $16 \times 10^8$  |
| 40                      | 7                      | $14 \times 10^6$   | $14 \times 10^8$  |
| 60                      | 5.5                    | $16 \times 10^6$   | $16 \times 10^8$  |
| $1.0 \times 10^2$       | 4                      | $20 \times 10^6$   | $20 \times 10^8$  |
| $2.0 \times 10^2$       | 3.5                    | $19 \times 10^6$   | $19 \times 10^8$  |
| $3.0 \times 10^2$       | 3.5                    | $16 \times 10^6$   | $16 \times 10^8$  |
| $4.0 \times 10^2$       | 3.5                    | $14 \times 10^6$   | $14 \times 10^8$  |

**120.015: Units of Activity**

For purposes of 105 CMR 120.000, activity is expressed in the SI unit of becquerel (Bq) or in the special unit of curie (Ci), or their multiples, or disintegrations or transformations per unit of time.

(A) One becquerel (Bq) = 1 disintegration or transformation per second (dps or tps).

(B) One curie (Ci) =  $3.7 \times 10^{10}$  disintegrations or transformations per second (dps or tps) =  $3.7 \times 10^{10}$  becquerel (Bq) =  $2.22 \times 10^{12}$  disintegrations or transformations per minute (dpm or tpm).

**ENFORCEMENT****120.016: Enforcement Policy and Procedures**

(A) **Purpose.** The purpose of the enforcement program of the Agency is to promote and protect the radiological health and safety of the public, including employees' health and safety, and the environment by:

\* Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-centimeter diameter cylinder tissue-equivalent phantom.

\*\* Monoenergetic neutrons incident normally on a 30-centimeter diameter cylinder tissue-equivalent phantom.

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- (1) Ensuring compliance with regulations and conditions of license;
- (2) Obtaining prompt correction of violations that may affect safety;
- (3) Deterring future violations; and
- (4) Encouraging improvement of licensee, registrant and vendor performance, and by example, that of industry, including the prompt identification and reporting of potential safety problems.

Consistent with the purpose of this program, prompt and vigorous enforcement action will be taken when dealing with all persons who do not comply with regulations. In no case will licensees who do not achieve and maintain adequate levels of protection be permitted to conduct licensed activities.

(B) Grounds for Immediate Suspension of a License or Certificate of Registration or Issuance of an Order to Immediately Cease Activity. In accordance with M.G.L. c. 111, § 50, the Commissioner may summarily suspend a license or certificate of registration or order immediate cessation of an activity, without a prior hearing, whenever the Department finds that public health, safety or the environment would be threatened by delay in issuance of an order. A facility or person may not operate during the period of a suspension of his/its license or certificate of registration and may not conduct a prohibited activity after notification of an order requiring the immediate cessation of an activity. However, upon request by the licensee or registrant, a hearing shall be provided promptly after the issuance of such suspension or order.

(C) Grounds for Denial, Modification, Limitation, Revocation or Refusal to Renew a License or Certificate of Registration.

(1) Specific Grounds. The Department may issue an order denying, revoking, modifying, limiting, or refusing to renew a license or certificate of registration sought or issued under 105 CMR 120.000, or issue an order to cease an activity, for any one of the following reasons:

- (a) The applicant, licensee or registrant has failed to submit the information required for licensure or registration under 105 CMR 120.000.
- (b) The applicant failed to meet the requirements for licensure or registration as specified in 105 CMR 120.000.
- (c) The applicant, licensee or registrant is not suitable and responsible to operate a facility as required or provide the service as licensed or registered.
- (d) The applicant, licensee or registrant has obtained or attempted to obtain or maintain a certificate of registration or license by fraud, misrepresentation, or by the submission of incorrect, false or misleading information.
- (e) The applicant, licensee or registrant has failed to pay licensure and/or registration fees.
- (f) The applicant, licensee or registrant has failed to pay civil penalties or criminal fines levied in accordance with of M.G.L. c. 111, § 50 or 5P and/or 105 CMR 120.000.
- (g) The applicant, licensee or registrant has:
  1. failed to allow duly authorized agents of the Agency to conduct inspections; or
  2. attempted to impede the work of duly authorized representatives of the Agency or the enforcement of any provisions of M.G.L. c. 111 §§ 5N through 5P or 105 CMR 120.000.
- (h) The applicant, licensee or registrant has been convicted of, pleaded guilty to, or has, in a judicial proceeding, admitted facts sufficient for a finding that he/she is guilty of, any criminal violation relating directly or indirectly to his/her fitness to be licensed or registered under 105 CMR 120.000.
- (i) The applicant, licensee or registrant has been the subject of proceedings which resulted in the suspension, denial, modification, limitation, or revocation of a similar license or certificate of registration or refusal of renewal of a similar license.
- (j) The applicant, licensee or registrant has violated 105 CMR 120.000 or a license condition and has a history of non-compliance with the same or similar violation or has received a warning letter from the Department within the last five years for the same or similar violation.
- (k) The applicant, licensee or registrant has been disciplined in another jurisdiction in any way by a licensing authority for reasons substantially the same as those set forth in 105 CMR 120.016(C).



