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August 28, 2001

Frederick C. Combs, Deputy Director
Office of State and Tribal Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Combs:

This letter is to inform the U.S. Nuclear Regulatory Commission that the proposed revision to Nebraska's regulations, Title 180, Chapter 1-19 became effective July 22, 2001.

These regulations include the following changes:

- Title 180, Chapter 1, Sections 001-019 in now Title 180, Chapters 1-19.
- Changed the name of Title 180 to "Control of Radiation" from "Nebraska Regulations for Control of Radiation-Ionizing"
- The Chapters were renumber and reformat in order to comply with the Health and Human Services System uniform procedures for regulations.
- Technical and editorial changes were made for better clarity such as: The phrase "the effective date of these regulations" was removed and the actual effective date of the regulation was inserted throughout. 180 NAC 15-013 (formerly 180 NAC 1-015.13) was rewritten to improve clarity but no substantive changes were made.
- Renumbered and reformatted forms.
- Reserved all of 180 NAC 3-012 due to the material being transferred to other Chapters in previous updates.
- Changed 180 NAC 4-015.02 item 3 (formerly 180 NAC 1-004.16.B3), by inserting the word "within" after "decommissioning plan" in the first line and after the word "Agency" in the third line. This word was inserted to be compatible with the U.S. Nuclear Regulatory Commission's regulations.
- Reserved 180 NAC 15-007 as the requirements are in 180 NAC 7.
- Changed 180 NAC 17 Appendix 17-A (formerly 180 NAC 1-017 Appendix 017-A), (C. Severity III – Significant Violations, item 3 from "immediately" to "within 30 days".

Please find enclosed a copy of Title 180 and the Radiation Control Act dated 4-14-200. The regulations are also located at <http://www.hhs.state.ne.us/reg/t180.htm> I have also enclosed a table for statutory authority for each chapter of the regulations.

If you have any questions, please feel free to contact me at (402)471-0928 or Trudy Hill at (402)471-0560.

Sincerely,

Sue Semerena, Section Administrator
Consumer Health Services

Enclosure

2000

STATE OF NEBRASKA

Radiation Control Act

Neb. Rev. Stat. Sections 71-3501 to 71-3519

NEBRASKA HEALTH AND HUMAN SERVICES SYSTEM



Department of Health and Human Services Regulation and Licensure
Public Health Assurance Division
Nebraska State Office Building
301 Centennial Mall South, Third Floor
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Lincoln, NE 68509-5007

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RADIATION CONTROL ACT

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Radiation Control Act
Neb. Rev. Stat. sections 71-3501 to 71-3519

71-3501. Public policy. It is the policy of the State of Nebraska in furtherance of its responsibility to protect occupational and public health and safety and the environment:

- (1) To institute and maintain a regulatory program for Sources of radiation so as to provide for:
 - (a) Compatibility and equivalency with the standards and regulatory programs of the federal government;
 - (b) A single effective system of regulation within the state; and
 - (c) A system consonant insofar as possible with those of other states;
- (2) To institute and maintain a program to permit development and utilization of Sources of radiation for peaceful purposes consistent with the protection of occupational and public health and safety and the environment;
- (3) To maximize the protection practicable for the citizens of Nebraska from ionizing radiation by establishing requirements for appropriate qualifications of persons practicing medical radiography;
- (4) To provide for the availability of capacity either within or outside the state for the management of low-level radioactive waste generated within the state, except for waste generated as a result of defense or federal research and development activities, and to recognize that such radioactive waste can be most safely and efficiently managed on a regional basis; and
- (5) To maximize the protection practicable for the citizens of Nebraska from radon or its decay products by establishing requirements for (a) appropriate qualifications for persons providing measurement and mitigation services of radon or its decay products and (b) radon mitigation system installations.

Source: Laws 1963, c. 406, §1, p. 1296; Laws 1975, LB 157, §1; Laws 1984, LB 716, §1; Laws 1987, LB 390, §2; Laws 1993, LB 536, §82; Laws 1995, LB 406, §40.

71-3502. Purpose of act; programs provided. It is the purpose of the Radiation Control Act to effectuate the policies set forth in section 71-3501 by providing for:

- (1) A program of effective regulation of Sources of radiation for the protection of occupational and public health and safety and the environment;
- (2) A program to promote an orderly regulatory pattern within the state, among the states, and between the federal government and the state and facilitate intergovernmental cooperation with respect to use and regulation of Sources of radiation to the end that duplication of regulation may be minimized;
- (3) A program to establish procedures for assumption and performance of certain regulatory responsibilities with respect to Sources of radiation;
- (4) A program to permit maximum utilization of Sources of radiation consistent with the health and safety of the public; and
- (5) A program which establishes requirements and standards for appropriate education, training, and testing of persons practicing medical radiography.

Source: Laws 1963, c. 406, §2, p. 1296; Laws 1975, LB 157, §2; Laws 1984, LB 716, §2; Laws 1987, LB 390, §3; Laws 1995, LB 406, §41.

71-3503. Terms, defined. For purposes of the Radiation Control Act, unless the context otherwise requires:

- (1) Radiation means ionizing radiation and nonionizing radiation as follows:
 - (a) Ionizing radiation means gamma rays, X-rays, alpha and beta particles, high-speed electrons, neutrons, protons, and other atomic or nuclear particles or rays but does not include sound or radio waves or visible, infrared, or ultraviolet light; and
 - (b) Nonionizing radiation means (i) any electromagnetic radiation which can be generated during the operations of electronic products to such energy density levels as to present a biological hazard to occupational and public health and safety and the environment, other than ionizing electromagnetic radiation, and (ii) any sonic, ultrasonic, or infrasonic waves which are emitted from an electronic product as a result of the operation of an electronic circuit in such product and to such energy density levels as to present a biological hazard to occupational and public health and safety and the environment;
- (2) Radioactive material means any material, whether solid, liquid, or gas, which emits ionizing radiation spontaneously. Radioactive material includes, but is not limited to, accelerator-produced material, byproduct material, naturally occurring material, Source material, and special nuclear material;
- (3) Radiation-generating equipment means any manufactured product or device, component part of such a product or device, or machine or system which during operation can generate or emit radiation except devices which emit radiation only from radioactive material;
- (4) Sources of radiation means any radioactive material, any radiation-generating equipment, or any device or equipment emitting or capable of emitting radiation or radioactive material;
- (5) Undesirable radiation means radiation in such quantity and under such circumstances as determined from time to time by rules and regulations adopted and promulgated by the department;

- (6) Person means any individual, corporation, partnership, limited liability company, 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;
- (7) Registration means registration with the department pursuant to the Radiation Control Act;
- (8) Department means the Department of Health and Human Services Regulation and Licensure;
- (9) Coordinator means the Director of Regulation and Licensure;
- (10) Council means the radiation advisory council provided for in section 71-3506;
- (11) Electronic product means any manufactured product, device, assembly, or assemblies of such products or devices which, during operation in an electronic circuit, can generate or emit a physical field of radiation;
- (12) License means:
- (a) A general license issued pursuant to rules and regulations adopted and promulgated by the department without the filing of an application with the department or the issuance of licensing documents to particular persons to transfer, acquire, own, possess, or use quantities of or devices or equipment utilizing radioactive materials;
- (b) A specific license, issued to a named person upon application filed with the department pursuant to the Radiation Control Act and rules and regulations adopted and promulgated pursuant to the act, to use, manufacture, produce, transfer, receive, acquire, own, or possess quantities of or devices or equipment utilizing radioactive materials;
- (c) A license issued to a radon measurement specialist, radon measurement technician, radon mitigation specialist, radon mitigation technician, radon measurement business, or radon mitigation business; or
- (d) A license issued to a medical radiographer or limited radiographer;
- (13) Byproduct material means:
- (a) Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material; and
- (b) The tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its Source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by such solution extraction operations do not constitute byproduct material;
- (14) Source material means:
- (a) Uranium or thorium or any combination thereof in any physical or chemical form; or
- (b) Ores which contain by weight one-twentieth of one percent or more of uranium, thorium, or any combination thereof. Source material does not include special nuclear material;
- (15) Special nuclear material means:
- (a) Plutonium, uranium 233, or uranium enriched in the isotope 233 or in the isotope 235 and any other material that the United States Nuclear Regulatory Commission pursuant to the provisions of section 51 of the federal Atomic Energy Act of 1954, as amended, determines to be special nuclear material but does not include Source material; or
- (b) Any material artificially enriched by any material listed in subdivision (15) (a) of this section but does not include Source material;
- (16) Users of Sources of radiation means:
- (a) Physicians using radioactive material or radiation-generating equipment for human use;
- (b) Natural persons using radioactive material or radiation-generating equipment for education, research, or development purposes;
- (c) Natural persons using radioactive material or radiation-generating equipment for manufacture or distribution purposes;
- (d) Natural persons using radioactive material or radiation-generating equipment for industrial purposes; and
- (e) Natural persons using radioactive material or radiation-generating equipment for any other similar purpose;
- (17) Civil penalty means any monetary penalty levied on a licensee or registrant because of violations of statutes, rules, regulations, licenses, or registration certificates but does not include criminal penalties;
- (18) Closure means all activities performed at a waste handling, processing, management, or disposal site, such as stabilization and contouring, to assure that the site is in a stable condition so that only minor custodial care, surveillance, and monitoring are necessary at the site following termination of licensed operation;
- (19) Decommissioning means final operational activities at a facility to dismantle site structures, to decontaminate site surfaces and remaining structures, to stabilize and contain residual radioactive material, and to carry out any other activities to prepare the site for postoperational care;
- (20) Disposal means the permanent isolation of low-level radioactive waste pursuant to the Radiation Control Act and rules and regulations adopted and promulgated pursuant to such act;
- (21) Generate means to produce low-level radioactive waste when used in relation to low-level radioactive waste;
- (22) High-level radioactive waste means:
- (a) Irradiated reactor fuel;
- (b) Liquid wastes resulting from the operation of the first cycle solvent extraction system or equivalent and the concentrated wastes from subsequent extraction cycles or the equivalent in a facility for reprocessing irradiated reactor fuel; and
- (c) Solids into which such liquid wastes have been converted;

(23) Low-level radioactive waste means radioactive waste not defined as high-level radioactive waste, spent nuclear fuel, or byproduct material as defined in subdivision (13) (b) of this section;

(24) Management of low-level radioactive waste means the handling, processing, storage, reduction in volume, disposal, or isolation of such waste from the biosphere in any manner, except the commercial disposal of low-level radioactive waste in a disposal facility, designated by the Central Interstate Low-Level Radioactive Waste Compact Commission;

(25) Source material mill tailings or mill tailings means the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its Source material content, including discrete surface wastes resulting from underground solution extraction processes, but not including underground ore bodies depleted by such solution extraction processes;

(26) Source material milling means any processing of ore, including underground solution extraction of unmined ore, primarily for the purpose of extracting or concentrating uranium or thorium therefrom and which results in the production of Source material and Source material mill tailings;

(27) Spent nuclear fuel means irradiated nuclear fuel that has undergone at least one year of decay since being used as a Source of energy in a power reactor. Spent nuclear fuel includes the special nuclear material, byproduct material, Source material, and other radioactive material associated with fuel assemblies;

(28) Transuranic waste means radioactive waste containing alpha-emitting transuranic elements, with radioactive half-lives greater than five years, in excess of one hundred nanocuries per gram;

(29) Licensed practitioner means a person licensed to practice medicine, dentistry, podiatry, chiropractic, osteopathic medicine and surgery, or as an osteopathic physician;

(30) X-ray system means an assemblage of components for the controlled production of X-rays, including, but not limited to, an X-ray high-voltage generator, an X-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system;

(31) Limited radiographer means a person licensed to practice medical radiography pursuant to subsection (2) of section 71-3515.01. Limited radiographer does not include a person certified under section 71-176.01;

(32) Medical radiographer means a person licensed to practice medical radiography pursuant to subsection (1) of section 71-3515.01;

(33) Medical radiography means the application of radiation to humans for diagnostic purposes, including, but not limited to, adjustment or manipulation of X-ray systems and accessories including image receptors, positioning of patients, processing of films, and any other action that materially affects the radiation dose to patients; and

(34) Licensed facility operator means any person or entity who has obtained a license under the Low-Level Radioactive Waste Disposal Act to operate a facility, including any person or entity to whom an assignment of a license is approved by the Department of Environmental Quality.

Source: Laws 1963, c. 406, §3, p. 1297; Laws 1975, LB 157, §3; Laws 1978, LB 814, §3; Laws 1984, LB 716, §3; Laws 1987, LB 390, §4; Laws 1989, LB 342, §32; Laws 1990, LB 1064, §17; Laws 1993, LB 121, §434; Laws 1993, LB 536, §83; Laws 1995, LB 406, §42; Laws 1996, LB 1044, §651; Laws 1996, LB 1201, §1. The changes made by LB 1201, section 1, became effective July 19, 1996. The changes made by LB 1044, section 651, became operative January 1, 1997.

71-3504. Radiation control activities; Director of Regulation and Licensure, coordinator; powers and duties. (1) The Director of Regulation and Licensure shall be the coordinator of radiation control activities and may designate a Director of Radiation Control. The Director of Regulation and Licensure shall:

(a) Advise the Governor and agencies of the state on matters relating to radiation; and

(b) Coordinate regulatory activities of the state relating to radiation, including cooperation with other states and the federal government.

(2) The Director of Regulation and Licensure shall:

(a) Review before and after the holding of any public hearing required under the Administrative Procedure Act, prior to promulgation, the proposed rules and regulations of all agencies of the state relating to use and control of radiation to assure that such rules and regulations are consistent with rules and regulations of other agencies of the state;

(b) When he or she determines that proposed rules or regulations or parts thereof are inconsistent with rules and regulations of other agencies of the state, consult with the radiation advisory council in an effort to resolve such inconsistencies. Upon notification by the council that such inconsistencies have not been resolved, the Governor may, after consultation with the council and the Director of Regulation and Licensure, find that the proposed rules and regulations or parts thereof are inconsistent with rules and regulations of other agencies of the state or the federal government and may issue an order to that effect, in which event the proposed rules and regulations or parts thereof shall not become effective. The Governor may, in the alternative, upon a similar determination, direct the appropriate agency or agencies to amend or repeal existing rules and regulations to achieve consistency with the proposed rules and regulations;

(c) Advise, consult, and cooperate with other agencies of the state, the federal government, other states, interstate agencies, political subdivisions, and other organizations concerned with control of Sources of radiation; and

(d) Collect and disseminate information relating to the control of Sources of radiation and maintain (i) a file of all registrants, license applications, issuances, denials, amendments, transfers, renewals, modifications, inspections, recommendations pertaining to

radiation, suspensions, and revocations, (ii) a file of registrants possessing or using Sources of radiation requiring registration under the Radiation Control Act and any administrative or judicial action pertaining to such registration, and (iii) a file of all rules and regulations relating to the regulation of Sources of radiation, pending or promulgated, and proceedings on such rules and regulations thereon.

(3) The several agencies of the state and political subdivisions shall keep the coordinator fully and currently informed as to their activities relating to development of new uses and regulation of Sources of radiation.

Source: Laws 1963, c. 406, §4, p. 1298; Laws 1975, LB 157, §4; Laws 1987, LB 390, §5; Laws 1996, LB 1044, §652.
Operative date January 1, 1997.

71-3505. Department; powers and duties. Matters relative to radiation as they relate to occupational and public health and safety and the environment shall be a responsibility of the department. The department shall:

(1) Develop comprehensive policies and programs for the evaluation and determination of undesirable radiation associated with the production, use, storage, or disposal of radiation sources and formulate, adopt, promulgate, and repeal rules and regulations which may provide (a) for registration or licensure under section 71-3507 or 71-3509 and (b) for registration or licensure of (i) any other source of radiation, (ii) persons providing services for collection, detection, measurement, or monitoring of sources of radiation, including, but not limited to, radon and its decay products, (iii) persons providing services to reduce the effects of sources of radiation, (iv) persons practicing medical radiography, and (v) persons practicing industrial radiography, as specified by rule or regulation so as to reasonably protect occupational and public health and safety and the environment in a manner compatible with regulatory programs of the federal government. The department for identical purposes may also adopt and promulgate rules and regulations for the issuance of licenses, either general or specific, to persons for the purpose of using, manufacturing, producing, transporting, transferring, receiving, acquiring, owning, or possessing any radioactive material. Such rules and regulations may prohibit the use of radiation for uses found by the department to be detrimental to occupational and public health or safety or the environment and shall carry out the purposes and policies set out in sections 71-3501 and 71-3502. Such rules and regulations shall not prohibit or limit the kind or amount of radiation purposely prescribed for or administered to a patient by doctors of medicine and surgery, dentistry, osteopathic medicine, chiropractic, podiatry, and veterinary medicine, while engaged in the lawful practice of such profession, or administered by other professional personnel, such as allied health personnel, medical radiographers, limited radiographers, nurses, and laboratory workers, acting under the supervision of a licensed practitioner. Violation of rules and regulations adopted and promulgated by the department pursuant to the Radiation Control Act shall be due cause for the suspension, revocation, or limitation of a license issued by the department. Any licensee may request a hearing before the department on the issue of such suspension, revocation, or limitation. Procedures for notice and opportunity for a hearing before the department shall be pursuant to the Administrative Procedure Act. The decision of the department may be appealed, and the appeal shall be in accordance with the Administrative Procedure Act;

(2) Inform the council of any such rules and regulations at least thirty days prior to their adoption and consider any recommendations of the council;

(3) Have the authority to accept and administer loans, grants, or other funds or gifts, conditional or otherwise, in furtherance of its functions, from the federal government and from other sources, public or private;

(4) Encourage, participate in, or conduct studies, investigations, training, research, and demonstrations relating to the control of sources of radiation;

(5) Collect and disseminate health education information relating to radiation protection;

(6) Make its facilities available so that any person or any agency may request the department to review and comment on plans and specifications of installations submitted by the person or agency with respect to matters of protection and safety for the control of undesirable radiation;

(7) Be empowered to inspect radiation sources and their shieldings and surroundings for the determination of any possible undesirable radiation or violations of rules and regulations adopted and promulgated by the department and provide the owner, user, or operator with a report of any known or suspected deficiencies; and

(8) Collect a fee for emergency response or environmental surveillance, or both, offsite from each nuclear power plant equal to the cost of completing the emergency response or environmental surveillance and any associated report. In no event shall the fee for any nuclear power plant exceed the lesser of the actual costs of such activities or fifty-three thousand dollars per annum. Commencing July 1, 1997, the accounting division of the Department of Administrative Services shall recommend an inflationary adjustment equivalent which shall be based upon the Consumer Price Index for All Urban Consumers of the United States Department of Labor, Bureau of Labor Statistics, and shall not exceed five percent per annum. Such adjustment shall be applied to the annual fee for nuclear power plants. The fee collected shall be credited to the Department of Health and Human Services Regulation and Licensure Cash Fund. This fee shall be used solely for the purpose of defraying the direct costs of the emergency response and environmental surveillance at Cooper Nuclear Station and Fort Calhoun Station conducted by the department. The department may charge additional fees when mutually agreed upon for services, training, or equipment that are a part of or in addition to matters in this section.

Source: Laws 1963, c. 406, § 5, p. 1299; Laws 1969, c. 577, § 1, p. 2324; Laws 1975, LB 157, § 5; Laws 1978, LB 814, § 4; Laws 1987, LB 390, § 6; Laws 1988, LB 352, § 131; Laws 1989, LB 342, § 33; Laws 1990, LB 1064, § 18; Laws 1995, LB 406, § 43; Laws 1996, LB 1044, § 653; Laws 1997, LB 658, § 13; Laws 2000, LB 1115, § 72. Effective date April 14, 2000.

71-3506. Radiation advisory council; members; appointment; term of office; compensation; duties. (1) There is hereby established a radiation advisory council within the department consisting of nine members to be appointed by the Governor. The Governor shall appoint to the council one individual with experience relating to radiation from each of the following fields: (a) Radiology; (b) medicine, exclusive of radiology; (c) radiation or health physics; (d) law; (e) agriculture; (f) labor; (g) business or industry; (h) dentistry; and (i) chiropractic, osteopathic medicine and surgery, or podiatry. Each appointed member shall hold office for a term of three years, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which his or her predecessor was appointed shall be appointed for the remainder of such term. The terms of office of the members first taking office shall expire, as designated at the time of appointment, three at the end of the first year, three at the end of the second year, and three at the end of the third year. After the date of appointment, appointed council members, while serving on business of the council, shall receive compensation at the rate of twenty dollars per day and shall also be entitled to receive actual and necessary travel and subsistence expenses while so serving as provided in sections 81-1174 to 81-1177 for state employees.

(2) The council shall:

(a) Elect a chairperson to serve at the pleasure of the council;

(b) Meet on call of the chairperson or at the request of any three members;

(c) Review and evaluate policies and programs of the state relating to radiation; and

(d) Make recommendations to the coordinator and the department and furnish such technical advice as may be required on matters relating to the development, utilization, and regulation of Sources of radiation.

Source: Laws 1963, c. 406, §6, p. 1301; Laws 1975, LB 157, §6; Laws 1981, LB 204, §126; Laws 1989, LB 342, §34.

71-3507. Licenses or registration; rules and regulations; exemptions; reciprocity; department; right of entry; surveys and inspections. (1) The department shall adopt and promulgate rules and regulations for the issuance, amendment, suspension, and revocation of general and specific licenses. Such licenses shall be for byproduct material, source material, special nuclear material, and radioactive material not under the authority of the federal Nuclear Regulatory Commission and for devices or equipment utilizing such materials. The rules and regulations shall provide:

(a) For written applications for a specific license which include the technical, financial, and other qualifications determined by the department to be reasonable and necessary to protect occupational and public health and safety and the environment;

(b) For additional written statements and inspections, as required by the department, at any time after filing an application for a specific license and before the expiration of the license to determine whether the license should be issued, amended, suspended, or revoked;

(c) That all applications and statements be signed by the applicant or licensee;

(d) The form, terms, and conditions of general and specific licenses;

(e) That no license or right to possess or utilize sources of radiation granted by a license shall be assigned or in any manner disposed of without the written consent of the department; and

(f) That the terms and conditions of all licenses are subject to amendment by rules, regulations, or orders issued by the department.

(2) The department may require registration or licensing of radioactive material not enumerated in subsection (1) of this section in order to maintain compatibility and equivalency with the standards and regulatory programs of the federal government or to protect the occupational and public health and safety and the environment.

(3) The department shall require licensure of persons providing measurement and mitigation services of radon or its decay products in order to protect the occupational and public health and safety and the environment. The department shall adopt and promulgate rules and regulations establishing education, experience, training, and examination requirements for radon measurement specialists, radon measurement technicians, radon mitigation specialists, and radon mitigation technicians. The department shall adopt and promulgate rules and regulations establishing staffing, proficiency, quality control, reporting, worker health and safety, equipment, and record-keeping requirements for radon measurement businesses and radon mitigation businesses and mitigation system installation requirements for radon mitigation businesses.

(4) The department shall license persons practicing medical radiography, including medical radiographers and limited radiographers, in order to protect the occupational and public health and safety and the environment. The licenses shall be renewable biennially. For medical radiographers and limited radiographers, the department shall adopt and promulgate rules and regulations establishing examination requirements for licensure, continuing education requirements for renewal of a license, and approval requirements for examinations. For medical radiographers, the department shall adopt and promulgate rules and regulations establishing requirements for education and training and for approval of courses of training. Persons authorized under sections 71-193.15 and 71-193.17 to practice as dental hygienists and dental assistants who meet the requirements of section 71-193.13 shall not be required to be licensed under this section.

(5) The department may exempt certain sources of radiation or kinds of uses or users from licensing or registration requirements established under the Radiation Control Act when the department finds that the exemption will not constitute a significant risk to occupational and public health and safety and the environment.

(6) The department may provide by rule and regulation for the recognition of other state or federal licenses compatible and equivalent with the standards established by the department for Nebraska licensees.

(7) The department may accept accreditation for an industrial radiographer by a recognized independent accreditation body, a public agency, or the federal Nuclear Regulatory Commission, which has standards that are at least as stringent as those of the State of Nebraska, as evidence that the industrial radiographer complies with the rules and regulations adopted and promulgated pursuant to the act. The department may adopt and promulgate rules and regulations which list accreditation bodies, public agencies, and federal programs that meet this standard.

(8) The department may enter at all reasonable times upon any private or public property for the purpose of determining whether or not there is compliance with the act and rules and regulations adopted and promulgated pursuant to the act, except that entry into areas under the jurisdiction of the federal government shall be effected only with the concurrence of the federal government or its duly designated representative.

(9) The department shall cause to be registered with the department such sources of radiation as the department determines to be reasonably necessary to protect occupational and public health and safety and the environment as follows:

(a) The department shall, by public notice, establish a date on or before which date such sources of radiation shall be registered with the department, and the department shall provide appropriate forms for such registration. Each application for registration shall be in writing and shall state such information as the department by rules or regulations may determine to be necessary and reasonable to protect occupational and public health and safety and the environment;

(b) Registration of sources of radiation shall be an initial registration with appropriate notification to the department in the case of alteration of equipment, acquisition of new sources of radiation, or the transfer, loss, or destruction of sources of radiation and shall include the registration of persons installing or servicing sources of radiation;

(c) Failure to register or reregister sources of radiation in accordance with rules and regulations adopted and promulgated by the department shall be subject to a fine of not less than fifty dollars nor more than two hundred dollars; and

(d) The department may provide by rule and regulation for reregistration of sources of radiation.

(10) The results of any surveys or inspections of sources of radiation conducted by the department shall be public records subject to sections 84-712 to 84-712.09. In addition, the following information shall be deemed confidential:

(a) The names of individuals in dosimetry reports;

(b) Emergency response procedures which would present a clear threat to security or disclose names of individuals; and

(c) Any other information that is likely to present a clear threat to the security of radioactive material. The department shall make such reports of results of surveys or inspections available to the owner or operator of the source of radiation together with any recommendations of the department regarding deficiencies noted.

(11) The department shall have the right to survey or inspect again any source of radiation previously surveyed without limitation of the number of surveys or inspections conducted on a given source of radiation.

(12) The department may enter into contracts with persons or corporations to perform the inspection of X-ray radiation-generating equipment or devices which emit radiation from radioactive materials and to aid the department in the administration of the act.

Source: Laws 1963, c. 406, § 7, p. 1301; Laws 1975, LB 157, § 7; Laws 1978, LB 814, § 5; Laws 1987, LB 390, § 7; Laws 1990, LB 1064, § 19; Laws 1993, LB 536, § 84; Laws 1995, LB 406, § 44; Laws 1999, LB 800, § 11; Laws 2000, LB 1115, § 73. Effective date April 14, 2000.

71-3508. Radiation; possession or use; records; contents; user of sources of radiation; qualifications; exemptions. (1)

The department shall require each person who possesses or uses a Source of radiation to maintain records relating to its receipt, storage, transfer, or disposal and such other records as the department may require subject to such exemptions as may be provided by rules or regulations. These records shall be made available for inspection by or copies shall be submitted to the department on request.

(2) The department shall require each person who possesses or uses a Source of radiation to maintain appropriate records showing the radiation exposure of all individuals for whom personnel monitoring is required by rules and regulations of the department. Copies of these records and those required to be kept by subsection (1) of this section shall be submitted to the department on request. Any person possessing or using a Source of radiation shall furnish to each employee for whom personnel monitoring is required a copy of each employee's personal exposure record at any time such employee has received exposure in excess of the amount specified in the rules and regulations of the department and upon termination of employment. A copy of the annual exposure record shall be furnished to the employee as required under rules and regulations adopted under the Radiation Control Act.

(3) The department may adopt and promulgate rules and regulations establishing qualifications pertaining to the education, knowledge of radiation safety procedures, training, experience, utilization, facilities, equipment, and radiation protection program that an individual user of Sources of radiation shall possess prior to using any Source of radiation or radiation-generating equipment. Individuals who are currently licensed in the State of Nebraska as podiatrists, chiropractors, dentists, physicians and surgeons, osteopathic physicians, physician assistants, and veterinarians shall be exempt from the rules and regulations of the department pertaining to the qualifications of persons for the use of X-ray radiation-generating equipment operated for diagnostic purposes.

Source: Laws 1963, c. 406, § 8, p. 1303; Laws 1975, LB 157, § 8; Laws 1978, LB 814, § 6; Laws 1980, LB 816, § 1; Laws 1987, LB 390, § 8; Laws 1989, LB 342, § 35; Laws 1995, LB 406, § 45; Laws 1996, LB 1108, § 21. Effective date April 16, 1996.

71-3508.01. Radioactive materials license; terms and conditions; termination of license; transfer of land; effect; department; powers and duties. (1) Any radioactive materials license issued or renewed after August 30, 1987, for any activity which results in the production of byproduct material as defined in subdivision (13) (b) of section 71-3503 shall contain such terms and conditions as the department determines to be necessary to assure that prior to termination of such license:

(a) The licensee shall comply with decontamination, decommissioning, and reclamation standards prescribed by the department which shall be equivalent, to the extent practicable, or more stringent than those of the federal Nuclear Regulatory Commission for sites (i) at which ores are processed primarily for their Source material content and (ii) at which such byproduct material or mill tailings are deposited; and

(b) Ownership of any disposal site and such byproduct material or mill tailings which resulted from the licensed activity will, subject to subsection (2) of this section, be transferred to (i) the United States or (ii) this state if the state exercises the option to acquire land used for the disposal of such byproduct material or mill tailings. Any license which is in effect on August 30, 1987, and which is subsequently terminated without renewal shall comply with subdivisions (1) (a) and (b) of this section upon termination.

(2) (a) The department shall require by rule, regulation, or order that prior to the termination of any license which is issued after August 30, 1987, title to the land, including any interests therein, other than land held in trust by the United States for any Indian tribe or owned by an Indian tribe subject to a restriction against alienation imposed by the United States or land already owned by the United States or by the state, which is used pursuant to such license for the disposal of byproduct material or Source material mill tailings will be transferred to (i) the United States or (ii) this state, unless the federal Nuclear Regulatory Commission determines prior to such termination that transfer of title to such land and such byproduct material or mill tailings is not necessary or desirable to protect the occupational and public health and safety and the environment or to minimize danger to life or property.

(b) If transfer to the state of title to such byproduct material or mill tailings and land is required, the state may assume title, following the federal Nuclear Regulatory Commission's determination that the licensee has complied with applicable standards and requirements under the license, and the department shall maintain the byproduct material or mill tailings and land in such manner as will protect the occupational and public health and safety and the environment.

(c) The department may undertake such monitoring, maintenance, and emergency measures as are necessary to protect the occupational and public health and safety and the environment for those materials and property to which the state has assumed title pursuant to this section.

(d) The transfer of title to the United States or this state shall not relieve any licensee of liability for any fraudulent or negligent acts done prior to such transfer.

(e) Title transferred pursuant to this section shall be transferred without cost to the United States or this state other than the administrative and legal costs incurred in carrying out such transfer.

(3) In the licensing and regulation of byproduct material and Source material mill tailings or of any activity which results in the production of byproduct material or mill tailings, the department shall require compliance with applicable standards adopted and promulgated by the department which are equivalent, to the extent practicable, or more stringent than standards adopted and enforced by the federal Nuclear Regulatory Commission for the same purpose, including requirements and standards promulgated by the federal Environmental Protection Agency.

Source: Laws 1987, LB 390, §9.

71-3508.02. Acquisition of sites; use; management. (1) Lands and appurtenances which are used for the management of low-level radioactive waste shall be acquired and held in fee simple absolute by the licensed facility operator so long as such ownership does not preclude licensure or operation of the facility under federal law and until title to the land and appurtenances is transferred to the state pursuant to subsection (1) of section 81-15,102. Such lands and appurtenances shall be used exclusively for the disposal of low-level radioactive waste until the department determines that such exclusive use is not required to protect the occupational and public health and safety or the environment. Before such site is leased for other use, the radioactive waste history of the site shall be recorded in the permanent land records of the site.

(2) The department may contract with third parties for management of a low-level radioactive waste site. A contractor shall be subject to the surety and long-term care funding provisions of section 71-3508.04 and to appropriate licensing by the federal Nuclear Regulatory Commission or by the department.

Source: Laws 1987, LB 390, §10; Laws 1994, LB 72, §1; Laws 1996, LB 1201, §2. Effective date July 19, 1996.

71-3508.03. Fees; costs; use; exemptions; failure to pay; effect. (1) The department shall establish by rule and regulation annual fees for the radioactive materials licenses, for inspections of radioactive materials, for the registration and inspection of radiation-generating equipment and other Sources of radiation, and for radon measurement and mitigation licenses and inspections of radon mitigation systems installations under the Radiation Control Act, except that the annual fee for registration and inspection of X-ray radiation-generating equipment shall not exceed seventy dollars per X-ray machine. In determining such fees, the department shall, as an objective, obtain sufficient funds from the fees to pay for a portion of the direct and indirect costs of administering the act without loss or reduction of the General Fund allocation to the department. No fee shall exceed the actual cost to the department for licensure, inspection, or registration. The department may also contract with a registrant, a licensee, another state, or a federal agency to partially or fully recover the cost of administering the act. The fees collected shall be deposited in the Department of Health and

Human Services Regulation and Licensure Cash Fund and shall be used solely for the purpose of defraying the direct and indirect costs of administering the act. The department shall collect such fees. The cost of environmental surveillance activities performed by the department to assess the radiological impact of activities conducted by licensees and registrants shall be in addition to the annual fees.

(2) The department may, upon application by an interested person or on its own initiative, grant such exemptions from the requirements of this section as it determines are in the public interest. Applications for exemption under this subsection may include, but shall not be limited to, the use of licensed materials for educational or noncommercial displays or scientific collections.

(3) When a registrant or licensee fails to pay the applicable fee, the department may suspend or revoke the registration or license or may issue an appropriate order.

Source: Laws 1987, LB 390, §11; Laws 1990, LB 1064, §20; Laws 1993, LB 536, §85; Laws 1996, LB 1044, §654.
Operative date January 1, 1997.

71-3508.04. Licensee; surety; long-term site surveillance and care; funds; disposition; powers and duties. (1) For licensed activities involving Source material milling, Source material mill tailings, and management of low-level radioactive waste, the department shall, and for other classes of licensed activities the department may, adopt and promulgate rules and regulations which establish standards and procedures to ensure that the licensee will provide an adequate surety or other financial arrangement to permit the completion of all requirements established by the department for the licensure, regulation, decontamination, closure, decommissioning, and reclamation of sites, structures, and equipment used in conjunction with such licensed activity in case the licensee should default for any reason in performing such requirements. All sureties required which are forfeited shall be paid to the department and remitted to the State Treasurer for credit to the Department of Health and Human Services Regulation and Licensure Cash Fund. Money in such fund remitted pursuant to this subsection shall be expended by the department as necessary to complete the closure and reclamation requirements and shall not be used for normal operating expenses of the department.

(2) For licensed activities involving the disposal of Source material mill tailings and management of low-level radioactive waste, the department shall, and for other classes of licensed activities when radioactive material which will require surveillance or care is likely to remain at the site after the licensed activities cease the department may, adopt and promulgate rules and regulations which establish standards and procedures to ensure that the licensee, before termination of the license, will make available such funding arrangements as may be necessary to provide for long-term site surveillance and care. All such funds collected from licensees shall be paid to the department and remitted to the State Treasurer for credit to the fund. All funds accrued as interest on money credited to the fund pursuant to this subsection may be expended by the department for the continuing long-term surveillance, maintenance, and other care of facilities from which such funds are collected as necessary for protection of the occupational and public health and safety and the environment. If title to and custody of any radioactive material and its disposal site are transferred to the United States upon termination of any license for which funds have been collected for such long-term care, the collected funds and interest accrued thereon shall be transferred to the United States.

(3) The sureties or other financial arrangements and funds required by this section shall be established in amounts sufficient to ensure compliance with standards, if any, established by the department pertaining to licensure, regulation, closure, decommissioning, reclamation, and long-term site surveillance and care of such facilities and sites.

(4) To provide for the proper care and surveillance of sites subject to subsection (2) of this section which are not subject to section 71-3508.01 or 71-3508.02, the state may acquire by gift or transfer from another governmental agency or private person any land and appurtenances necessary to fulfill the purposes of this section. Any such gift or transfer shall be subject to approval and acceptance by the Legislature.

(5) The department may by contract, agreement, lease, or license with any person, including another state agency, provide for the decontamination, closure, decommissioning, reclamation, surveillance, or other care of a site subject to this section as needed to carry out the purposes of this section.

(6) If a person licensed by any governmental agency other than the department desires to transfer a site to the state for the purpose of administering or providing long-term care, a lump-sum deposit shall be made to the department and remitted to the State Treasurer for credit to the Department of Health and Human Services Regulation and Licensure Cash Fund. The amount of such deposit shall be determined by the department taking into account the factors stated in subsections (1) and (2) of this section.

Source: Laws 1987, LB 390, §12; Laws 1991, LB 703, §37; Laws 1996, LB 1044, §655. Operative date January 1, 1997.

71-3509. Sources of radiation; agreements with federal agency; Governor; license; expiration. (1) The Governor, on behalf of this state, may enter into agreements with the federal Nuclear Regulatory Commission pursuant to the federal Atomic Energy Act of 1954, section 274b, as amended, providing for discontinuance of certain of such commission's licensing and related regulatory authority with respect to byproduct material, Source material, and special nuclear material and the assumption of regulatory authority for such materials by this state.

(2) The department may, upon discontinuance of certain of such commission's licensing and related regulatory authority with respect to byproduct material, Source material, and special nuclear material and the assumption of regulatory authority for such materials by the state, cause to be licensed by the department such materials over which the state has assumed licensing and related regulatory authority under the terms of the agreement authorized in subsection (1) of this section.

(3) Any person who, on the effective date of an agreement under subsection (1) of this section, possesses a license issued by the federal Nuclear Regulatory Commission for radioactive material subject to the agreement shall be deemed to possess a license like those issued under the Radiation Control Act. Such license shall expire either ninety days after receipt from the department of a notice of expiration of such license, or on the date of expiration specified in the federal Nuclear Regulatory Commission license, whichever is the earlier.

Source: Laws 1963, c. 406, §9, p. 1303; Laws 1975, LB 157, §9; Laws 1987, LB 390, §13.

71-3510. Federal government; other states; agreements; control of sources of radiation; department; powers. (1) The department may enter into an agreement or agreements with the federal Nuclear Regulatory Commission pursuant to the federal Atomic Energy Act of 1954, section 274i, as amended, other federal governmental agencies as authorized by law, other states, or interstate agencies whereby this state will perform on a cooperative basis with the federal Nuclear Regulatory Commission, other federal governmental agencies, other states, or interstate agencies inspections or other functions relating to control of Sources of radiation.