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- (l) The applicant or licensee operated a facility after the expiration of the license.
  - (m) The applicant, licensee or registrant has failed to remedy or correct a cited violation by the date specified in the written notice from the Department under M.G.L. c. 111, § 50 or by the date specified in the plan of correction accepted or modified by the Department, unless the applicant, licensee or registrant demonstrates to the satisfaction of the Department that such failure was not due to neglect of duty and occurred despite his/her good faith attempt to make corrections by the specified time.
  - (n) The applicant or licensee has engaged in or aided in the falsification of test results or any other records required to be maintained in accordance with 105 CMR 120.000.
  - (o) The applicant, licensee or registrant receives, possesses, uses, transfers, owns or operates or uses radioactive materials or machines which emit ionizing radiation in a manner which endangers public health, safety, or the environment.
  - (2) Other Grounds. The Department reserves the right to deny, modify, limit revoke or refuse to renew a license or certificate of registration for any other sufficient reason not listed in 105 CMR 120.016(C)(1) if it reasonably considers such action necessary to protect the public health, safety or the environment. In addition, nothing in 105 CMR 120.000 shall be deemed to limit the Department's authority to establish or recognize further general or specific grounds for discipline through rulemaking, adjudication, the issuance of policies or advisories or other similar means.
- (D) Severity of Violations.
- (1) Violations of 105 CMR 120.000 are categorized in terms of five levels of severity to show their relative importance within each of the following five activity areas:
    - (a) Health Physics;
    - (b) Transportation;
    - (c) Materials Operations;
    - (d) Miscellaneous Matters; and,
    - (e) Emergency Preparedness.
  - (2) Within each activity area, Severity Level I has been assigned to violations that are the most significant and Severity Level V to those that are the least significant. Severity Level I and II violations are of very significant regulatory concern. In general, violations that are included in these categories involve actual or high potential impact on the public. Severity Level III violations are cause for significant concern. Severity Level IV violations are less serious but are of more than minor concern; *i.e.* if left uncorrected, they could lead to a more serious concern. Severity Level V violations are of minor safety or environmental concern.
  - (3) Comparisons of significance between activity areas are inappropriate. For example, the immediacy of any hazard to the public associated with Severity Level I violations in Health Physics is not directly comparable to that associated with Severity Level I violations in Emergency Preparedness.
  - (4) While examples are provided in 105 CMR 120.019: *Appendix A* for determining the appropriate severity level for violations in each of the five activity areas, the examples are neither exhaustive nor controlling. These examples do not create new requirements. Each of the examples is predicated on a violation of an existing regulatory requirement. Each is designed to illustrate the significance which the Department places on a particular type of violation of regulatory requirements.
  - (5) In each case, the severity of a violation will be characterized at the level best suited to the significance of the particular violation. In some cases, violations may be evaluated in the aggregate and a single severity level assigned for a group of violations.

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(6) The severity level of a violation may be increased if the circumstances surrounding the matter involve careless disregard of requirements, deception, or other indication of willfulness. The term "willfulness" includes, but is not limited to, the deliberate violation of any provision of M.G.L. c. 111, §§ 3, 5M, 5N, 5O, and 5P or careless disregard of the requirements of M.G.L. c. 111, §§ 3, 5M, 5N, 5O, and 5P. Willfulness does not include acts which do not rise to the level of careless disregard, e.g. inadvertent clerical errors in a document submitted to the Agency. In determining the specific severity level of a violation involving willfulness, consideration will be given to such factors as the position of the person involved in the violation (e.g., first-line supervisor or senior manager), the significance or any underlying violation, the intent of the violator (i.e. negligence not amounting to careless disregard, careless disregard, or deliberateness), and the economic advantage, if any, gained as a result of the violation. The relative weight given to each of these factors in arriving at the appropriate severity level will be dependent on the circumstances of the violation.