(2) The department may institute training programs for the purpose of qualifying personnel to carry out the Radiation Control Act and may make such personnel available for participation in any program or programs of the federal government, other states, or interstate agencies in furtherance of the purposes of such act.

Source: Laws 1963, c. 406, §10, p. 1304; Laws 1975, LB 157, §10; Laws 1987, LB 390, §14.

71-3511. Radiation; ordinance, resolution, or regulation; superseded; when. Any ordinance, resolution, or regulation, now or hereafter in effect, of the governing body of a municipality, county, or state agency relating to Sources of radiation that is inconsistent with the Radiation Control Act, amendments thereto, or rules and regulations adopted and promulgated pursuant to the act is superseded by the act.

Source: Laws 1963, c. 406, §11, p. 1304; Laws 1975, LB 157, §11; Laws 1984, LB 716, §4; Laws 1987, LB 390, §15.

71-3512. Repealed. Laws 1987, LB 390, §28.

71-3513. Rules and regulations; licensure; department; powers; duties; appeal. (1) In any proceeding for the issuance or modification of rules or regulations relating to control of Sources of radiation, the department shall provide an opportunity for public participation through written comments and a public hearing.

(2) In any proceeding for the denial of an application for a license or for the amendment, suspension, or revocation of a license, the department shall provide the applicant or licensee an opportunity for a hearing on the record.

(3) In any proceeding for licensing ores processed primarily for their Source material content and management of byproduct material and Source material mill tailings, or for licensing management of low-level radioactive waste, the department shall provide:

(a) An opportunity, after public notice, for written comments and a public hearing with a transcript;

(b) An opportunity for cross-examination; and

(c) A written determination of the action to be taken which is based upon findings included in the determination and upon evidence presented during the public comment period.

(4) In any proceeding for licensing ores processed primarily for their Source material content and disposal of byproduct material and Source material mill tailings, or for licensing management of low-level radioactive waste, the department shall prepare, for each licensed activity which has a significant impact on the occupational or public health and safety or the environment, a written analysis of the impact of such licensed activity. The analysis shall be available to the public before the commencement of the hearing and shall include:

(a) An assessment of the radiological and nonradiological impacts to the public health;

(b) An assessment of any impact on any waterway and ground water;

(c) Consideration of alternatives, including alternative sites and engineering methods, to the activities to be conducted; and

(d) Consideration of the long-term impacts, including decommissioning, decontamination, and reclamation of facilities and sites associated with the licensed activities and management of any radioactive materials which will remain on the site after such decommissioning, decontamination, and reclamation.

(5) The department shall prohibit any major construction with respect to any activity for which an environmental impact analysis is required by this section prior to completion of such analysis.

(6) Whenever the department finds that an emergency exists with respect to radiation requiring immediate action to protect occupational or public health and safety or the environment, the department may, without notice, hearing, or submission to the coordinator, issue a regulation or order reciting the existence of such emergency and requiring that such action be taken as is necessary to meet the emergency. Notwithstanding any provisions of the Radiation Control Act, such regulation or order shall be effective immediately. Any person to whom such regulation or order is directed shall comply immediately, but on application to the department shall be afforded a hearing not less than fifteen days and not more than thirty days after filing of the application. On the basis of such hearing, the emergency regulation or order shall be continued, modified, or revoked within thirty days after such hearing, and the department shall mail the applicant a copy of its findings of fact and determination.

(7) Any final department action or order entered pursuant to subsection (1), (2), (3), or (6) of this section may be appealed, and the appeal shall be in accordance with the Administrative Procedure Act.

Source: Laws 1963, c. 406, §13, p. 1305; Laws 1975, LB 157, §12; Laws 1987, LB 390, §16; Laws 1988, LB 352, §132.

71-3514. Violation of act; remedies. Whenever, in the judgment of the department, any person has engaged in or is about to engage in any acts or practices which constitute or will constitute a violation of any provision of the Radiation Control Act or any rule, regulation, or order issued pursuant to the act, the Attorney General or any county attorney may make application to the district court for an order enjoining such acts or practices or for an order directing compliance, and upon a showing by the department that such person has engaged or is about to engage in any such acts or practices, a permanent or temporary injunction, restraining order, or other order may be granted.

Source: Laws 1963, c. 406, §14, p. 1305; Laws 1987, LB 390, §17.

71-3515. Radiation; acts; registration or license required. It shall be unlawful for any person to use, manufacture, produce, distribute, sell, transport, transfer, install, repair, receive, acquire, own, or possess any Source of radiation unless registered with or licensed by the department as required by section 71-3505, 71-3507, or 71-3509.

Source: Laws 1963, c. 406, §15, p. 1306; Laws 1975, LB 157, §13; Laws 1978, LB 814, §7; Laws 1984, LB 716, §5; Laws 1987, LB 390, §18.

71-3515.01. Medical radiographer; limited radiographer; requirements; exception. (1) A person licensed as a medical radiographer by the department may practice medical radiography on any part of the human anatomy for interpretation by and under the direction of a licensed practitioner, excluding interpretative fluoroscopic procedures. Such person shall:

(a) Prior to issuance of a license as a medical radiographer, (i) complete an educational program in radiography incorporating the course material as provided in the rules and regulations of the department pursuant to subsection (1) of section 71-3515.02 and (ii) complete an application which includes such person's social security number and successfully complete an examination approved by the department on the course material. Presentation of proof of registration in radiography with the American Registry of Radiologic Technologists is proof of meeting the requirements of this subdivision (a) of this subsection; and

(b) Prior to renewal of licensure as a medical radiographer, have an average of twelve units of continuing education per year as approved by the department. Presentation of proof of current registration in radiography with the American Registry of Radiologic Technologists is proof of meeting the requirements of subdivisions (a) and (b) of this subsection.

(2) A person licensed as a limited radiographer by the department may practice medical radiography on limited regions of the human anatomy, using only routine radiographic procedures, for the interpretation by and under the direction of a licensed practitioner, excluding computed tomography, the use of contrast media, and the use of fluoroscopic or mammographic equipment. Such person shall:

(a) Prior to issuance of a license as a limited radiographer, complete an application which includes the applicant's social security number and successfully complete an examination approved by the department, as described in subdivision (2) (a) of section 71-3515.02 and at least one of the anatomical regions listed in subdivision (2) (b) of such section. The license issued shall be specific to the anatomical region or regions for which the applicant has passed an approved examination, except that an applicant may be licensed in the anatomical region of Abdomen upon successful passage of the examinations described in subdivisions (2) (a) and (2) (b) (iv) of section 71-3515.02 and upon a finding by the department that continued provision of service for a community would be in jeopardy; and

(b) Prior to renewal of licensure as a limited radiographer, have an average of twelve units of continuing education per year as approved by the department.

(3) The requirements of this section do not apply to a student while enrolled and participating in an educational program in medical radiography who, as a part of an educational program, applies X-rays to humans while under the supervision of the licensed practitioners or medical radiographers associated with the educational program. Students who have completed at least twelve months of the training course described in subsection (1) of section 71-3515.02 may apply for licensure as a temporary medical radiographer. Temporary medical radiographer licenses shall expire eighteen months after issuance and shall not be renewed. Persons licensed as temporary medical radiographers shall be permitted to perform the duties of a limited radiographer licensed in all anatomical regions of subdivision (2) (b) of such section and Abdomen.

Source: Laws 1987, LB 390, §23; Laws 1995, LB 406, §46; Laws 1997, LB 752, §181. Effective date September 13, 1997.

71-3515.02. Educational programs; testing; requirements; provisional licenses; fees. (1) The educational program for medical radiographers shall consist of twenty-four months of instruction in radiography approved by the department which includes, but is not limited to, radiographic procedures, imaging equipment, image production and evaluation, film processing, radiation physics, radiation protection, radiation biology, radiographic pathology, and quality assurance activities. The department shall recognize equivalent courses of instruction successfully completed by individuals who are applying for licensure as medical radiographers by the department when determining if the requirements of section 71-3515.01 have been met.

(2) The examination for limited radiographers shall include, but not be limited to:

(a) Radiation protection, equipment maintenance and operation, image production and evaluation, and patient care and management; and

(b) The anatomy of, and positioning for, specific regions of the human anatomy. The anatomical regions shall include at least one of the following:

- (i) Chest;
- (ii) Extremities;
- (iii) Skull and sinus;
- (iv) Spine; or
- (v) Ankle and foot.

(3) The department shall adopt and promulgate rules and regulations regarding the examinations required in subdivisions (1)(a)(ii) and (2)(a) of section 71-3515.01. Such rules and regulations shall provide for (a) the administration of examinations based upon national standards, such as the Examination in Radiography from the American Registry of Radiologic Technologists for medical radiographers, the Examination for the Limited Scope of Practice in Radiography from the American Registry of Radiologic Technologists for limited radiographers, or equivalent examinations that, as determined by the department, meet the standards for educational and psychological testing as recommended by the American Psychological Association, the American Educational Research Association, and the National Council on Measurement in Education, (b) procedures to be followed for examinations, (c) the method of grading and the passing grades for such examinations, (d) security protection for questions and answers, and (e) for medical radiographers, the contents of such examination based on the course requirements for medical radiographers prescribed in subsection (1) of this section. Any costs incurred in determining the extent to which examinations meet the examining standards of this subsection shall be paid by the individual or organization proposing the use of such examination.

(4) Any person employed in medical radiography before and on June 2, 1995, who is not otherwise licensed may apply for a license as a provisional limited radiographer before January 1, 1996. A person licensed as a provisional limited radiographer may perform the duties of a limited radiographer licensed in all anatomical regions listed in subdivision (2)(b) of this section and the anatomical region of Abdomen. A provisional limited radiographer shall not radiograph children under the age of six months, except (a) upon a finding by the department that continued provision of service for a community would be in jeopardy if this provision is enforced, (b) for an employee of a hospital licensed and in good standing under Chapter 71 and located in a rural area as defined in section 71-5653, or (c) in a bona fide emergency situation. No examination shall be required of individuals applying for a license as a provisional limited radiographer. All provisional limited radiographer licenses expire January 1, 2005. A license as a provisional limited radiographer is subject to discipline for violations of the Radiation Control Act and rules and regulations adopted pursuant to the act, including, but not limited to, revocation for nonpayment of fees or failure to meet continuing education requirements of subdivision (2)(b) of section 71-3515.01.

(5) No applicant for a license as a limited radiographer may take the examination for licensure, or for licensure for any specific anatomical region, more than three times without first waiting a period of one year after the last unsuccessful attempt of the examination and submitting proof to the department of completion of twelve units of continuing education meeting the requirements of subdivision (2)(b) of section 71-3515.01 for each subsequent attempt.

(6) The department shall adopt and promulgate rules and regulations establishing fees for the implementation of this section and section 71-3515.01, including an examination fee, initial and renewal licensure fees for persons performing medical radiography, and a fee for approval of courses of instruction. In determining such fees, the department shall obtain sufficient funds from the fees to pay the direct and indirect costs of administering such sections. No fee shall exceed the actual cost to the department for examination and licensure. The fees shall be collected and remitted by the department to the State Treasurer for credit to the Department of Health and Human Services Regulation and Licensure Cash Fund and shall be used solely for the purpose of defraying the direct and indirect costs of administering such sections.

Source: Laws 1987, LB 390, § 24; Laws 1990, LB 1064, § 21; Laws 1995, LB 406, § 47; Laws 1996, LB 1044, § 656; Laws 2000, LB 1115, § 74. Effective date April 14, 2000.

71-3516. Emergency; impounding sources of radiation; department. The department shall have the authority in the event of an emergency affecting occupational or public health and safety or the environment to impound or order the impounding of Sources of radiation in the possession of any person who is not equipped to observe or fails to observe the provisions of the Radiation Control Act or any rules or regulations issued pursuant to such act.

Source: Laws 1963, c. 406, §16, p. 1306; Laws 1975, LB 157, §14; Laws 1987, LB 390, §19.

71-3517. Violations; civil and criminal penalties; appeal. (1) Any person who violates any of the provisions of the Radiation Control Act shall be guilty of a Class IV misdemeanor.

(2) In addition to the penalty provided in subsection (1) of this section, any person who violates any provision of the Radiation Control Act or any rule, regulation, or order issued pursuant to such act or any term, condition, or limitation of any license or registration certificate issued pursuant to such act shall be subject to:

- (a) License revocation, suspension, modification, condition, or limitation;
- (b) The imposition of a civil penalty; or

(c) The terms of any appropriate order issued by the department.

(3) Whenever the department proposes to subject a person to the provisions of subsection (2) of this section, the department shall notify the person in writing (a) setting forth the date, facts, and nature of each act or omission with which the person is charged, (b) specifically identifying the particular provision or provisions of the section, rule, regulation, order, license, or registration certificate involved in the violation, (c) of the time, date, and place at which a full and fair hearing will be had on such charge, (d) that the department may revoke, suspend, modify, condition, or limit a license, impose a civil penalty, or enter an appropriate order, and (e) that upon failure to pay the civil penalty, if any, subsequently determined by the department, the penalty may be collected by civil action. The notice shall be delivered to each alleged violator not less than ten days before the time set for the hearing by personal service, by certified or registered mail to his or her last-known address, or by publication. Notice by publication shall only be made if personal service or service by mail cannot be effectuated.

(4) Hearings held pursuant to subsection (3) of this section shall be held in accordance with rules and regulations adopted and promulgated by the department and shall provide for the alleged violator to present such evidence as may be proper. Witnesses may be subpoenaed by either party and shall be allowed fees at a rate prescribed by the rules and regulations of the department. A full and complete record shall be kept of the proceedings.

(5) Following the hearing, the director shall determine whether the charges are true or not, and if true, the director may (a) issue a declaratory order finding the charges to be true, (b) revoke, suspend, modify, condition, or limit the license, (c) impose a civil penalty in an amount not to exceed ten thousand dollars for each violation, or (d) enter an appropriate order. If any violation is a continuing one, each day of such violation shall constitute a separate violation for the purpose of computing the applicable civil penalty and the amount of the penalty shall be based on the severity of the violation. A copy of such decision setting forth the finding of facts and the particular reasons upon which it is based shall be sent by either certified or registered mail to the alleged violator. The decision may be appealed, and the appeal shall be in accordance with the Administrative Procedure Act.

(6) Any civil penalty assessed and unpaid under subsection (5) of this section shall constitute a debt to the State of Nebraska which may be collected in the manner of a lien foreclosure or sued for and recovered in any proper form of action in the name of the State of Nebraska in the district court of the county in which the violator resides or owns property. The department shall, within thirty days from receipt, transmit any collected civil penalty to the State Treasurer for deposit in the permanent school fund.

Source: Laws 1963, c. 406, §17, p. 1306; Laws 1977, LB 39, §172; Laws 1987, LB 390, §20; Laws 1988, LB 352, §133.

71-3518. License or registration; common carrier exempt. Nothing in the Radiation Control Act shall be deemed to require the licensing or registration by any common carrier, contract carrier, private carrier, railway freight carrier, or railway express carrier transporting, storing, or handling any of the materials described in such act in the ordinary course of such carrier's business.

Source: Laws 1963, c. 406, §18, p. 1306; Laws 1987, LB 390, §21.

71-3519. Act, how cited. Sections 71-3501 to 71-3519 shall be known and may be cited as the Radiation Control Act.

Source: Laws 1963, c. 406, §20, p. 1306; Laws 1987, LB 390, §22.

71-3520. Act, how construed. Nothing in the Radiation Control Act shall be construed to allow the department to duplicate regulation by the federal government.

Source: Laws 1987, LB 390, §25.

TITLE 180
NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATION AND LICENSURE
CONTROL OF RADIATION/REGULATIONS

CHAPTER 1 - 19 REGULATIONS FOR "CONTROL OF RADIATION"

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TITLE 180
NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATION AND LICENSURE
CONTROL OF RADIATION/REGULATIONS

CHAPTER 1 – 19 REGULATIONS FOR “CONTROL OF RADIATION”

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<u>SECTIONS</u>		<u>EFFECTIVE DATES</u>
LICENSING		OCTOBER 1, 1966
REGISTRATION		JANUARY 1, 1967
REVISED	ALL SECTIONS	JANUARY 1, 1974
REVISED	SECTIONS A, B, C, D, E, G, AND J	AUGUST 22, 1982
REVISED	SECTIONS F, H, AND I	JUNE 27, 1983
REVISED	ALL SECTIONS	NOVEMBER 25, 1990
REVISED	SECTION 011	OCTOBER 27, 1993
REVISED	SECTIONS 001, 003, 004, 005, 006 (Pages 6-1, 6-2, 6-17 through 6-28, 6-41, 6-42, 6-53, 6-54, 6-73 and 6-74), SECTIONS 007, 008, 009, 010, 012, 014 AND 017	MAY 30, 1994
REVISED	SECTIONS 017 AND 018	JUNE 13, 1995
REVISED	Subsection 004.21 (Pages 4-18, 4-19, and 4-20) Subsection 015.26 (Pages 15-1, 15- 2, 15-31, and 15-32)	OCTOBER 30, 1996
ADDED	SECTION 019	OCTOBER 30, 1996
REVISED	SECTIONS 001, 003, 004, 007, 009, 012, 015 FORMS NRH-3, NRH-5, NRH-5 (Medical/Teletherapy), NRH-5 (Medical/Teletherapy) Supplement A, NRH-5 (Medical/Teletherapy) Supplement B, NRH-9, NRH-11, NRH-17	SEPTEMBER 17, 1997
ADDED	FORM NRH-5 (Medical/Teletherapy) Supplement C, NRH-60	SEPTEMBER 17, 1997
DELETED	FORMS NRH-5 (Teletherapy) Supplement A, NRH-5 (Teletherapy) Supplement B	SEPTEMBER 17, 1997
REVISED	SECTIONS 004, 010, 012, AND 013 SECTION 004 (Appendix 004-C and 004-D) SECTION 013 (Table A-1 and A-2)	DECEMBER 15, 1998
ADDED	SECTION 004 (FORMS 540, 540A, 541, 541A, 542 and 542A)	

REVISED	SECTIONS 001, 002, 003, 004, 005, 006, 007, 008, 009, 010, 011, 012, 013, 014, 015, 017, 018, 019 FORMS NRH-3, NRH-5, NRH-5A (Teletherapy) and supplements A through C, NRH-9, NRH-11, NRH-17, and NRH-60.	May 27, 2000
REVISED	ALL SECTIONS 001 -019 became CHAPTERS 1-19	July 22, 2001

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TITLE 180 CONTROL OF RADIATION

CHAPTER 1 GENERAL PROVISIONS

1-001 SCOPE AND AUTHORITY: Except as otherwise specifically provided, Title 180 applies to all persons who receive, possess, use, transfer, own, or acquire: (1) any radiation generating equipment; (2) any naturally occurring or accelerator produced radioactive material; and (3) any radioactive: (a) source material; (b) byproduct material; and, (c) special nuclear material; in quantities not sufficient to form a critical mass. The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Rev. Stat. sections 71-3501 - 71-3519.

1-002 DEFINITIONS: As used in Title 180 , these terms have the definitions set forth below. Additional definitions used only in certain Title 180 Chapters will be found in that Chapter.

A₁ means the maximum activity of special form radioactive material permitted in a Type A package. A₂ 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 Appendix A of 180 NAC 13, Table A-1, or may be derived in accordance with the procedure prescribed in Appendix A of 180 NAC 013.

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

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

Act means Radiation Control Act. Sections 71-3501 to 71-3519, Reissue Revised Statutes of Nebraska, 1943. As amended.

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 Department of Health and Human Services Regulation and Licensure.

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 subsection 274b. 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, particulates, mists, vapors, or gases.

Airborne radioactivity area means a room, enclosure, or area in which airborne radioactive materials exist in concentrations

- (1) In excess of the derived air concentrations (DACs) specified in Appendix B, Table I of 180 NAC 4, or
- (2) 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 percent of the annual limit on intake (ALI) or 12 DAC-hours.

As low as is reasonably achievable (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these regulations 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 nuclear energy and licensed or registered sources of radiation in the public interest.

Background radiation means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and 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. 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 1 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 Title 180, 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 utilizing special nuclear material; and
2. The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground

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ore bodies depleted by solution extraction operations do not constitute byproduct 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 their method for determining calendar quarters except 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, hydroxycarboxylic acids, gluconic acid, and polycarboxylic acids.

Civil penalty means any monetary penalty levied on a licensee or registrant because of violations of statutes, rules, regulations, licenses, or registration certificates, but does not include criminal penalties.

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.

Committed dose equivalent (CDE) ($H_{T,50}$) 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 (CEDE) ($H_{E,50}$) is 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 ($H_{E,50} = \sum w_T H_{T,50}$).

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 radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of $3.7E+10$ disintegrations or transformations per second (dps or tps).

Custodial care means the continued observation, monitoring, and care of a management facility for a minimum of one hundred years following transfer of ownership of the management facility from the operator to the Agency.

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

Decommissioning means final operational activities at a facility to dismantle site structures, to decontaminate site surfaces and remaining structures, to stabilize and contain residual radioactive material, and to carry out any other activities to prepare the site for postoperational care.

Deep dose equivalent (DDE) (H_d), which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm^2).

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

Director means Director of Regulation and Licensure.

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 180 NAC, radiation dose is an equivalent term.

Dose equivalent (H_i) 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 these regulations. For purposes of these regulations, limits is an equivalent term.

Effective dose equivalent (EDE) (H_E) means the sum of the products of the dose equivalent to each organ or tissue (H_T) and the weighting factor (w_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \sum w_T H_T$).

Electronic product means any manufactured product, device, assembly, or assemblies of such products or devices which, during operation in an electronic circuit, can generate or emit a physical field of radiation.

Embryo/fetus means the developing human organism from conception until the time of birth.

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

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

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E (Exponent) indicates that the number 10 is to be raised to a given power. This power is indicated to the right of the symbol E. For example: 3E+4 symbolizes 3×10^4 and 3E-4 symbolizes 3×10^{-4} .

Exposure means being exposed to ionizing radiation or to radioactive material.

Exposure¹ 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 SI unit of exposure is the coulomb per kilogram (C/kg). See 180 NAC 1-015.01 Units of Exposure and Dose for the special unit .

Exposure rate means the exposure per unit of time, such as roentgen per minute (R/min) or milliroentgen per hour (mR/h).

External dose means that portion of the dose equivalent received from any source of radiation outside the body.

Extremity means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

Eye dose equivalent (LDE) means the external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeter (300 mg/cm^2).

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.

Generally applicable environmental radiation standards means standards issued by the U.S. Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

Gray (Gy) means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).

Hazardous waste means those wastes designated as hazardous in 40 CFR Chapter I, Part 261, Subpart A, Sections 261.2 - 261.4 and Subpart D, attached hereto as Attachment Number 1-1 and incorporated herein by this reference.

Healing arts means diagnostic and/or healing treatment of human and animal maladies including but not limited to the following which are duly licensed by the State of Nebraska for the lawful practice of: medicine and its associated specialties, dentistry, veterinary medicine, osteopathy, chiropractic, and podiatry.

High-level radioactive waste means:

¹When not underlined as above [or indicated as "exposure" (X)] the term "exposure" has a more general meaning in Title 180.

1. Irradiated reactor fuel;
2. Liquid wastes resulting from the operation of the first cycle solvent extraction system or equivalent and the concentrated wastes from subsequent extraction cycles or the equivalent in a facility for reprocessing irradiated reactor fuel; and
3. Solids into which such liquid wastes have been converted.
4. Other highly radioactive waste material as defined by the U.S. Nuclear Regulatory Commission.

High radiation area means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from any source of radiation or from any surface that the radiation penetrates.

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

Individual means any human being. Individual monitoring means the assessment of:

1. Dose equivalent (a) by the use of individual monitoring devices or (b) by the use of survey data; or
2. Committed effective dose equivalent (a) by bioassay or (b) by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours. [See the definition of DAC-hours in 180 NAC 4].

Individual monitoring devices means devices designed to be worn by a single individual for the assessment of dose equivalent. For the purposes of these regulations, personnel dosimeter and dosimeter are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, and personal air sampling devices.

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 Agency. The licensee or registrant is notified of any items of noncompliance and/or recommendation of the Agency.

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.

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

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

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Licensed material means radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by the Agency.

Licensed practitioner means a person licensed to practice medicine, dentistry, podiatry, chiropractic, osteopathic medicine and surgery, or as an osteopathic physician.

Licensee means any person who is licensed by the Agency in accordance with these regulations and the Act.

Limits [See Dose limits]

Lost or missing source of radiation means source of radiation whose location is unknown. This definition includes licensed material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

Low-level radioactive waste means radioactive waste not defined as high-level radioactive waste, spent nuclear fuel, or byproduct material as defined in 180 NAC 1-002 byproduct material item 2.

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 180 NAC 13-002, items 14 and 15 and in 10 CFR Chapter I, Part 71, Subpart A, Section 71.4 attached hereto as part of Attachment Number 1-2 and incorporated herein by this reference.

Management facility means the land, buildings, and equipment which is intended to be used for the management of radioactive wastes.

Management of low-level radioactive waste means the handling, processing, storage, reduction in volume, disposal, or isolation of such waste from the biosphere in any manner, except the commercial disposal of low-level radioactive waste in a disposal facility, designated by the Central Interstate Low-Level Radioactive Waste Compact Commission.

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

Minor means an individual less than 18 years of age.

Mixed waste means low-level radioactive waste that also contains hazardous waste that is identified in Title 128, Nebraska Administrative Code.

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 the purposes of Title 180 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.

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Natural radioactivity means radioactivity of naturally occurring nuclides.

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 involve exposure to sources of radiation from licensed or unlicensed sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 180 NAC 7-030, from voluntary participation in medical research programs, or as a member of the public.

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

Particle accelerator [See "Accelerator"]

Person means any individual, corporation, partnership, limited liability company, 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 [See Individual monitoring devices].

Pharmacist means an individual licensed by this State to compound and dispense drugs, prescriptions, and poisons.

Physician means an individual licensed by this State to dispense drugs in the practice of medicine.

Public dose means the dose received by a member of the public from exposure to sources of radiation released by a licensee or registrant, or to any other source of radiation under the control of a licensee or registrant. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 180 NAC 7-030, or from voluntary participation in medical research programs.

Pyrophoric liquid means any liquid that ignites spontaneously in dry or moist air at or below 130°F (54.4 °C). A pyrophoric solid is any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

Quality factor (Q) means the modifying factor, listed in Tables I and II of 180 NAC 1-015, that is used to derive dose equivalent from absorbed dose.

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Rad means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 gray).

Radiation means ionizing and nonionizing radiation as follows: (a) ionizing radiation means gamma rays, x-rays, alpha and beta particles, high-speed electrons, neutrons, protons, and other atomic or nuclear particles or rays, but shall not include sound or radiowaves or visible, infrared, or ultraviolet light; and (b) nonionizing radiation means (i) any electromagnetic radiation which can be generated during the operations of electronic products to such energy density levels as to present a biological hazard to occupational and public health and safety and the environment, other than ionizing electromagnetic radiation, and (ii) any sonic, ultrasonic, or infrasonic waves which are emitted from an electronic product as a result of the operation of an electronic circuit in such product and to such energy density levels as to present a biological hazard to occupational and public health and safety, and the environment.

Radiation area means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

Radiation Dose [See "Dose"]

Radiation generating equipment means any manufactured product or device, component part of such a product or device, or machine or system which during operation can generate or emit radiation except devices which emit radiation only from radioactive material.

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

Radioactive material means any material whether solid, liquid, or gas, which emits ionizing radiation spontaneously. Radioactive material includes, but is not limited to, accelerator-produced material, byproduct material, naturally occurring material, source material, and special nuclear material.

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

Radiobioassay. [See "Bioassay"]

Registrant means any person who is registered with the Agency and is legally obligated to register with the Agency pursuant to Title 180 and the Act.

Registration means registration with the Agency pursuant to the Act and in accordance with the regulations adopted by the Agency.

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

Rem means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 Sv).

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.

Residual radioactivity means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of 180 NAC 4.

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

Roentgen means the special unit of exposure. One roentgen (R) equals $2.58E-4$ coulombs per kilogram of air (see "Exposure" and 180 NAC 1-015).

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.

Shallow dose equivalent (SDE) (H_s), which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter ($7mg/cm^2$) averaged over an area of 1 square centimeter.

SI means the abbreviation for the International System of Units.

Sievert means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

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 1 percent (0.05 percent) or more of uranium, thorium or any combination of uranium and thorium. Source material does not include special nuclear material.

Source material milling means any processing of ore, including underground solution extraction of unmined ore, primarily for the purpose of extracting or concentrating uranium or thorium there from and which results in the production of source material mill tailings.

Sources of radiation means any radioactive material, any radiation-generating equipment or any device or equipment emitting or capable of emitting radiation or radioactive material.

Special form radioactive material means radioactive material that satisfies the following conditions:

- (1) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;
- (2) The piece or capsule has at least one dimension not less than 5 millimeters (0.2 inch); and
- (3) It satisfies the test requirements specified by the U.S. Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the U.S. Nuclear Regulatory Commission requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation either designed or constructed after June 30, 1985, must meet requirements of this definition applicable at the time of its design or construction.

Special nuclear material means:

- (1) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the U.S. Nuclear Regulatory Commission, pursuant to the provisions of section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or
- (2) Any material artificially enriched by any material listed in part (1) of this definition, but does not include source material.

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; uranium-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. For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{175(\text{grams contained U - 235})}{350} + \frac{50(\text{grams U - 233})}{200} + \frac{50(\text{grams Pu})}{200} = 1$$

Spent nuclear fuel means irradiated nuclear fuel that has undergone at least one year of decay since being used as a source of energy in a power reactor. Spent nuclear fuel includes the special nuclear material, byproduct material, source material, and other radioactive material associated with fuel assemblies.

Survey means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive material present.

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Test means the process of verifying compliance with an applicable regulation.

These regulations mean all Chapters of Title 180 "Control of Radiation".

Total effective dose equivalent (TEDE) means the sum of the deep-dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

Total organ dose equivalent (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in 180 NAC 4-050.01, item 1.

Transuranic waste means radioactive waste containing alpha-emitting transuranic elements, with radioactive half-lives greater than five years, in excess of one hundred nanocuries per gram.

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, 42 U.S.C. 5814, 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.)

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

Unrestricted area means an area, access to which is neither limited nor controlled by the licensee or registrant. For purposes of these regulations, uncontrolled area is an equivalent term.

Violation means an infringement of any rule, license or registration condition, order of the Agency, or any provision of the Act.

Waste means those low-level radioactive wastes that are acceptable for disposal in a management facility. For the purposes of this definition, low-level waste has the same meaning as in the Low-Level Radioactive Waste Policy Act, P.L. 96-573, as amended by P.L. 99-240, effective January 15, 1986; that is, radioactive waste (a) not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in Section 11e.(2) of the Atomic Energy Act (uranium or thorium tailings and waste) and (b) classified as low-level radioactive waste consistent with existing law and in accordance with (a) by the U.S. Nuclear Regulatory Commission.

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

Week means 7 consecutive days starting on Sunday.

Whole body means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

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Worker means an individual engaged in work under a license or registration issued by the Agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

Working level (WL) means any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of $1.3E+5$ MeV of potential alpha particle energy. The short-lived radon daughters are – for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.

Working level month (WLM) means an exposure to 1 working level for 170 hours – 2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

Year means the period of time beginning in January used to determine compliance with the provisions of Title 180. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

1-003 EXEMPTIONS

1-003.01 General Provision: The Agency may, upon application or upon its own initiative, grant such exemptions or exceptions from the requirements of Chapter of NAC 180 as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

1-003.02 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 this State is exempt from these regulations 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 and the U.S. Nuclear Regulatory Commission jointly determine:

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- 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.

1-004 RECORDS: 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 Title 180.

1-005 INSPECTIONS

1-005.01 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.

1-005.02 Each licensee and registrant shall make available to the Agency for inspection, upon reasonable notice, records maintained pursuant to Title 180.

1-006 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:

1. Sources of radiation;
2. Facilities wherein sources of radiation are used or stored;
3. Radiation detection and monitoring instruments; and
4. Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

1-007 ADDITIONAL REQUIREMENTS: The Agency may, by rule, regulation, or order, impose upon any licensee or registrant such requirements in addition to those established in these regulations as it deems appropriate or necessary to minimize danger to public health and safety or property.

1-008 VIOLATIONS: An injunction or other court order may be obtained prohibiting any violation of any provision of the Act. Any person who violates any provision of the Act may be guilty of a Class IV misdemeanor and, upon conviction, may be punished as determined by the court. (See 180 NAC 17.)

1-009 IMPOUNDING: Sources of radiation shall be subject to impounding pursuant to Section 71-3516 of the Act.

1-010 PROHIBITED USES

1. 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.

2. A shoe-fitting fluoroscopic device shall not be used.

TESTING FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES

1-011 TESTS FOR LEAKAGE AND/OR CONTAMINATION OF SEALED SOURCES

1-011.01 The licensee or registrant in possession of any sealed source shall assure that:

1. Each sealed source, except as specified in 180 NAC 1-011.02, is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee or registrant has a certificate from the transferor indicating that the sealed source was tested within 6 months before transfer to the licensee or registrant.
2. Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 6 months or at alternative intervals approved by the Agency, after evaluation of information specified by 180 NAC 3-014.12, item 4 and 5 of these regulations, or by an Agreement State, or the U.S. Nuclear Regulatory Commission.
3. Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 3 months or at alternative intervals approved by the Agency, after evaluation of information specified by 180 NAC 3-014.12, item 4 and 5, or by an Agreement State or the U.S. Nuclear Regulatory Commission.
4. For each sealed source that is required to be tested for leakage or contamination, at any other time there is reason to suspect that the sealed source might have been damaged or might be leaking, the licensee or registrant shall assure that the sealed source is tested for leakage or contamination before further use.
5. Tests for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium, shall be capable of detecting the presence of 185 Bq (0.005 μ Ci) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which one might expect contamination to accumulate. For a sealed source contained in a device, test samples are obtained when the source is in the "off" position.
6. The test for leakage for brachytherapy sources manufactured to contain radium shall be capable of detecting an absolute leakage rate of 37 Bq (0.001 μ Ci) of radon-222 in a 24 hour period when the collection efficiency for radon-222 and its daughters has been determined with respect to collection method, volume and time.
7. Tests for contamination from radium daughters shall be taken on the interior surface of brachytherapy source storage containers and shall be capable of detecting the presence of 185 Bq (0.005 μ Ci) of a radium daughter which has a half-life greater than 4 days.

1-011.02 A licensee or registrant need not perform test for leakage or contamination on the following sealed sources:

1. Sealed sources containing only radioactive material with a half-life of less than 30 days;
2. Sealed sources containing only radioactive material as a gas;
3. Sealed sources containing 3.7 MBq (100 μ Ci) or less of beta or photon-emitting material or 370 kBq (10 μ Ci) or less of alpha-emitting material;
4. Sealed sources containing only hydrogen-3;
5. Seeds of iridium-192 encased in nylon ribbon; and
6. Sealed sources, except teletherapy and brachytherapy sources, which are stored, not being used and identified as in storage. The licensee or registrant shall, however, test each such sealed source for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within 6 months before the date of use or transfer.

1-011.03 Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the Agency, an Agreement State, or the U.S. Nuclear Regulatory Commission to perform such services.

1-011.04 Test results shall be kept in units of Becquerel or microcurie and maintained for inspection by the Agency.

1-011.05 The following shall be considered evidence that the sealed source is leaking:

1. The presence of 185 Bq (0.005 μ Ci) or more of removable contamination on any test sample.
2. sources manufactured to contain radium.
3. The presence of removable contamination resulting from the decay of 185 Bq (0.005 μ Ci) or more of radium.

1-011.06 The licensee or registrant shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with 180 NAC 1.

1-011.07 Reports of test results for leaking or contaminated sealed sources shall be made pursuant to 180 NAC 4-062.

1-012 COMMUNICATIONS: All communications and reports concerning Title 180, and applications filed thereunder, should be addressed to the Agency at its office located at

Department of Health and Human Services Regulation and Licensure
Public Health Assurance Division
301 Centennial Mall South
P.O. Box 95007
Lincoln, Nebraska 68509-5007

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1-013 RESERVED

1-014 DISCRIMINATION PROHIBITED: No person shall on the ground of sex be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity licensed by this Agency. This provision will be enforced through provisions established, with respect to racial and other discrimination, under the Nebraska Fair Employment Act. This remedy is not exclusive, however, and will not prejudice or cut off any other legal remedies available to a discriminatee.

1-015 UNITS OF EXPOSURE AND DOSE

1-015.01 As used in Title 180, the unit of exposure is the coulomb per kilogram (C/kg) of air. One roentgen is equal to 2.58E-4 coulomb per kilogram of air.

1-015.02 As used in 180 NAC, the units of dose are:

1. Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).
2. Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 Gy).
3. Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 Sv).
4. Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

1-015.03 As used in Title 180, the quality factors for converting absorbed dose to dose equivalent are shown in Table I.

TABLE I
QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

TYPE OF RADIATION	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent ^a
X, gamma, or beta radiation and high-energy electrons	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

^aAbsorbed dose in gray equal to 1 Sv or the absorbed dose in rad equal to 1 rem.

1-015.04 If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in rems per hour or sieverts per hour, as provided in 001.15C, 0.01 Sv (1 rem) of neutron radiation of unknown energies may, for purposes of these regulations, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from Table II to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem.

TABLE II

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

	Neutron Energy (MeV)	Quality Factor ^a (Q)	Fluence per Unit Dose Equivalent ^b (neutrons cm ⁻² rem ⁻¹)	Fluence per Unit Dose Equivalent ^b (neutrons cm ⁻² sievert ⁻¹)
(thermal)	2.5E-8	2	980E+6	980E+8
	1E-7	2	980E+6	980E+8
	1E-6	2	810E+6	810E+8
	1E-5	2	810E+6	810E+8
	1E-4	2	840E+6	840E+8
	1E-3	2	980E+6	980E+8
	1E-2	2.5	1010E+6	1010E+8
	1E-1	7.5	170E+6	170E+8
	5E-1	11	39E+6	39E+8
	1	11	27E+6	27E+8
	2.5	9	29E+6	29E+8
	5	8	23E+6	23E+8
	7	7	24E+6	24E+8
	10	6.5	24E+6	24E+8
	14	7.5	17E+6	17E+8
	20	8	16E+6	16E+8
	40	7	14E+6	14E+8
	60	5.5	16E+6	16E+8
	1E+2	4	20E+6	20E+8
	2E+2	3.5	19E+6	19E+8
	3E+2	3.5	16E+6	16E+8
	4E+2	3.5	14E+6	14E+8

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

^bMonoenergetic neutrons incident normally on a 30-centimeter diameter cylinder tissue-equivalent phantom.