(7) The Agency expects licensees to provide complete, timely, and accurate information and reports. Accordingly, unless otherwise categorized in 105 CMR 120.019: *Appendix A* the severity level of a violation involving the failure to make a required report to the Agency will be based upon the significance of and the circumstances surrounding the matter that should have been reported. A licensee will not normally be cited for a failure to report a condition or event unless the licensee was actually aware of the condition or event which it failed to report or should have been aware of the condition or event. However, the severity level of an untimely report, in contrast to no report, may be reduced depending on the circumstances surrounding the matter.

(E) Enforcement Conference. Whenever the Agency has learned of the existence of a potential violation for which a civil penalty or other escalated enforcement action may be warranted, or recurring nonconformance on the part of a vendor, the Agency may schedule an enforcement conference with the licensee or vendor prior to taking enforcement action. The Agency may also elect to hold an enforcement conference for other violations, e.g. Severity Level IV violation which, if repeated, could lead to escalated enforcement action. The purpose of the enforcement conference is to:

- (a) Discuss the violations or nonconformance, their significance and causes, and the licensee's or vendor's corrective actions;
- (b) Determine whether there are any aggravating or mitigating circumstances;
- (c) Obtain other information which will help determine the appropriate enforcement action; and
- (d) Provide an opportunity for the licensee to explain what corrective actions have been taken or will be taken in response to the Notice of Violation. (See 105 CMR 120.016(F)).

(F) Enforcement Procedures.

(1)(a) Notice of Violation. Whenever the Agency finds upon inspection, investigation of a complaint or through information in its possession that an applicant, licensee or registrant is not in compliance with provisions of M.G.L. c. 111, §§ 5N through 5P or a regulation promulgated thereunder, the Agency shall notify the applicant, licensee or registrant of such violation or deficiency. The notice shall include a statement of the violations or deficiencies found, the provision of the law relied upon, and a reasonable period of time for correction. A violation or deficiency may result in denial, suspension, revocation or refusal to renew a license or certificate of registration; a modification or limitation of a license or certificate of registration; a cease and desist order; and/or the imposition of a civil penalty and/or criminal sanctions.

(b) Confirmatory Action Letters. The Agency may issue Confirmatory Action Letters confirming a licensee's, registrant's, or vendor's agreement to take certain actions to remove significant concerns about health and safety, safeguards, or the environment.

(2) Plan of Correction.

(a) The applicant, licensee or registrant shall within ten days of receipt of the notice, file with the Agency a written plan of correction. The plan shall clearly identify the licensee or registrant, state the date, reference the violation(s) cited, state specific corrective action(s) and timetable(s) and date(s) for completion for each violation cited, and shall be signed by either the applicant, licensee or registrant or his/her designee.



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(b) The Agency may re-inspect a facility in order to determine whether the corrections have been made. If upon review of plan of correction and/or reinspection the Agency finds that the applicant, licensee or registrant is in compliance with 105 CMR 120.000 and that the applicant, licensee or registrant has submitted an acceptable plan of correction, the Agency shall notify the applicant, licensee or registrant of its findings of compliance and/or its acceptance or modification of the plan of correction.

(c) If upon review of plan of correction and/or reinspection the Agency finds the plan of correction is unacceptable, the Agency may request that the applicant, licensee or registrant amend and resubmit the plan of correction within five days of the date of notice of the required amendment to the plan of correction or such other time as the Agency may specify for resubmission.

(d) If upon review of the plan of correction and/or reinspection the Agency determines that an applicant, licensee or registrant remains non-compliant with applicable laws and regulations regarding licensure, or the Agency determines that further enforcement action is necessary to ensure compliance with regulatory requirements and deter future non-compliance the Department may initiate enforcement procedures as set forth in 105 CMR 120.016.

(3) Notice of Department's Intent to Issue an Order.

(a) Except as specified in 105 CMR 120.016(F)(4)(b), prior to the Department issuing an order to modify, limit, deny, revoke or refuse to renew a license, and/or to require a person to cease and desist any activity, and/or to impose civil penalties, the applicant, licensee or registrant shall be notified in writing of the Agency's Intent to Issue an Order. The Notice of Intent to Issue an Order shall include the grounds for the Department's action, the provision(s) of law relied upon, the amount of any civil penalty or the requirements of the proposed order, and a right to request an adjudicatory hearing.