1-016 UNITS OF ACTIVITY: For the purposes of these regulations, 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.

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

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2. One curie = $3.7E+10$ disintegrations or transformations per second (dps or tps) = $3.7E+10$ becquerel (Bq) = $2.22E+12$ disintegrations or transformations per minute (dpm or tpm).

ATTACHMENT 1-1

40 CFR Chapter I, Part 261, Subpart A, Sections 261.2 - 261.4 and Subpart D

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PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

Subpart A—General

- Sec.
- ~~261.1 Purpose and scope.~~
- 261.2 Definition of solid waste.
- 261.3 Definition of hazardous waste.
- 261.4 Exclusions.
- ~~261.5 Special requirements for hazardous waste generated by conditionally exempt small quantity generators.~~
- 261.6 Requirements for recyclable materials.
- 261.7 Residues of hazardous waste in empty containers.

Subpart B—Criteria for Identifying the Characteristics of Hazardous Waste and for Listing Hazardous Wastes

- 261.10 Criteria for identifying the characteristics of hazardous waste.
- 261.11 Criteria for listing hazardous waste.

Subpart C—Characteristics of Hazardous Waste

- 261.20 General.
- 261.21 Characteristic of ignitability.
- 261.22 Characteristic of corrosivity.
- 261.23 Characteristic of reactivity.
- ~~261.24 Characteristic of EP toxicity.~~

Subpart D—Lists of Hazardous Wastes

- 261.30 General.
- 261.31 Hazardous wastes from non-specific sources.
- 261.32 Hazardous wastes from specific sources.
- 261.33 Discarded commercial chemical products, off-specification species, container residues, and spill residues thereof.

APPENDICES

- ~~APPENDIX I—REPRESENTATIVE SAMPLING METHODS~~
- ~~APPENDIX II—EP TOXICITY TEST PROCEDURES~~
- ~~APPENDIX III—CHEMICAL ANALYSIS TEST METHODS~~
- ~~APPENDIX IV—(RESERVED FOR RADIOACTIVE WASTE TEST METHODS)~~
- ~~APPENDIX V—(RESERVED FOR INFECTIOUS WASTE TREATMENT SPECIFICATIONS)~~
- ~~APPENDIX VI—(RESERVED FOR ETIOLOGIC AGENTS)~~
- ~~APPENDIX VII—BASIS FOR LISTING HAZARDOUS WASTE~~
- ~~APPENDIX VIII—HAZARDOUS CONSTITUENTS~~
- ~~APPENDIX IX—WASTES EXCLUDED UNDER §§ 260.30 AND 260.22~~

APPENDIX X—METHOD OF ANALYSIS FOR CHLORINATED DIBENZO-P-DIOXINS AND DIBENZOFURANS

AUTHORITY: 42 U.S.C. 6905, 6912(a), 6921, 6922, and 6938.

SOURCE: 45 FR 33119, May 19, 1980, unless otherwise noted.

Subpart A—General

~~§ 261.1 Purpose and scope.~~

(a) This part identifies those solid wastes which are subject to regulation as hazardous wastes under Parts 262 through 265, 268, and Parts 270, 271, and 274 of this chapter and which are subject to the notification requirements of section 3010 of RCRA. In this part:

(1) Subpart A defines the terms "solid waste" and "hazardous waste", identifies those wastes which are excluded from regulation under Parts 262 through 266, 268 and 270 and establishes special management requirements for hazardous waste produced by conditionally exempt small quantity generators and hazardous waste which is recycled.

(2) Subpart B sets forth the criteria used by EPA to identify characteristics of hazardous waste and to list particular hazardous wastes.

(3) Subpart C identifies characteristics of hazardous waste.

(4) Subpart D lists particular hazardous wastes.

(b)(1) The definition of solid waste contained in this part applies only to wastes that also are hazardous for purposes of the regulations implementing Subtitle C of RCRA. For example, it does not apply to materials (such as non-hazardous scrap, paper, textiles, or rubber) that are not otherwise hazardous wastes and that are recycled.

(2) This part identifies only some of the materials which are solid wastes and hazardous wastes under sections 3007, 3013, and 7003 of RCRA. A material which is not defined as a solid waste in this part, or is not a hazardous waste identified or listed in this part, is still a solid waste and a hazardous waste for purposes of these sections if:

(i) In the case of sections 3007 and 3013, EPA has reason to believe that

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the material may be a solid waste within the meaning of section 1004(27) of RCRA and a hazardous waste within the meaning of section 1004(5) of RCRA; or

(ii) In the case of section 7003, the statutory elements are established.

(c) For the purposes of §§ 261.2 and 261.6:

(1) A "spent material" is any material that has been used and as a result of contamination can no longer serve the purpose for which it was produced without processing;

(2) "Sludge" has the same meaning used in § 260.10 of this chapter;

(3) A "by-product" is a material that is not one of the primary products of a production process and is not solely or separately produced by the production process. Examples are process residues such as slags or distillation column bottoms. The term does not include a co-product that is produced for the general public's use and is ordinarily used in the form it is produced by the process.

(4) A material is "reclaimed" if it is processed to recover a usable product, or if it is regenerated. Examples are recovery of lead values from spent batteries and regeneration of spent solvents.

(5) A material is "used or reused" if it is either:

(i) Employed as an ingredient (including use as an intermediate) in an industrial process to make a product (for example, distillation bottoms from one process used as feedstock in another process). However, a material will not satisfy this condition if distinct components of the material are recovered as separate end products (as when metals are recovered from metal-containing secondary materials); or

(ii) Employed in a particular function or application as an effective substitute for a commercial product (for example, spent pickle liquor used as phosphorous precipitant and sludge conditioner in wastewater treatment).

(6) "Scrap metal" is bits and pieces of metal parts (e.g., bars, turnings, rods, sheets, wire) or metal pieces that may be combined together with bolts or soldering (e.g., radiators, scrap automobiles, railroad box cars), which

when worn or superfluous can be recycled.

(7) A material is "recycled" if it is used, reused, or reclaimed.

(8) A material is "accumulated speculatively" if it is accumulated before being recycled. A material is not accumulated speculatively, however, if the person accumulating it can show that the material is potentially recyclable and has a feasible means of being recycled; and that during the calendar year (commencing on January 1)—the amount of material that is recycled, or transferred to a different site for recycling, equals at least 75 percent by weight or volume of the amount of that material accumulated at the beginning of the period. In calculating the percentage of turnover, the 75 percent requirement is to be applied to each material of the same type (e.g., slags from a single smelting process) that is recycled in the same way (i.e., from which the same material is recovered or that is used in the same way). Materials accumulating in units that would be exempt from regulation under § 261.4(c) are not to be included in making the calculation. (Materials that are already defined as solid wastes also are not to be included in making the calculation.) Materials are no longer in this category once they are removed from accumulation for recycling, however.

(45 FR 33119, May 19, 1980, as amended at 45 FR 14293, Apr. 1, 1983; 50 FR 643, Jan. 4, 1985; 51 FR 10174, Mar. 24, 1986; 51 FR 40424, Nov. 7, 1986)

§ 261.2 Definition of solid waste.

(a)(1) A solid waste is any discarded material that is not excluded by § 261.4(a) or that is not excluded by variance granted under §§ 260.30 and 260.31.

(2) A discarded material is any material which is:

(i) Abandoned, as explained in paragraph (b) of this section; or

(ii) Recycled, as explained in paragraph (c) of this section; or

(iii) Considered inherently waste-like, as explained in paragraph (d) of this section.

(b) Materials are solid waste if they are abandoned by being:

- (1) Disposed of; or
- (2) Burned or incinerated; or
- (3) Accumulated, stored, or treated (but not recycled) before or in lieu of being abandoned by being disposed of, burned, or incinerated.

(c) Materials are solid wastes if they are recycled—or accumulated, stored, or treated before recycling—as specified in paragraphs (c)(1) through (4) of this section.

(1) *Used in a manner constituting disposal.* (i) Materials noted with a "*" in Column 1 of Table I are solid wastes when they are:

(A) Applied to or placed on the land in a manner that constitutes disposal; or

(B) Used to produce products that are applied to or placed on the land or are otherwise contained in products that are applied to or placed on the land (in which cases the product itself remains a solid waste).

(ii) However, commercial chemical products listed in § 261.33 are not solid wastes if they are applied to the land and that is their ordinary manner of use.

(2) *Burning for energy recovery.* (i) Materials noted with a "*" in column 2 of Table I are solid wastes when they are:

(A) Burned to recover energy;
(B) Used to produce a fuel or are otherwise contained in fuels (in which cases the fuel itself remains a solid waste).

(ii) However, commercial chemical products listed in § 261.33 are not solid wastes if they are themselves fuels.

(3) *Reclaimed.* Materials noted with a "*" in column 3 of Table I are solid wastes when reclaimed.

(4) *Accumulated speculatively.* Materials noted with a "*" in column 4 of Table I are solid wastes when accumulated speculatively.

TABLE I

	Use constituting disposal (§ 261.2(c)(1))	Energy recovery/fuel (§ 261.2(c)(2))	Reclamation (§ 261.2(c)(3))	Speculative accumulation (§ 261.2(c)(4))
	(1)	(2)	(3)	(4)
Spent Materials.....	(*)	(*)	(*)	(*)
Sludges (listed in 40 CFR Part 261.31 or 261.32).....	(*)	(*)	(*)	(*)
Sludges exhibiting a characteristic of hazardous waste.....	(*)	(*)	(*)	(*)
By-products (listed in 40 CFR Part 261.31 or 261.32).....	(*)	(*)	(*)	(*)
By-products exhibiting a characteristic of hazardous waste.....	(*)	(*)	(*)	(*)
Commercial chemical products listed in 40 CFR 261.33.....	(*)	(*)	(*)	(*)
Scrap metal.....	(*)	(*)	(*)	(*)

Note: The terms "spent materials", "sludges", "by-products," and "scrap metal" are defined in § 261.1.

(d) *Inherently waste-like materials.* The following materials are solid wastes when they are recycled in any manner:

(1) Hazardous Waste Nos. F020, F021 (unless used as an ingredient to make a product at the site of generation), F022, F023, F026, and F028.

(2) The Administrator will use the following criteria to add wastes to that list:

(i)(A) The materials are ordinarily disposed of, burned, or incinerated; or

(B) The materials contain toxic constituents listed in Appendix VIII of Part 261 and these constituents are not ordinarily found in raw materials or products for which the materials

substitute (or are found in raw materials or products in smaller concentrations) and are not used or reused during the recycling process; and

(ii) The material may pose a substantial hazard to human health and the environment when recycled.

(e) *Materials that are not solid waste when recycled.* (1) Materials are not solid wastes when they can be shown to be recycled by being:

(i) Used or reused as ingredients in an industrial process to make a product, provided the materials are not being reclaimed; or

(ii) Used or reused as effective substitutes for commercial products; or

(iii) Returned to the original process from which they are generated, without first being reclaimed. The material must be returned as a substitute for raw material feedstock, and the process must use raw materials as principal feedstocks.

(2) The following materials are solid wastes, even if the recycling involves use, reuse, or return to the original process (described in paragraphs (e)(1) (i) through (iii) of this section):

(i) Materials used in a manner constituting disposal, or used to produce products that are applied to the land; or

(ii) Materials burned for energy recovery, used to produce a fuel, or contained in fuels; or

(iii) Materials accumulated speculatively; or

(iv) Materials listed in paragraph (d)(1) of this section.

(f) *Documentation of claims that materials are not solid wastes or are conditionally exempt from regulation.* Respondents in actions to enforce regulations implementing Subtitle C of RCRA who raise a claim that a certain material is not a solid waste, or is conditionally exempt from regulation, must demonstrate that there is a known market or disposition for the material, and that they meet the terms of the exclusion or exemption. In doing so, they must provide appropriate documentation (such as contracts showing that a second person uses the material as an ingredient in a production process) to demonstrate that the material is not a waste, or is exempt from regulation. In addition, owners or operators of facilities claiming that they actually are recycling materials must show that they have the necessary equipment to do so.

[50 FR 664, Jan. 4, 1985, as amended at 50 FR 33642, Aug. 20, 1985]

§ 261.3 Definition of hazardous waste.

(a) A solid waste, as defined in § 261.2, is a hazardous waste if:

(1) It is not excluded from regulation as a hazardous waste under § 261.4(b); and

(2) It meets any of the following criteria:

(i) It exhibits any of the characteristics of hazardous waste identified in Subpart C.

(ii) It is listed in Subpart D and has not been excluded from the lists in Subpart D under §§ 260.20 and 260.22 of this chapter.

(iii) It is a mixture of a solid waste and a hazardous waste that is listed in Subpart D solely because it exhibits one or more of the characteristics of hazardous waste identified in Subpart C, unless the resultant mixture no longer exhibits any characteristic of hazardous waste identified in Subpart C.

(iv) It is a mixture of solid waste and one or more hazardous wastes listed in Subpart D and has not been excluded from this paragraph under §§ 260.20 and 260.22 of this chapter; however, the following mixtures of solid wastes and hazardous wastes listed in Subpart D are not hazardous wastes (except by application of paragraph (a)(2) (i) or (ii) of this section) if the generator can demonstrate that the mixture consists of wastewater the discharge of which is subject to regulation under either section 402 or section 307(b) of the Clean Water Act (including wastewater at facilities which have eliminated the discharge of wastewater) and:

(A) One or more of the following spent solvents listed in § 261.31—carbon tetrachloride, tetrachloroethylene, trichloroethylene—*Provided*, That the maximum total weekly usage of these solvents (other than the amounts that can be demonstrated not to be discharged to wastewater) divided by the average weekly flow of wastewater into the headworks of the facility's wastewater treatment or pretreatment system does not exceed 1 part per million; or

(B) One or more of the following spent solvents listed in § 261.31—methylene chloride, 1,1,1-trichloroethane, chlorobenzene, o-dichlorobenzene, cresols, cresylic acid, nitrobenzene, toluene, methyl ethyl ketone, carbon disulfide, isobutanol, pyridine, spent chlorofluorocarbon solvents—*provided* that the maximum total weekly usage of these solvents (other than the amounts that can be demonstrated not to be discharged to wastewater) divided

ed by the average weekly flow of wastewater into the headworks of the facility's wastewater treatment or pre-treatment system does not exceed 25 parts per million; or

(C) One of the following wastes listed in § 261.32—heat exchanger bundle cleaning sludge from the petroleum refining industry (EPA Hazardous Waste No. K050); or

(D) A discarded commercial chemical product, or chemical intermediate listed in § 261.33, arising from *de minimis* losses of these materials from manufacturing operations in which these materials are used as raw materials or are produced in the manufacturing process. For purposes of this subparagraph, "*de minimis*" losses include those from normal material handling operations (e.g. spills from the unloading or transfer of materials from bins or other containers, leaks from pipes, valves or other devices used to transfer materials); minor leaks of process equipment, storage tanks or containers; leaks from well-maintained pump packings and seals; sample purgings; relief device discharges; discharges from safety showers and rinsing and cleaning of personal safety equipment; and rinseate from empty containers or from containers that are rendered empty by that rinsing; or

(E) Wastewater resulting from laboratory operations containing toxic (T) wastes listed in Subpart D. *Provided*, That the annualized average flow of laboratory wastewater does not exceed one percent of total wastewater flow into the headworks of the facility's wastewater treatment or pre-treatment system, or provided the wastes, combined annualized average concentration does not exceed one part per million in the headworks of the facility's wastewater treatment or pre-treatment facility. Toxic (T) wastes used in laboratories that are demonstrated not to be discharged to wastewater are not to be included in this calculation.

(b) A solid waste which is not excluded from regulation under paragraph (a)(1) of this section becomes a hazardous waste when any of the following events occur:

(1) In the case of a waste listed in Subpart D, when the waste first meets

the listing description set forth in Subpart D.

(2) In the case of a mixture of solid waste and one or more listed hazardous wastes, when a hazardous waste listed in Subpart D is first added to the solid waste.

(3) In the case of any other waste (including a waste mixture), when the waste exhibits any of the characteristics identified in Subpart C.

(c) Unless and until it meets the criteria of paragraph (d):

(1) A hazardous waste will remain a hazardous waste.

(2)(i) Except as otherwise provided in paragraph (c)(2)(ii) of this section, any solid waste generated from the treatment, storage, or disposal of a hazardous waste, including any sludge, spill residue, ash, emission control dust, or leachate (but not including precipitation run-off) is a hazardous waste. (However, materials that are reclaimed from solid wastes and that are used beneficially are not solid wastes and hence are not hazardous wastes under this provision unless the reclaimed material is burned for energy recovery or used in a manner constituting disposal.)

(ii) The following solid wastes are not hazardous even though they are generated from the treatment, storage, or disposal of a hazardous waste, unless they exhibit one or more of the characteristics of hazardous waste: (A) Waste pickle liquor sludge generated by lime stabilization of spent pickle liquor from the iron and steel industry (SIC Codes 331 and 332).

(B) Waste from burning any of the materials exempted from regulation by § 261.6(a)(3)(v) through (ix).

(d) Any solid waste described in paragraph (c) of this section is not a hazardous waste if it meets the following criteria:

(1) In the case of any solid waste, it does not exhibit any of the characteristics of hazardous waste identified in Subpart C.

(2) In the case of a waste which is a listed waste under Subpart D, contains a waste listed under Subpart D or is derived from a waste listed in Subpart D, it also has been excluded from paragraph (c) under §§ 260.20 and 260.22 of this chapter.

(45 FR 33119, May 19, 1980, as amended at 46 FR 56588, Nov. 17, 1981; 50 FR 14219, Apr. 11, 1985; 50 FR 49202, Nov. 29, 1985; 52 FR 11821, Apr. 13, 1987)

§ 261.4 Exclusions.

(a) *Materials which are not solid wastes.* The following materials are not solid wastes for the purpose of this part:

(1)(i) Domestic sewage; and

(ii) Any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment. "Domestic sewage" means untreated sanitary wastes that pass through a sewer system.

(2) Industrial wastewater discharges that are point source discharges subject to regulation under section 402 of the Clean Water Act, as amended.

(Comment: This exclusion applies only to the actual point source discharge. It does not exclude industrial wastewaters while they are being collected, stored or treated before discharge, nor does it exclude sludges that are generated by industrial wastewater treatment.)

(3) Irrigation return flows.

(4) Source, special nuclear or by-product material as defined by the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2011 *et seq.*

(5) Materials subjected to in-situ mining techniques which are not removed from the ground as part of the extraction process.

(6) Pulping liquors (i.e., black liquor) that are reclaimed in a pulping liquor recovery furnace and then reused in the pulping process, unless it is accumulated speculatively as defined in § 261.1(c) of this chapter.

(7) Spent sulfuric acid used to produce virgin sulfuric acid, unless it is accumulated speculatively as defined in § 261.1(c) of this chapter.

(8) Secondary materials that are reclaimed and returned to the original process or processes in which they were generated where they are reused in the production process provided:

(i) Only tank storage is involved, and the entire process through completion of reclamation is closed by being entirely connected with pipes or other comparable enclosed means of conveyance;

(ii) Reclamation does not involve controlled flame combustion (such as occurs in boilers, industrial furnaces, or incinerators);

(iii) The secondary materials are never accumulated in such tanks for over twelve months without being reclaimed; and

(iv) The reclaimed material is not used to produce a fuel, or used to produce products that are used in a manner constituting disposal.

(b) *Solid wastes which are not hazardous wastes.* The following solid wastes are not hazardous wastes:

(1) Household waste, including household waste that has been collected, transported, stored, treated, disposed, recovered (e.g., refuse-derived fuel) or reused. "Household waste" means any material (including garbage, trash and sanitary wastes in septic tanks) derived from household (including single and multiple residences, hotels and motels, bunk houses, ranger stations, crew quarters, campgrounds, picnic grounds and day use recreation areas). A resource recovery facility managing municipal solid waste shall not be deemed to be treating, storing, disposing of, or otherwise managing hazardous wastes for the purposes of regulation under this subtitle, if such facility:

(i) Receives and burns only (A) Household waste (from single and multiple dwellings, hotels, motel and other residential sources) and

(B) Solid waste from commercial (industrial sources that does not contain hazardous waste; and

(ii) Such facility does not accept hazardous wastes and the owner or operator of such facility has established contractual requirements or other appropriate notification or inspection procedures to assure that hazardous wastes are not received at or burned such facility.

(2) Solid wastes generated by any the following and which are returned to the soils as fertilizers:

(i) The growing and harvesting agricultural crops.

(ii) The raising of animals, including animal manures.

(3) Mining overburden returned to the mine site.

(4) Fly ash waste, bottom ash waste, slag waste, and flue gas emission control waste generated primarily from the combustion of coal or other fossil fuels.

(5) Drilling fluids, produced waters, and other wastes associated with the exploration, development, or production of crude oil, natural gas or geothermal energy.

(6)(i) Wastes which fail the test for the characteristic of EP toxicity because chromium is present or are listed in Subpart D due to the presence of chromium, which do not fail the test for the characteristic of EP toxicity for any other constituent or are not listed due to the presence of any other constituent, and which do not fail the test for any other characteristic, if it is shown by a waste generator or by waste generators that:

(A) The chromium in the waste is exclusively (or nearly exclusively) trivalent chromium; and

(B) The waste is generated from an industrial process which uses trivalent chromium exclusively (or nearly exclusively) and the process does not generate hexavalent chromium; and

(C) The waste is typically and frequently managed in non-oxidizing environments.

(ii) Specific wastes which meet the standard in paragraphs (b)(6)(i)(A), (B) and (C) (so long as they do not fail the test for the characteristic of EP toxicity, and do not fail the test for any other characteristic) are:

(A) Chrome (blue) trimmings generated by the following subcategories of the leather tanning and finishing industry: hair pulp/chrome tan/retan/wet finish; hair save/chrome tan/retan/wet finish; retan/wet finish; no beamhouse; through-the-blue; and shearing.

(B) Chrome (blue) shavings generated by the following subcategories of the leather tanning and finishing industry: hair pulp/chrome tan/retan/wet finish; hair save/chrome tan/retan/wet finish; retan/wet finish; no beamhouse; through-the-blue; and shearing.

(C) Buffing dust generated by the following subcategories of the leather tanning and finishing industry: hair pulp/chrome tan/retan/wet finish;

hair save/chrome tan/retan/wet finish; retan/wet finish; no beamhouse; through-the-blue.

(D) Sewer screenings generated by the following subcategories of the leather tanning and finishing industry: hair pulp/chrome tan/retan/wet finish; hair save/chrome tan/retan/wet finish; retan/wet finish; no beamhouse; through-the-blue; and shearing.

(E) Wastewater treatment sludges generated by the following subcategories of the leather tanning and finishing industry: hair pulp/chrome tan/retan/wet finish; hair save/chrome tan/retan/wet finish; retan/wet finish; no beamhouse; through-the-blue; and shearing.

(F) Wastewater treatment sludges generated by the following subcategories of the leather tanning and finishing industry: hair pulp/chrome tan/retan/wet finish; hair save/chrome tan/retan/wet finish; and through-the-blue.

(G) Waste scrap leather from the leather tanning industry, the shoe manufacturing industry, and other leather product manufacturing industries.

(H) Wastewater treatment sludges from the production of TiO₂ pigment using chromium-bearing ores by the chloride process.

(7) Solid waste from the extraction, beneficiation and processing of ores and minerals (including coal), including phosphate rock and overburden from the mining of uranium ore. For the purposes of this paragraph, solid waste from the processing of ores and minerals does not include:

(i) Acid plant blowdown slurry/sludge resulting from the thickening of blowdown slurry from primary copper production;

(ii) Surface impoundment solids contained in the dredged from surface impoundments at primary lead smelting facilities;

(iii) Sludge from treatment of process wastewater and/or acid plant blowdown from primary zinc production;

(iv) Spent potliners from primary aluminum reduction;

(v) Emission control dust or sludge from ferrocromiumsilicon production;

(vi) Emission control dust or sludge from ferrocromium production.

(8) Cement kiln dust waste.

(9) Solid waste which consists of discarded wood or wood products which fails the test for the characteristic of EP toxicity and which is not a hazardous waste for any other reason if the waste is generated by persons who utilize the arsenical-treated wood and wood products for these materials' intended end use.

(c) Hazardous wastes which are exempted from certain regulations. A hazardous waste which is generated in a product or raw material storage tank, a product or raw material transport vehicle or vessel, a product or raw material pipeline, or in a manufacturing process unit or an associated non-waste-treatment-manufacturing unit, is not subject to regulation under Parts 262 through 265, 268, 270, 271 and 124 of this chapter or to the notification requirements of section 3010 of RCRA until it exits the unit in which it was generated, unless the unit is a surface impoundment, or unless the hazardous waste remains in the unit more than 90 days after the unit ceases to be operated for manufacturing, or for storage or transportation of product or raw materials.

(d) *Samples.* (1) Except as provided in paragraph (d)(2) of this section, a sample of solid waste or a sample of water, soil, or air, which is collected for the sole purpose of testing to determine its characteristics or composition, is not subject to any requirements of this part or Parts 262 through 268 or Part 270 or Part 124 of this chapter or to the notification requirements of section 3010 of RCRA, when:

(i) The sample is being transported to a laboratory for the purpose of testing; or

(ii) The sample is being transported back to the sample collector after testing; or

(iii) The sample is being stored by the sample collector before transport to a laboratory for testing; or

(iv) The sample is being stored in a laboratory before testing; or

(v) The sample is being stored in a laboratory after testing but before it is returned to the sample collector; or

(vi) The sample is being stored temporarily in the laboratory after testing for a specific purpose (for example, until conclusion of a court case or enforcement action where further testing of the sample may be necessary).

(2) In order to qualify for the exemption in paragraphs (d)(1) (i) and (ii) of this section, a sample collector shipping samples to a laboratory and a laboratory returning samples to a sample collector must:

(i) Comply with U.S. Department of Transportation (DOT), U.S. Postal Service (USPS), or any other applicable shipping requirements; or

(ii) Comply with the following requirements if the sample collector determines that DOT, USPS, or other shipping requirements do not apply to the shipment of the sample:

(A) Assure that the following information accompanies the sample:

(1) The sample collector's name, mailing address, and telephone number;

(2) The laboratory's name, mailing address, and telephone number;

(3) The quantity of the sample;

(4) The date of shipment; and

(5) A description of the sample.

(B) Package the sample so that does not leak, spill, or vaporize from its packaging.

(3) This exemption does not apply if the laboratory determines that the waste is hazardous but the laboratory is no longer meeting any of the conditions stated in paragraph (d)(1) of this section.

(e) *Treatability Study Samples.* Except as provided in paragraph (e)(4) of this section, persons who generate or collect samples for the purpose of conducting treatability studies as defined in section 260.10, are not subject to any requirement of Parts 262 through 263 of this chapter or to the notification requirements of Section 3010 of RCRA, nor are such samples included in the quantity determinations of § 261.5 and § 262.34(d) when:

(i) The sample is being collected a prepared for transportation by the generator or sample collector; or

(ii) The sample is being accumulated or stored by the generator or sample collector prior to transportation to a laboratory or testing facility; or

(iii) The sample is being transported to the laboratory or testing facility for the purpose of conducting a treatability study.

(2) The exemption in paragraph (e)(1) of this section is applicable to samples of hazardous waste being collected and shipped for the purpose of conducting treatability studies provided that:

(i) The generator or sample collector uses (in "treatability studies") no more than 1000 kg of any non-acute hazardous waste, 1 kg of acute hazardous waste, or 250 kg of soils, water, or debris contaminated with acute hazardous waste for each process being evaluated for each generated waste stream; and

(ii) The mass of each sample shipment does not exceed 1000 kg of non-acute hazardous waste, 1 kg of acute hazardous waste, or 250 kg of soils, water, or debris contaminated with acute hazardous waste; and

(iii) The sample must be packaged so that it will not leak, spill, or vaporize from its packaging during shipment and the requirements of paragraph A or B of this subparagraph are met.

(A) The transportation of each sample shipment complies with U.S. Department of Transportation (DOT), U.S. Postal Service (USPS), or any other applicable shipping requirements; or

(B) If the DOT, USPS, or other shipping requirements do not apply to the shipment of the sample, the following information must accompany the sample:

(1) The name, mailing address, and telephone number of the originator of the sample;

(2) The name, address, and telephone number of the facility that will perform the treatability study;

(3) The quantity of the sample;

(4) The date of shipment; and

(5) A description of the sample, including its EPA Hazardous Waste Number.

(iv) The sample is shipped to a laboratory or testing facility which is exempt under § 261.4(f) or has an appropriate RCRA permit or interim status.

(v) The generator or sample collector maintains the following records for

a period ending 3 years after completion of the treatability study:

(A) Copies of the shipping documents;

(B) A copy of the contract with the facility conducting the treatability study;

(C) Documentation showing:

(1) The amount of waste shipped under this exemption;

(2) The name, address, and EPA identification number of the laboratory or testing facility that received the waste;

(3) The date the shipment was made; and

(4) Whether or not unused samples and residues were returned to the generator.

(vi) The generator reports the information required under paragraph (e)(v)(C) of this section in its biennial report.

(3) The Regional Administrator, or State Director (if located in an authorized State), may grant requests, on a case-by-case basis, for quantity limits in excess of those specified in paragraph (e)(2)(i) of this section, for up to an additional 500 kg of non-acute hazardous waste, 1 kg of acute hazardous waste, and 250 kg of soils, water, or debris contaminated with acute hazardous waste, to conduct further treatability study evaluation when: There has been an equipment or mechanical failure during the conduct of a treatability study; there is a need to verify the results of a previously conducted treatability study; there is a need to study and analyze alternative techniques within a previously evaluated treatment process; or there is a need to do further evaluation of an ongoing treatability study to determine final specifications for treatment. The additional quantities allowed are subject to all the provisions in paragraphs (e)(1) and (e)(2)(i)(v) of this section. The generator or sample collector must apply to the Regional Administrator in the Region where the sample is collected and provide in writing the following information:

(i) The reason why the generator or sample collector requires additional quantity of sample for the treatability study evaluation and the additional quantity needed;

(ii) Documentation accounting for all samples of hazardous waste from the waste stream which have been sent for or undergone treatability studies including the data each previous sample from the waste stream was shipped, the quantity of each previous shipment, the laboratory or testing facility to which it was shipped, what treatability study processes were conducted on each sample shipped, and the available results of each treatability study;

(iii) A description of the technical modifications or change in specifications which will be evaluated and the expected results;

(iv) If such further study is being required due to equipment or mechanical failure, the applicant must include information regarding the reason for the failure or breakdown and also include what procedures or equipment improvements have been made to protect against further breakdowns; and

(v) Such other information that the Regional Administrator considers necessary.

(f) *Samples Undergoing Treatability Studies at Laboratories and Testing Facilities.* Samples undergoing treatability studies and the laboratory or testing facility conducting such treatability studies (to the extent such facilities are not otherwise subject to RCRA requirements) are not subject to any requirement of this Part, Part 124, Parts 262-266, 268, and 270, or to the notification requirements of Section 3010 of RCRA provided that the conditions of paragraphs (f) (1) through (11) of this section are met. A mobile treatment unit (MTU) may qualify as a testing facility subject to paragraphs (f) (1) through (11) of this section. Where a group of MTUs are located at the same site, the limitations specified in (f) (1) through (11) of this section apply to the entire group of MTUs collectively as if the group were one MTU.

(1) No less than 45 days before conducting treatability studies, the facility notifies the Regional Administrator, or State Director (if located in an authorized State), in writing that it intends to conduct treatability studies under this paragraph.

(2) The laboratory or testing facility conducting the treatability study has an EPA identification number.

(3) No more than a total of 250 kg of "as received" hazardous waste is subjected to initiation of treatment in all treatability studies in any single day. "As received" waste refers to the waste as received in the shipment from the generator or sample collector.

(4) The quantity of "as received" hazardous waste stored at the facility for the purpose of evaluation in treatability studies does not exceed 1000 kg; the total of which can include 500 kg of soils, water, or debris contaminated with acute hazardous waste or 1 kg of acute hazardous waste. This quantity limitation does not include:

(i) Treatability study residues; and

(ii) Treatment materials (including nonhazardous solid waste) added to "as received" hazardous waste.

(5) No more than 90 days have elapsed since the treatability study for the sample was completed, or no more than one year has elapsed since the generator or sample collector shipped the sample to the laboratory or testing facility, whichever date first occurs.

(6) The treatability study does not involve the placement of hazardous waste on the land or open burning of hazardous waste.

(7) The facility maintains records for 3 years following completion of each study that show compliance with the treatment rate limits and the storage time and quantity limits. The following specific information must be included for each treatability study conducted:

(i) The name, address, and EPA identification number of the generator or sample collector of each waste sample;

(ii) The date the shipment was received;

(iii) The quantity of waste accepted in storage each day;

(iv) The quantity of "as received" waste introduced to treatment each day;

(v) The date the treatability study was initiated and the amount of "received" waste introduced to treatment each day;

(vi) The date the treatability study was concluded;

(vii) The date any unused sample residues generated from the treatability study were disposed of.

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ity study were returned to the generator or sample collector or, if sent to a designated facility, the name of the facility and the EPA identification number.

(8) The facility keeps, on-site, a copy of the treatability study contract and all shipping papers associated with the transport of treatability study samples to and from the facility for a period ending 3 years from the completion date of each treatability study.

(9) The facility prepares and submits a report to the Regional Administrator, or State Director (if located in an authorized State), by March 15 of each year that estimates the number of studies and the amount of waste expected to be used in treatability studies during the current year, and includes the following information for the previous calendar year:

(i) The name, address, and EPA identification number of the facility conducting the treatability studies;

(ii) The types (by process) of treatability studies conducted;

(iii) The names and addresses of persons for whom studies have been conducted (including their EPA identification numbers);

(iv) The total quantity of waste in storage each day;

(v) The quantity and types of waste subjected to treatability studies;

(vi) When each treatability study was conducted;

(vii) The final disposition of residues and unused sample from each treatability study.

(10) The facility determines whether any unused sample or residues generated by the treatability study are hazardous waste under § 261.3 and, if so, are subject to Parts 261 through 268, and Part 270 of this Chapter, unless the residues and unused samples are returned to the sample originator under the § 261.4(e) exemption.

(11) The facility notifies the Regional Administrator, or State Director (if located in an authorized State), by letter when the facility is no longer planning to conduct any treatability studies at the site.

(Approved by the Office of Management and Budget control number 2050-0088)

(45 PR 33110, May 19, 1980)

EDITORIAL NOTE: FOR FEDERAL REGISTER citations affecting § 261.4, see the List of CFR Sections Affected in the Finding Aids section of this volume.

~~§ 261.5 Special requirements for hazardous waste generated by conditionally exempt small quantity generators.~~

(a) A generator is a conditionally exempt small quantity generator in a calendar month if he generates no more than 100 kilograms of hazardous waste in that month.

(b) Except for those wastes identified in paragraphs (e), (f), (g), and (j) of this section, a conditionally exempt small quantity generator's hazardous wastes are not subject to regulation under Parts 262 through 266, 268, and Parts 270 and 124 of this chapter, and the notification requirements of section 3010 of RCRA, provided the generator complies with the requirements of paragraphs (f), (g), and (j) of this section.

(c) Hazardous waste that is not subject to regulation or that is subject only to § 262.11, § 262.12, § 262.40(c), and § 262.41 is not included in the quantity determinations of this part and Parts 262 through 266, 268, and 270 and is not subject to any of the requirements of those parts. Hazardous waste that is subject to the requirements of § 261.6 (b) and (c) and Subparts C, D, and F of Part 266 is included in the quantity determination of this part and is subject to the requirements of Parts 262 through 266 and 270.

(d) In determining the quantity of hazardous waste generated, a generator need not include:

(1) Hazardous waste when it is removed from on-site storage; or

(2) Hazardous waste produced by on-site treatment (including reclamation) of his hazardous waste, so long as the hazardous waste that is treated was counted once; or

(3) Spent materials that are generated, reclaimed, and subsequently reused on-site, so long as such spent materials have been counted once.

(e) If a generator generates acute hazardous waste in a calendar month in quantities greater than set forth

below, all quantities of that acute hazardous waste are subject to full regulation under Parts 262 through 266, 268, and Parts 270 and 124 of this chapter, and the notification requirements of section 3010 of RCRA:

(1) A total of one kilogram of acute hazardous wastes listed in §§ 261.31, 261.32, or 261.33(e).

(2) A total of 100 kilograms of any residue or contaminated soil, waste, or other debris resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in §§ 261.31, 261.32, or 261.33(e).

[Comment: "Full regulation" means those regulations applicable to generators of greater than 1,000 kg of non-acutely hazardous waste in a calendar month.]

(f) In order for acute hazardous wastes generated by a generator of acute hazardous wastes in quantities equal to or less than those set forth in paragraph (e)(1) or (2) of this section to be excluded from full regulation under this section, the generator must comply with the following requirements:

(1) Section 262.11 of this chapter;

(2) The generator may accumulate acute hazardous waste on-site. If he accumulates at any time acute hazardous wastes in quantities greater than those set forth in paragraph (e)(1) or (e)(2) of this section, all of those accumulated wastes are subject to regulation under Parts 262 through 266, 268, and Parts 270 and 124 of this chapter, and the applicable notification requirements of section 3010 of RCRA. The time period of § 262.34(a) of this chapter, for accumulation of wastes on-site, begins when the accumulated wastes exceed the applicable exclusion limit;

(3) A conditionally exempt small quantity generator may either treat or dispose of his acute hazardous waste in an on-site facility or ensure delivery to an off-site treatment, storage or disposal facility, either of which, if located in the U.S., is:

(i) Permitted under Part 270 of this chapter;

(ii) In interim status under Parts 270 and 265 of this chapter;

(iii) Authorized to manage hazardous waste by a State with a hazardous waste management program approved

under Part 271 of this chapter;

(iv) Permitted, licensed, or registered by a State to manage municipal or industrial solid waste; or

(v) A facility which:

(A) Beneficially uses or reuses, or legitimately recycles or reclaims its waste; or

(B) Treats its waste prior to beneficial use or reuse, or legitimate recycling or reclamation.