(b) If a license or certificate of registration is to be denied, modified, limited, revoked or refused renewal or if an activity is to be ceased or a civil penalty imposed by the Department, then the aggrieved applicant, licensee or registrant may request an adjudicatory hearing within 21 days of receipt of notification of the Department's Intent to Issue an Order. Said request shall be filed in accordance with 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedures*.

(4) Administrative Hearings: Procedure.

(a) Immediate Suspension of a License or Certificate of Registration or Issuance of an Order to Immediately Cease an Activity:

1. The Department shall give the licensee or registrant written notice stating the reason(s) for the immediate suspension or issuance of an order to immediately cease an activity and the provisions of law relied upon. The immediate suspension or order to immediately cease an activity shall take effect immediately upon issuance of the notice.

2. The Department shall provide for a hearing pursuant to 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedures* promptly after the issuance of an order of immediate suspension or an order to immediately cease an activity.

3. In cases of immediate suspension of a license or certificate of registration or issuance of an order to immediately cease an activity, the Hearing Officer shall determine whether the Department has proved by a preponderance of the evidence that there existed, immediately prior to or at the time of the immediate suspension or cease and desist order, a threat to public health, safety or the environment.

4. In the event that the Department determines that the violation of state law or of 105 CMR 120.000 which posed a threat to public health, safety or the environment is corrected prior to the decision of the Hearing Officer, the Department may lift the immediate suspension by giving written notice to the licensee or registrant.

(b) Denial, Modification, Limitation, Revocation, or Refusal to Renew a License or Certificate of Registration Based on Failure to File Reports or Pay Fees or Maintain Insurance: In accordance with M.G.L. c. 30A, § 13, no Notice of Intent to Issue an Order shall be required and no hearing shall be offered where denial, modification, limitation, revocation, suspension or refusal to renew is based solely upon failure of the licensee or registrant to file timely reports, schedules or applications or to pay lawfully prescribed fees, or to maintain insurance coverage as required by any law or regulation.



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## (c) Denial, Modification, Limitation, Revocation or Refusal to Renew a License or Certificate of Registration; Orders to Cease an Activity; Civil Penalties:

1. All adjudicatory proceedings shall be conducted in accordance with M.G.L. c. 30A and 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedures*.

2. Except for circumstances specified in 105 CMR 120.016(F)(4)(b), if the Department determines that a license or certificate of registration should be denied, modified, limited, revoked, or refused renewal, and/or that a facility should cease an activity, and/or that a civil penalty should be imposed, and if the Department notifies the applicant, licensee or registrant of its intended action, upon receipt of a Notice of Claim for an Adjudicatory Proceeding, the Department shall initiate a hearing pursuant to 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedures*.

3. The Hearing Officer shall determine whether the Department has proved by a preponderance of the evidence that the license or certificate of registration should be denied, modified, limited, revoked or refused renewal; that an activity should be ceased; and/or that a civil penalty be imposed based on relevant facts as they existed at or prior to the time the Department initiated the hearing procedure.

4. If the Hearing Officer finds any single ground for denial, modification, limitation, revocation, suspension, or refusal to renew a license or certificate of registration; for a cessation of an activity; and/or for imposition of a civil penalty, then the Hearing Officer shall render a recommended decision affirming the issuance of the Department's Order.

(d) Final Agency Decision and Judicial Review:

1. The recommended decision of a Hearing Officer in any adjudicatory proceeding conducted under 105 CMR 120.000 shall be reviewed by the Commissioner. The Commissioner's decision upon this review shall constitute a final agency decision in an adjudicatory proceeding subject to judicial review pursuant to M.G.L. c. 30A, § 14.

2. Any applicant, licensee or registrant that fails to exercise its right to an adjudicatory proceeding under 105 CMR 120.000 waives its right to an adjudicatory hearing, its right to administrative review by the Commissioner and its right to judicial review pursuant to M.G.L. c. 30A, § 14.

(G) Civil Penalties.