(g) In order for hazardous waste generated by a conditionally exempt small quantity generator in quantities of less than 100 kilograms of hazardous waste during a calendar month to be excluded from full regulation under this section, the generator must comply with the following requirements:

(1) Section 262.11 of this chapter;

(2) The conditionally exempt small quantity generator may accumulate hazardous waste on-site. If he accumulates at any time more than a total of 1000 kilograms of his hazardous wastes, all of those accumulate wastes are subject to regulation under the special provisions of Part 263 applicable to generators of between 10 kg and 1000 kg of hazardous waste in calendar month as well as the requirements of Parts 263 through 266, 268 and Parts 270 and 124 of this chapter and the applicable notification requirements of section 3010 of RCRA. The time period of § 262.34(d) for a cumulation of wastes on-site begins for a conditionally exempt small quantity generator when the accumulated wastes exceed 1000 kilograms;

(3) A conditionally exempt small quantity generator may either treat or dispose of his hazardous waste in an on-site facility or ensure delivery to an off-site treatment, storage or disposal facility, either of which, if located in the U.S., is:

(i) Permitted under Part 270 of this chapter;

(ii) In interim status under Parts 270 and 265 of this chapter;

(iii) Authorized to manage hazardous waste by a State with a hazardous waste management program approved under Part 271 of this chapter;

(iv) Permitted, licensed, or registered by a State to manage municipal or industrial solid waste; or

(v) A facility

~~§ 261.21 Characteristic of ignitability.~~

(a) A solid waste exhibits the characteristic of ignitability if a representative sample of the waste has any of the following properties:

(1) It is a liquid, other than an aqueous solution containing less than 24 percent alcohol by volume and has flash point less than 60°C (140°F), as determined by a Pensky-Martens Closed Cup Tester, using the test method specified in ASTM Standard D-93-79 or D-93-80 (incorporated by reference, see § 260.11), or a Setaflash Closed Cup Tester, using the test method specified in ASTM Standard D-3278-78 (incorporated by reference, see § 260.11), or as determined by an equivalent test method approved by the Administrator under procedures set forth in §§ 260.20 and 260.21.

(2) It is not a liquid and is capable, under standard temperature and pressure, of causing fire through friction, absorption of moisture or spontaneous chemical changes and, when ignited, burns so vigorously and persistently that it creates a hazard.

(3) It is an ignitable compressed gas as defined in 49 CFR 173.300 and as determined by the test methods described in that regulation or equivalent test methods approved by the Administrator under §§ 260.20 and 260.21.

(4) It is an oxidizer as defined in 49 CFR 173.151.

(b) A solid waste that exhibits the characteristic of ignitability, but is not listed as a hazardous waste in Subpart D, has the EPA Hazardous Waste Number of D001.

[45 FR 33119, May 19, 1980, as amended at 46 FR 35247, July 7, 1981]

~~§ 261.22 Characteristic of corrosivity.~~

(a) A solid waste exhibits the characteristic of corrosivity if a representative sample of the waste has either of the following properties:

(1) It is aqueous and has a pH less than or equal to 2 or greater than or equal to 12.5, as determined by a pH meter using either an EPA test method or an equivalent test method approved by the Administrator under the procedures set forth in §§ 260.20 and 260.21. The EPA test method for pH is specified as Method 5.2 in "Test

~~Methods for the Evaluation of Solid Waste, Physical/Chemical Methods" (incorporated by reference, see § 260.11).~~

(2) It is a liquid and corrodes steel (SAE 1020) at a rate greater than 6.35 mm (0.250 inch) per year at a test temperature of 55°C (130°F) as determined by the test method specified in NACE (National Association of Corrosion Engineers Standard TM-01-69 as standardized in "Test Methods for the Evaluation of Solid Waste, Physical/Chemical Methods" (incorporated by reference, see § 260.11) or an equivalent test method approved by the Administrator under the procedures set forth in §§ 260.20 and 260.21.

(b) A solid waste that exhibits the characteristic of corrosivity, but is not listed as a hazardous waste in Subpart D, has the EPA Hazardous Waste Number of D002.

[45 FR 33119, May 19, 1980, as amended at 46 FR 35247, July 7, 1981]

~~§ 261.23 Characteristic of reactivity.~~

(a) A solid waste exhibits the characteristic of reactivity if a representative sample of the waste has any of the following properties:

(1) It is normally unstable and readily undergoes violent change without detonating.

(2) It reacts violently with water.

(3) It forms potentially explosive mixtures with water.

(4) When mixed with water, it generates toxic gases, vapors or fumes in a quantity sufficient to present a danger to human health or the environment.

(5) It is a cyanide or sulfide bearing waste which, when exposed to pH conditions between 2 and 12.5, can generate toxic gases, vapors or fumes in a quantity sufficient to present a danger to human health or the environment.

(6) It is capable of detonation or explosive reaction if it is subjected to a strong initiating source or if heated under confinement.

(7) It is readily capable of detonation or explosive decomposition or reaction at standard temperature and pressure.

(8) It is a forbidden explosive as defined in 49 CFR 173.51, or a Class A explosive as defined in 49 CFR 173.53,

~~or a Class B explosive as defined in 49 CFR 173.88.~~

(b) A solid waste that exhibits the characteristic of reactivity, but is not listed as a hazardous waste in Subpart D, has the EPA Hazardous Waste Number of D003.

~~§ 261.24 Characteristic of EP toxicity.~~

(a) A solid waste exhibits the characteristic of EP toxicity if, using the test methods described in Appendix II or equivalent methods approved by the Administrator under the procedures set forth in §§ 260.20 and 260.21, the extract from a representative sample of the waste contains any of the contaminants listed in Table I at a concentration equal to or greater than the respective value given in that Table. Where the waste contains less than 0.5 percent filterable solids, the waste itself, after filtering, is considered to be the extract for the purposes of this section.

(b) A solid waste that exhibits the characteristic of EP toxicity, but is not listed as a hazardous waste in Subpart D, has the EPA Hazardous Waste Number specified in Table I which corresponds to the toxic contaminant causing it to be hazardous.

TABLE I—MAXIMUM CONCENTRATION OF CONTAMINANTS FOR CHARACTERISTIC OF EP TOXICITY

EPA hazardous waste number	Contaminant	Maximum concentration (milligrams per liter)
D004	Arsenic	5.0
D005	Barium	100.0
D006	Cadmium	1.0
D007	Chromium	5.0
D008	Lead	5.0
D009	Mercury	0.2
D010	Selenium	1.0
D011	Silver	5.0
D012	Endrin (1,2,3,4,10,10-hexachloro-1,7-epoxy-1,4,4a,5,6,7,8,8a-octahydro-1,4-endo, endo-5,6-dimethano-naphthalene)	0.02
D013	Lindane (1,2,3,4,5,6-hexachlorocyclohexane, gamma isomer)	0.4
D014	Methoxychlor (1,1,1-Trichloro-2,2-bis [p-methoxyphenyl]ethane)	10.0
D015	Toxaphene (C ₁₂ H ₈ Cl ₆ , Technical chlorinated camphene, 97-99 percent chiral)	0.6

TABLE I—MAXIMUM CONCENTRATION OF CONTAMINANTS FOR CHARACTERISTIC OF EP TOXICITY—Continued

EPA hazardous waste number	Contaminant	Maximum concentration (milligrams per liter)
D016	2,4-D, (2,4-Dichlorophenoxypropionic acid)	10
D017	2,4,5-TP Silver (2,4,5-Trichlorophenoxypropionic acid)	1

Subpart D—Lists of Hazardous Wastes

§ 261.30 General.

(a) A solid waste is a hazardous waste if it is listed in this subpart unless it has been excluded from this list under §§ 260.20 and 260.22.

(b) The Administrator will indicate his basis for listing the classes or type of wastes listed in this Subpart by employing one or more of the following Hazard Codes:

Ignitable Waste	I
Corrosive Waste	C
Reactive Waste	R
EP Toxic Waste	T
Acute Hazardous Waste	A
Toxic Waste	X

Appendix VII identifies the constituent which caused the Administrator to list the waste as an EP Toxic Waste (E) or Toxic Waste (T) in §§ 261.3 and 261.32.

(c) Each hazardous waste listed in this subpart is assigned an EPA Hazardous Waste Number which precedes the name of the waste. This number must be used in complying with the notification requirements of Section 3010 of the Act and certain record keeping and reporting requirements under Parts 262 through 265, 268, and Part 270 of this chapter.

(d) The following hazardous waste listed in § 261.31 or § 261.32 are subject to the exclusion limits for acutely hazardous wastes established in § 261.3 EPA Hazardous Wastes Nos. F021, F022, F023, F026, and F027.

[45 FR 33119, May 19, 1980, as amended at 48 FR 14294, Apr. 1, 1983; 50 FR 2000, Jan. 14, 1985; 51 FR 40636, Nov. 7, 1986]

§ 261.31 Hazardous wastes from non-specific sources.

The following solid wastes are listed hazardous wastes from non-specific sources unless they are excluded under §§ 260.20 and 260.22 and listed in Appendix IX.

Industry and EPA hazardous waste No.	Hazardous waste	Hazard code
Generic: F001	The following spent halogenated solvents used in degreasing: Tetrachloroethylene, trichloroethylene, methylene chloride, 1,1,1-trichloroethane, carbon tetrachloride, and chlorinated fluorocarbons; all spent solvent mixtures/blends used in degreasing containing, before use, a total of ten percent or more (by volume) of one or more of the above halogenated solvents or those solvents listed in F002, F004, and F005; and still bottoms from the recovery of these spent solvents and spent solvent mixtures.	(T)
F002	The following spent halogenated solvents: Tetrachloroethylene, methylene chloride, trichloroethylene, 1,1,1-trichloroethane, chlorobenzene, 1,1,2-trichloro-1,2,2-trifluoroethane, ortho-dichlorobenzene, trichlorofluoromethane, and 1,1,2-trichloroethane; all spent solvent mixtures/blends containing, before use, a total of ten percent or more (by volume) of one or more of the above halogenated solvents or those listed in F001, F004, or F005; and still bottoms from the recovery of these spent solvents and spent solvent mixtures.	(T)
F003	The following spent non-halogenated solvents: Xylene, acetone, ethyl acetate, ethyl benzene, ethyl ether, methyl isobutyl ketone, n-butyl alcohol, cyclohexanone, and methanol; all spent solvent mixtures/blends containing, before use, only the above spent non-halogenated solvents; and all spent solvent mixtures/blends containing, before use, one or more of the above non-halogenated solvents, and, a total of ten percent or more (by volume) of one or more of those solvents listed in F001, F002, F004, and F005; and still bottoms from the recovery of these spent solvents and spent solvent mixtures.	(T) (U)
F004	The following spent non-halogenated solvents: Cresols and cresylic acid, and nitrobenzene; all spent solvent mixtures/blends containing, before use, a total of ten percent or more (by volume) of one or more of the above non-halogenated solvents or those solvents listed in F001, F002, and F005; and still bottoms from the recovery of these spent solvents and spent solvent mixtures.	(T)
F006	The following spent non-halogenated solvents: Toluene, methyl ethyl ketone, carbon disulfide, isobutanol, pyridine, benzene, 2-ethoxyethanol, and 2-nitropropane; all spent solvent mixtures/blends containing, before use, a total of ten percent or more (by volume) of one or more of the above non-halogenated solvents or those solvents listed in F001, F002, or F004; and still bottoms from the recovery of these spent solvents and spent solvent mixtures.	(U, T)
F008	Wastewater treatment sludges from electroplating operations except from the following processes: (1) Sulfuric acid anodizing of aluminum; (2) tin plating on carbon steel; (3) zinc plating (segregated bath) on carbon steel; (4) aluminum or zinc-aluminum plating on carbon steel; (5) cleaning/stripping associated with tin, zinc and aluminum plating on carbon steel; and (6) chemical etching and milling of aluminum.	(T)
F019	Wastewater treatment sludges from the chemical conversion coating of aluminum	(T)
F007	Spent cyanide plating bath solutions from electroplating operations	(R, T)
F008	Plating bath residues from the bottom of plating baths from electroplating operations where cyanides are used in the process.	(R, T)
F009	Spent stripping and cleaning bath solutions from electroplating operations where cyanides are used in the process.	(R, T)
F010	Quenching bath residues from oil baths from metal heat treating operations where cyanides are used in the process.	(R, T)
F011	Spent cyanide solutions from salt bath pot cleaning from metal heat treating operations.	(R, T)
F012	Quenching waste water treatment sludges from metal heat treating operations where cyanides are used in the process.	(T)
F024	Wastes, including but not limited to, distillation residues, heavy ends, tars, and reactor clean-out wastes from the production of chlorinated aliphatic hydrocarbons, having carbon content from one to five, utilizing free radical catalyzed processes. (This listing does not include light ends, spent filters and filter aids, spent desiccants, wastewater, wastewater treatment sludges, spent catalysts, and wastes listed in § 261.32.)	(T)
F020	Wastes (except wastewater and spent carbon from hydrogen chloride purification) from the production or manufacturing use (as a reactant, chemical intermediate, or component in a formulating process) of tri- or tetrachlorophenol, or of intermediates used to produce their pesticide derivatives. (This listing does not include wastes from the production of Hexachlorophene from highly purified 2,4,5-trichlorophenol.)	(H)

Industry and EPA hazardous waste No.	Hazardous waste	Hazard code
F021	Wastes (except wastewater and spent carbon from hydrogen chloride purification) from the production or manufacturing use (as a reactant, chemical intermediate, or component in a formulating process) of pentachlorophenol, or of intermediates used to produce its derivatives.	(H)
F022	Wastes (except wastewater and spent carbon from hydrogen chloride purification) from the manufacturing use (as a reactant, chemical intermediate, or component in a formulating process) of tri-, penta-, or hexachlorobenzene under alkaline conditions.	(H)
F023	Wastes (except wastewater and spent carbon from hydrogen chloride purification) from the production of materials on equipment previously used for the production or manufacturing use (as a reactant, chemical intermediate, or component in a formulating process) of tri- and tetrachlorophenols. (This listing does not include wastes from equipment used only for the production or use of Hexachlorophene from highly purified 2,4,5-trichlorophenol.)	(H)
F026	Wastes (except wastewater and spent carbon from hydrogen chloride purification) from the production of materials on equipment previously used for the manufacturing use (as a reactant, chemical intermediate, or component in a formulating process) of tri-, penta-, or hexachlorobenzene under alkaline conditions.	(H)
F027	Discarded unused formulations containing tri-, tetra-, or pentachlorophenol or discarded unused formulations containing compounds derived from these chlorophenols. (This listing does not include formulations containing Hexachlorophene synthesized from prepurified 2,4,5-trichlorophenol as the sole component.)	(H)
F028	Residues resulting from the incineration or thermal treatment of soil contaminated with EPA Hazardous Waste Nos. F020, F021, F022, F023, F026, and F027.	(T)

(U, T) should be used to specify mixtures containing ignitable and toxic constituents.

(46 FR 4617, Jan. 16, 1981)

EDITORIAL NOTE: FOR FEDERAL REGISTER citations affecting § 261.31, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 261.32 Hazardous wastes from specific sources.

The following solid wastes are listed hazardous wastes from specific source unless they are excluded under §§ 260.20 and 260.22 and listed in Appendix IX

Industry and EPA hazardous waste No.	Hazardous waste	Hazard code
Wood preservation: K001	Bottom sediment sludge from the treatment of wastewaters from wood preserving processes that use creosote and/or pentachlorophenol.	(T)
Inorganic pigments: K002	Wastewater treatment sludge from the production of chrome yellow and orange pigments.	(T)
K003	Wastewater treatment sludge from the production of molybdate orange pigments	(T)
K004	Wastewater treatment sludge from the production of zinc yellow pigments	(T)
K005	Wastewater treatment sludge from the production of chrome green pigments	(T)
K006	Wastewater treatment sludge from the production of chrome oxide green pigments (anhydrous and hydrated).	(T)
K007	Wastewater treatment sludge from the production of iron blue pigments	(T)
K008	Oven residue from the production of chrome oxide green pigments	(T)
Organic chemicals: K009	Distillation bottoms from the production of acetaldehyde from ethylene	(T)
K010	Distillation side cuts from the production of acetaldehyde from ethylene	(R, T)
K011	Bottom stream from the wastewater stripper in the production of acrylonitrile	(R, T)
K013	Bottom stream from the acetonitrile column in the production of acrylonitrile	(T)
K014	Bottoms from the acetonitrile purification column in the production of acrylonitrile	(T)
K015	Still bottoms from the distillation of benzyl chloride	(T)
K016	Heavy ends or distillation residues from the production of carbon tetrachloride	(T)
K017	Heavy ends (still bottoms) from the purification column in the production of epichlorohydrin.	(T)
K018	Heavy ends from the fractionation column in ethyl chloride production	(T)
K019	Heavy ends from the distillation of ethylene dichloride in ethylene dichloride production.	(T)
K020	Heavy ends from the distillation of vinyl chloride in vinyl chloride monomer production.	(T)
K021	Aqueous spent antimony catalyst waste from fluoromethanes production	(T)
K022	Distillation bottom tars from the production of phenol/acetone from cumene	(T)
K023	Distillation light ends from the production of phthalic anhydride from naphthalene	(T)

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Industry and EPA hazardous waste No.	Hazardous waste	Hazard code
K024	Distillation bottoms from the production of phthalic anhydride from naphthalene	(T)
K093	Distillation light ends from the production of phthalic anhydride from ortho-xylene	(T)
K094	Distillation bottoms from the production of phthalic anhydride from ortho-xylene	(T)
K025	Distillation bottoms from the production of nitrobenzene by the nitration of benzene	(T)
K026	Stripping still tails from the production of methyl ethyl pyridines	(T)
K027	Centrifuge and distillation residues from toluene diisocyanate production	(R, T)
K028	Spent catalyst from the hydrochlorinator reactor in the production of 1,1,1-trichloroethane	(T)
K029	Waste from the product steam stripper in the production of 1,1,1-trichloroethane	(T)
K095	Distillation bottoms from the production of 1,1,1-trichloroethane	(T)
K098	Heavy ends from the heavy ends column from the production of 1,1,1-trichloroethane	(T)
K030	Column bottoms or heavy ends from the combined production of trichloroethylene and perchloroethylene	(T)
K083	Distillation bottoms from aniline production	(T)
K103	Process residues from aniline extraction from the production of aniline	(T)
K104	Combined wastewater streams generated from nitrobenzene/aniline production	(T)
K085	Distillation or fractionation column bottoms from the production of chlorobenzenes	(T)
K106	Separated aqueous stream from the reactor product washing step in the production of chlorobenzenes	(T)
K111	Product washwaters from the production of dinitrotoluene via nitration of toluene	(C, T)
K112	Reaction by-product water from the drying column in the production of toluenediamine via hydrogenation of dinitrotoluene	(T)
K113	Condensed liquid light ends from the purification of toluenediamine in the production of toluenediamine via hydrogenation of dinitrotoluene	(T)
K114	Vicinals from the purification of toluenediamine in the production of toluenediamine via hydrogenation of dinitrotoluene	(T)
K115	Heavy ends from the purification of toluenediamine in the production of toluenediamine via hydrogenation of dinitrotoluene	(T)
K116	Organic condensate from the solvent recovery column in the production of toluene diisocyanate via phosgenation of toluenediamine	(T)
K117	Wastewater from the reactor vent gas scrubber in the production of ethylene dibromide via bromination of ethene	(T)
K118	Spent adsorbent solids from purification of ethylene dibromide in the production of ethylene dibromide via bromination of ethene	(T)
K136	Still bottoms from the purification of ethylene dibromide in the production of ethylene dibromide via bromination of ethene	(T)
Inorganic chemicals:		
K071	Brine purification muds from the mercury cell process in chlorine production, where separately prepurified brine is not used	(T)
K073	Chlorinated hydrocarbon waste from the purification step of the diaphragm cell process using graphite anodes in chlorine production	(T)
K108	Wastewater treatment sludge from the mercury cell process in chlorine production	(T)
Pesticides:		
K031	By-product salts generated in the production of MSMA and cacodylic acid	(T)
K032	Wastewater treatment sludge from the production of chlordane	(T)
K033	Wastewater and scrub water from the chlorination of cyclopentadiene in the production of chlordane	(T)
K034	Filter solids from the filtration of hexachlorocyclopentadiene in the production of chlordane	(T)
K097	Vacuum stripper discharge from the chlordane chlorinator in the production of chlordane	(T)
K035	Wastewater treatment sludges generated in the production of creosote	(T)
K036	Still bottoms from toluene reclamation distillation in the production of disulfoton	(T)
K037	Wastewater treatment sludges from the production of disulfoton	(T)
K038	Wastewater from the washing and stripping of phosphate production	(T)
K039	Filter cake from the filtration of diethylphosphorodithioic acid in the production of phosphate	(T)
K040	Wastewater treatment sludge from the production of phosphate	(T)
K041	Wastewater treatment sludge from the production of toxaphene	(T)
K096	Untreated process wastewater from the production of toxaphene	(T)
K042	Heavy ends or distillation residues from the distillation of tetrachlorobenzene in the production of 2,4,5-T	(T)
K043	2,6-Dichlorophenol waste from the production of 2,4-D	(T)
K099	Untreated wastewater from the production of 2,4-D	(T)
K123	Process wastewater (including supernates, filtrates, and washwaters) from the production of ethylenedithiocarbamic acid and its salt	(T)
K124	Reactor vent scrubber water from the production of ethylenedithiocarbamic acid and its salts	(C, T)
K125	Filtration, evaporation, and centrifugation solids from the production of ethylenedithiocarbamic acid and its salts	(T)