(1) If the Department determines, after a notice has been issued and an opportunity for a hearing has been provided, that a licensee, registrant or vendor has not complied with an order issued pursuant to M.G.L. c. 111, § 50 or with any provision of M.G.L. c. 111, §§ 5N through 5P or with any applicable rule, regulation, license or certificate of registration adopted or issued thereunder, the Department, in lieu of, or in addition to suspending, denying, modifying, limiting, revoking, or refusing renewal of a license or certificate of registration, may assess civil penalties in an amount not exceeding \$100,000 per violation. Such civil penalty may be assessed whether or not the violation was willful.

(2) The decision whether to issue a civil penalty and the amount of any civil penalty depends on the facts of each case. Generally, civil penalties are most likely to be imposed for Severity Level I violations and if mitigating circumstances are absent, for Severity Level II violations. Civil penalties are considered for Severity Level III violations, and may be imposed for Severity Level IV violations that are similar to previous violations that occurred after the date of the last inspection or within two years, whichever period is greater for which the licensee did not take effective corrective action.

(3) Civil penalties may be assessed for known and conscious violations of the reporting requirements of 105 CMR 120.000 and for any willful violation of any Agency requirement including those at any severity level.

(4) Payment of civil penalties imposed under M.G.L. c. 111, § 50 shall be made by check, draft, or money order payable to the Commonwealth of Massachusetts, and mailed to the Radiation Control Program.

(5) Factors in Determining the Amount of Penalty. In determining the amount of the civil penalty, the Department shall consider the following:

- (a) The willfulness of the violation;
- (b) The actual and potential danger to the public health or the environment;
- (c) The actual or potential costs of such danger to the public health or the environment;



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- (d) The actual or potential damage or injury to the public health or environment;
- (e) The actual and potential cost of such damage or injury;
- (f) The actual or potential cost to the Commonwealth of enforcing provisions of 105 CMR 120.000;
- (g) Whether the person being assessed the civil penalty did everything reasonable to prevent failure to, to come into compliance promptly, and to remedy and mitigate whatever harm might have been done as a result of the failure to comply;
- (h) Whether the person being assessed the civil penalty has previously failed to comply with any order issued pursuant to M.G.L. c. 111, §§ 5N through 5P or any rule or regulation adopted hereunder;
- (i) Whether imposition of a civil penalty is likely to deter future non-compliance;
- (j) The financial condition of the person being assessed the civil penalty; and,
- (k) The public interest.

(H) Escalation of Enforcement Sanctions.

- (1) The Department considers violations of Severity Levels I, II or III to be of significant regulatory concern. When Severity Level I, II or III violations occur, the Department will, where necessary, issue orders in conjunction with civil penalties to achieve immediate corrective actions and to deter further recurrence of serious violations. The Department carefully considers the circumstances of each case in selecting and applying the sanction(s) appropriate to the case in accordance with the criteria described in 105 CMR 120.016(D).
- (2) The progression of enforcement actions for similar violations will usually be based on similar violations at an individual facility and not on similar violations under the same license. However, under some circumstances, *e.g.*, where there is common control over some facet of facility operations, similar violations may be charged even though the second violation occurred at a different facility or under a different license. For example, a health physics violation at one division of a dual unit hospital that repeats an earlier violation of the other division might be considered similar.

(I) Criminal Enforcement. The Department may elect to enforce any section of 105 CMR 120.000 or provision of M.G.L. c. 111, § 5P by seeking to have criminal sanctions imposed. Any person who violates M.G.L. c. 111, § 5N or § 5O or any rule, regulation, license, registration, or order adopted or issued under said M.G.L. c. 111, § 5N or § 5O shall be fined not less than \$100 nor more than \$2,000, or be imprisoned for a period of not more than two years, or both. Any person who continues to violate the provisions of the aforementioned laws after due notice by the Department shall be fined not less than \$1,000 nor more than \$20,000 or be imprisoned for a period of not more than 20 years, or both. After due notice has been issued by the Department, each day of such violation shall constitute a separate offense.

(J) Judicial Enforcement. The Department may apply directly to the Supreme Judicial Court or Superior Court to enforce any provision of M.G.L. c. 111, §§ 5N through 5P and/or any rule or regulation, license, registration, or order adopted and issued thereunder by the Department. When a person is engaged in or about to engage in any act or practice which constitutes or will constitute a violation of such provision, rule, regulation, license, registration, or order, the Department may seek to restrain such act or practice or the use or occupation of premises or parts thereof or such other equitable relief as public health and safety requires.

(K) Nonexclusivity of Enforcement Procedures. None of the enforcement procedures contained in 105 CMR 120.000 are mutually exclusive. Any enforcement procedures may be invoked simultaneously if the situation so requires.

(L) Deliberate Misconduct.

- (1) Any licensee, certificate of registration holder, applicant for a license or certificate of registration, employee of a licensee, certificate of registration holder or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or certificate of registration holder or applicant for a license or certificate of registration, who knowingly provides to any licensee, applicant, certificate holder, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, certificate holder's or applicant's activities in this part, may not:

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- (a) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, certificate of registration holder, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Agency; or
- (b) Deliberately submit to the Agency, a licensee, certificate of registration holder, an applicant, or a licensee's, certificate holder's or applicant's, contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Agency.
- (2) A person who violates 105 CMR 120.016(L)(1)(a) or (b) may be subject to enforcement action in accordance with the procedures in 105 CMR 120.016.
- (3) For the purposes of 105 CMR 120.016(L)(1)(a), deliberate misconduct by a person means an intentional act or omission that the person knows:
  - (a) Would cause a licensee, certificate of registration holder or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Agency; or
  - (b) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, certificate of registration holder, applicant, contractor, or subcontractor.

120.017: Severability

The provisions of 105 CMR 120.000 are severable. If any section, subsection, paragraph or provision is declared unconstitutional or invalid by a court of competent jurisdiction, the validity of the remaining provisions shall not be so affected.

120.018: Public Disclosure of Enforcement Actions

In accordance with M.G.L. c. 30A, the Administrative Procedures Act, all enforcement actions and licensees' responses are publicly available for inspection. In addition, press releases may be issued for civil penalties related to violations at Severity Level I, II, or III.

120.019: Appendix A -- Severity Categories

The following examples of severity levels are neither exhaustive nor controlling. They reflect only the seriousness of the violation and not the intent of the violator, the history of the violator, the amount necessary to deter future violations, or efforts to correct the violation.

(A) Severity Level 1 -- Most Significant Violations.

(1) Health Physics.

- (a) Single exposure of a worker in excess of 25 rems of radiation to the whole body, 150 rems to the skin of the whole body, or 375 rems to the feet, ankles, hands or forearms;
- (b) Annual whole body exposure of a member of the public in excess of 2.5 rems of radiation;
- (c) Release of radioactive material to an unrestricted area in excess of ten times the limits of 105 CMR 120.253;
- (d) Disposal of licensed material in quantities or concentrations in excess of ten times the limits of 105 CMR 120.253;
- (e) Exposure of a worker in restricted areas of ten times the limits of 105 CMR 120.212.

(2) Transportation.

- (a) Annual whole body radiation exposure of a member of the public in excess of 0.5 rems of radiation; or,
- (b) Breach of package integrity resulting in surface contamination or external radiation levels in excess of ten times the Agency limits.

(3) Materials Operations.

- (a) Radiation levels, contamination levels, or releases that exceed ten times the limits specified in the license;
- (b) A system designed to prevent or mitigate a serious safety event not being operable when actually required to perform its design function.



120.789: Advance Notification of Shipment of Nuclear Waste

- (A)(1) As specified in 105 CMR 120.789(B) through (D), each licensee shall provide advance notification to the governor of a State, or the governor's designee, of the shipment of licensed material, within or across the boundary of the State, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.
- (2) As specified in 105 CMR 120.789(B) through (D) each licensee shall provide advance notification to the Tribal official of participating Tribes referenced in 105 CMR 120.789(C)(3)(c), or the official's designee, of the shipment of licensed material, within or across the boundary of the Tribe's reservation, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

(B) Advance notification is required under 105 CMR 120.789 for shipment of licensed material meeting the following three conditions:

- (1) The licensed material is required by 10 CFR 71 to be in Type B packaging for transportation;
- (2) The licensed material is being transported into, within, or through a state en route to a disposal facility or to a collection point for transport to a disposal facility; and,
- (3) The quantity of licensed material in a single package exceeds the least of the following:
  - (a) 3000 times the  $A_1$  value of the radionuclides as specified in 105 CMR 120.795: *Appendix A*, Table A-1 for special form radioactive material;
  - (b) 3000 times the  $A_2$  value of the radionuclides as specified in 105 CMR 120.795: *Appendix A*, Table A-1 for normal form radioactive material; or,
  - (c) 1000 TBq (27,000 Ci).