Industry and EPA hazardous waste No.	Hazardous waste	Hazard code
K126	Baghouse dust and floor sweepings in milling and packaging operations from the production or formulation of ethylenedithiocarbamic acid and its salts	(T)
Explosives:		
K044	Wastewater treatment sludges from the manufacturing and processing of explosives	(R)
K045	Spent carbon from the treatment of wastewater containing explosives	(R)
K046	Wastewater treatment sludges from the manufacturing, formulation and loading of lead-based initiating compounds	(T)
K047	Pink/red water from TNT operations	(R)
Petroleum refining:		
K048	Dissolved air flotation (DAF) float from the petroleum refining industry	(T)
K049	Slip oil emulsion solids from the petroleum refining industry	(T)
K050	Heat exchanger bundle cleaning sludge from the petroleum refining industry	(T)
K051	API separator sludge from the petroleum refining industry	(T)
K052	Tank bottoms (leaded) from the petroleum refining industry	(T)
Iron and steel:		
K081	Emission control dust/sludge from the primary production of steel in electric furnaces	(T)
K082	Spent pickle liquor generated by steel finishing operations of facilities within the iron and steel industry (SIC Codes 331 and 332)	(C, T)
Primary copper:		
K064	Acid plant blowdown slurry/sludge resulting from the thickening of blowdown slurry from primary copper production	(T)
Primary lead:		
K085	Surface impoundment solids contained in and dredged from surface impoundments at primary lead smelting facilities	(T)
Primary zinc:		
K086	Sludge from treatment of process wastewater and/or acid plant blowdown from primary zinc production	(T)
Primary aluminum:		
K068	Spent potliners from primary aluminum reduction	(T)
Ferroalloys:		
K090	Emission control dust or sludge from ferrochromium/silicon production	(T)
K091	Emission control dust or sludge from ferrochromium production	(T)
Secondary lead:		
K069	Emission control dust/sludge from secondary lead smelting	(T)
K100	Waste leaching solution from acid leaching of emission control dust/sludge from secondary lead smelting	(T)
Veterinary pharmaceuticals:		
K084	Wastewater treatment sludges generated during the production of veterinary pharmaceuticals from arsenic or organo-arsenic compounds	(T)
K101	Distillation tar residues from the distillation of aniline-based compounds in the production of veterinary pharmaceuticals from arsenic or organo-arsenic compounds	(T)
K102	Residue from the use of activated carbon for decolorization in the production of veterinary pharmaceuticals from arsenic or organo-arsenic compounds	(T)
Ink formulation: K068		
Solvent washes and sludges, caustic washes and sludges, or water washes and sludges from cleaning tube and equipment used in the formulation of ink from pigments, driers, soaps, and stabilizers containing chromium and lead		
Coking:		
K060	Ammonia still lime sludge from coking operations	(T)
K067	Decanter tank tar sludge from coking operations	(T)

[46 FR 4618, Jan. 16, 1981]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 261.32, see the List of CF Sections Affected in the Finding Aids section of this volume.

§ 261.33 Discard d commercial chemical products, off-specification species, container residues, and spill residues thereof.

The following materials or items are hazardous wastes if and when they are discarded or intended to be discarded as described in § 261.2(a)(2)(1), when they are mixed with waste oil or used oil or other material and applied to

the land for dust suppression or for treatment, when they are otherwise applied to the land in lieu of the original intended use or when they are contained in products that are applied to the land in lieu of their original intended use, or when, in lieu of the original intended use, they are produced for use as (or as a component

of) a fuel, distributed for use as a fuel, or burned as a fuel.

(a) Any commercial chemical product, or manufacturing chemical intermediate having the generic name listed in paragraph (e) or (f) of this section.

(b) Any off-specification commercial chemical product or manufacturing chemical intermediate which, if it met specifications, would have the generic name listed in paragraph (e) or (f) of this section.

(c) Any residue remaining in a container or in an inner liner removed from a container that has held any commercial chemical product or manufacturing chemical intermediate having the generic name listed in paragraph (e) of this section, unless the container is empty as defined in § 261.7(b)(3) of the chapter.

[Comment: Unless the residue is being beneficially used or reused, or legitimately recycled or reclaimed; or being accumulated, stored, transported or treated prior to such use, re-use, recycling or reclamation, EPA considers the residue to be intended for discard, and thus, a hazardous waste. An example of a legitimate re-use of the residue would be where the residue remains in the container and the container is used to hold the same commercial chemical product or manufacturing chemical intermediate it previously held. An example of the discard of the residue would be where the drum is sent to a drum reconditioner who reconditions the drum but discards the residue.]

(d) Any residue or contaminated soil, water or other debris resulting from the cleanup of a spill into or on any land or water of any commercial chemical product or manufacturing chemical intermediate having the generic name listed in paragraph (e) or (f) of this section, or any residue or contaminated soil, water or other

debris resulting from the cleanup of a spill, into or on any land or water, of any off-specification chemical product and manufacturing chemical intermediate which, if it met specifications, would have the generic name listed in paragraph (e) or (f) of this section.

[Comment: The phrase "commercial chemical product or manufacturing chemical intermediate having the generic name listed in . . ." refers to a chemical substance which is manufactured or formulated for commercial or manufacturing use which consists of the commercially pure grade of the chemical, any technical grades of the chemical that are produced or marketed, and all formulations in which the chemical is the sole active ingredient. It does not refer to a material, such as a manufacturing process waste, that contains any of the substances listed in paragraph (e) or (f). Where a manufacturing process waste is deemed to be a hazardous waste because it contains a substance listed in paragraph (e) or (f), such waste will be listed in either § 261.31 or § 261.32 or will be identified as a hazardous waste by the characteristics set forth in Subpart C of this part.]

(e) The commercial chemical products, manufacturing chemical intermediates or off-specification commercial chemical products or manufacturing chemical intermediates referred to in paragraphs (a) through (d) of this section, are identified as acute hazardous wastes (H) and are subject to be the small quantity exclusion defined in § 261.5(e).

[Comment: For the convenience of the regulated community the primary hazardous properties of these materials have been indicated by the letters T (Toxicity), and R (Reactivity). Absence of a letter indicates that the compound only is listed for acute toxicity.]

These wastes and their corresponding EPA Hazardous Waste Numbers are:

Attachment Number 180 NACI 1

Hazardous waste No.	Chemical abstracts No.	Substance
P005	107-18-8	Allyl alcohol
P006	20859-73-8	Aluminum phosphide (R,T)
P007	2763-98-4	5-(Aminomethyl)-3-oxazolol
P008	804-24-6	4-Aminopyridine
P009	131-74-8	Ammonium picrate (R)
P119	7803-56-6	Ammonium vanadate
P099	506-81-8	Argentate(1-), bis(cyano-C)-, potassium
P010	7778-39-4	Arsenic acid H ₃ AsO ₄
P012	1327-63-3	Arsenic oxide As ₂ O ₃
P011	1303-28-2	Arsenic oxide As ₂ O ₅
P011	1303-28-2	Arsenic pentoxide
P012	1327-63-3	Arsenic trioxide
P036	692-42-2	Arsine, diethyl-
P036	696-28-6	Arsenous dichloride, phenyl-
P054	151-56-4	Azidine
P067	75-55-8	Azidine, 2-methyl-
P013	642-82-1	Barium cyanide
P024	106-47-8	Benzenamine, 4-chloro-
P077	100-01-6	Benzenamine, 4-nitro-
P028	100-44-7	Benzene, (chloromethyl)-
P042	51-43-4	1,2-Benzenediol, 4-[1-hydroxy-2-(methylamino)ethyl]-, (R)-
P046	122-09-8	Benzeneethanamine, alpha, alpha-dimethyl-
P014	106-98-5	Benzenethiol
P001	81-81-2	2H-1-Benzopyran-2-one, 4-hydroxy-3-[3-oxo-1-phenylbutyl]-, & salts, when present at concentrations greater than 0.3%
P026	100-44-7	Benzyl chloride
P016	7440-41-7	Beryllium
P017	598-31-2	Bromocelone
P018	357-57-3	Brucine
P046	39196-18-4	2-Butanone, 3,3-dimethyl-1-(methylthio)-, O-(methylamino)carbonyl oxime
P021	692-01-8	Calcium cyanide
P021	692-01-8	Calcium cyanide Ca(CN) ₂
P022	75-15-0	Carbon disulfide
P095	75-44-5	Carbonic dichloride
P023	107-20-0	Chloroacetaldehyde
P024	106-47-8	p-Chloroaniline
P026	5344-82-1	1-(o-Chlorophenyl)thiourea
P027	642-76-7	3-Chloropropionitrile
P029	544-92-3	Copper cyanide
P029	544-92-3	Copper cyanide Cu(CN) ₂
P030		Cyanides (soluble cyanide salts), not otherwise specified
P031	460-19-5	Cyanogen
P033	506-77-4	Cyanogen chloride
P033	506-77-4	Cyanogen chloride (CN)Cl
P034	131-89-6	2-Cyclohexyl-4,6-dinitrophenol
P016	642-88-1	Dichloromethyl ether
P036	696-28-6	Dichlorophenylarsine
P037	60-57-1	Dieldrin
P038	692-42-2	Diethylarsine
P041	311-45-5	Diethyl-p-nitrophenyl phosphate
P040	297-97-2	O,O-Diethyl O-pyrazinyl phosphorothioate
P043	55-91-4	Diisopropylfluorophosphate (DFF)
P004	309-00-2	1,4,5,8-Dimethanonaphthalene, 1,2,3,4,10,10-hexa-chloro-1,4,4a,5,6,8a-hexahydro-, (1alpha,4alpha,4beta,5beta,8alpha,8beta)-
P060	465-73-6	1,4,5,8-Dimethanonaphthalene, 1,2,3,4,10,10-hexa-chloro-1,4,4a,5,6,8a-hexahydro-, (1alpha,4alpha,4beta,5beta,8beta,8beta)-
P037	60-57-1	2,7,3,6-Dimethanonaphth[2,3-b]oxirene, 3,4,5,6,9,9-hexachloro-1a,2,2a,3,6,6a,7,7a-octahydro-, (1alpha,2beta,2alpha,3beta,6beta,6alpha,7beta,7alpha)-
P051	72-20-6	2,7,3,6-Dimethanonaphth[2,3-b]oxirene, 3,4,5,6,9,9-hexachloro-1a,2,2a,3,6,6a,7,7a-octahydro-, (1alpha,2beta,2alpha,3beta,6beta,7beta,7alpha)-, & metabolites
P044	60-51-5	Dimethoate
P046	122-09-8	alpha, alpha-Dimethylphenethylamine
P047	534-52-1	4,6-Dinitro-o-cresol, & salts
P048	51-28-5	2,4-Dinitrophenol
P020	88-85-7	Dinoseb
P065	152-16-9	Diphosphoramidate, octamethyl-
P111	107-49-3	Diphosphoric acid, tetraethyl ester
P039	298-04-4	Disulfoton

Hazardous waste No.	Chemical abstracts No.	Substance
P023	107-20-0	Acetaldehyde, chloro-
P002	591-06-2	Acetamide, N-(aminothioxomethyl)-
P057	640-19-7	Acetamide, 2-fluoro-
P058	62-74-8	Acetic acid, fluoro-, sodium salt
P002	591-06-2	1-Acetyl-2-thiourea
P003	107-02-8	Acrolein
P070	118-06-3	Aldicarb
P004	309-0	Alin

Max. edous waste No.	Chemical abstracts No.	Substance	Chemical abstracts No.	Substance
P049	541-53-7	Dithiocurel	P041	Phosphoric acid, diethyl 4-nitrophenyl ester
P050	115-29-7	Endosulfan	P039	Phosphorothioic acid, O,O-diethyl S-(2-ethylthio)ethyl ester
P066	145-73-3	Endosulfal	P064	Phosphorothioic acid, O,O-diethyl S-(ethylthio)ethyl ester
P051	72-30-8	Endrin	P044	Phosphorothioic acid, O,O-dimethyl S-(2-methylamino)-2-oxoethyl ester
P042	72-20-8	Endrin, & metabolites	P043	Phosphorothioic acid, bis(1-methylthio) ester
P031	51-40-4	Ephedrine	P089	Phosphorothioic acid, O,O-diethyl O-(4-nitrophenyl) ester
P068	460-19-5	Ethanedinitrile	P040	Phosphorothioic acid, O,O-diethyl O-pyrazinyl ester
P066	18752-77-8	Ethanedithioic acid, N-(((methylamino)carbonyl)oxy), methyl ester	P087	O-((4-((dimethylamino)sulfonyl)phenyl) O,O-dimethyl ester
P101	107-12-0	Ethyl cyanide	P071	Phosphorothioic acid, O,O-dimethyl O-(4-nitrophenyl) ester
P054	151-56-4	Ethylamine	P110	Pumaine, isobutyl
P087	52-85-7	Famphur	P110	Pumaine, isobutyl
P056	7782-41-4	Fluorine	P066	Potassium cyanide
P057	640-19-7	Fluorocitramide	P098	Potassium cyanide K(CN)
P058	82-74-8	Fluoroacetic acid, sodium salt	P099	Potassium silver cyanide
P065	828-86-4	Fulminic acid, mercury(2+) salt (R,T)	P070	Propenal, 2-methyl-2-(methylthio)-O-((methylamino)carbonyl)ouma
P069	76-44-8	Heptachlor	P101	Propanenitrile
P062	757-59-4	Hexaethyl silazophosphate	P027	Propanenitrile, 3-chloro-
P118	78-19-8	Hydrazinecarbothiamide	P069	Propanenitrile, 2-hydroxy-2-methyl-
P068	60-34-4	Hydrazine, methyl-	P081	1,2,3-Propanetriol, trisiate (R)
P063	74-90-8	Hydrocyanic acid	P017	2-Propanone, 1-bromo-
P063	74-90-8	Hydrogen cyanide	P102	Propargyl alcohol
P086	7803-51-2	Hydrogen phosphide	P002	2-Propenal
P060	465-73-6	Isoctin	P006	2-Propen-1-ol
P007	2783-98-4	3(2H)-Isotiazole, 5-(aminomethyl)-	P067	75-85-8 1,2-Propylenimine
P082	82-38-4	Mercury, bis(ato)-O(phenyl)-	P102	2-Propyn-1-ol
P065	828-86-4	Mercury luminite (R,T)	P006	4-Pyridinamine
P082	82-75-9	Methanamine, N-methyl-N-nitroso-	P075	Pyridine, 3-(1-methyl-2-pyrrolyl)-, (S), & salts
P016	824-83-9	Methane, isocyanato-	P114	12039-52-0 Selenous acid, diethyl(1+) salt
P016	542-88-1	Methane, ortho-chloro-	P103	Selenourea
P112	506-14-8	Methane, isocyanato-	P104	Silver cyanide
P118	75-70-7	Methanethiol, trichloro-	P104	Silver cyanide Ag(CN)
P050	115-29-7	6,9-Methano-2,4,3-benzodioxathiepin, 6,7,8,9,10,10,10-hexafluoro-1,5,5a,6,9a-hexahydro-, 3-oxide	P106	Sodium azide
P059	76-44-8	4,7-Methano-1H-indene, 1,4,5,6,7,8-heptachloro-3a,4,7,7-tetrahydro-	P108	Sodium cyanide Na(CN)
P066	18752-77-5	Mermomyl	P107	Sodium cyanide Na(CN)
P068	60-34-4	Methyl hydrazine	P108	Sodium cyanide Na(CN)
P064	824-83-9	Methyl isocyanate	P109	Synchroin-10-one, 2,3-dimethyl-
P089	75-86-5	2-Methylacetonitrile	P108	Synchroin, & salts
P071	208-00-0	Methyl parathion	P115	Sulfuric acid, diethyl(1+) salt
P072	86-88-4	alpha-Naphthylthiourea	P109	Tetraethylthiopyrophosphate
P073	13463-39-3	Nickel carbonyl	P110	Tetraethyl lead
P073	13463-39-3	Nickel carbonyl Ni(CO) ₄ , (T-4)-	P111	Tetraethyl pyrophosphate
P074	557-19-7	Nickel cyanide	P112	Tetraisothiazane (R)
P074	557-19-7	Nickel cyanide Ni(CN) ₄	P062	Tetrahydrofuran
P075	54-11-5	Nicotine, & salts	P113	Thalic oxide
P076	10102-43-8	Nitric oxide	P113	Thallium oxide Tl ₂ O
P077	100-01-8	p-Nitrotoluene	P114	Thallium(I) acetate
P078	10102-44-0	Nitrogen dioxide	P115	Thallium(I) sulfide
P078	10102-43-9	Nitrogen oxide NO	P109	Thiophosphoric acid, tetraethyl ester
P081	55-83-0	Nitrogen oxide NO ₂	P046	Thionitrosocarbonic diimide ((H ₂ NCO(S)) ₂) ₂ HN
P081	55-83-0	Nitrocytine (R)	P049	Thiophenol
P082	82-75-8	N-Nitrosodimethylamine	P014	Thiosemicarbazide
P084	4540-10-0	N-Nitrosodimethylamine	P116	Thiourea, (2-chlorophenyl)-
P085	152-16-9	Oxalimethylpyrophosphoramide	P026	Thiourea, 1-naphthylthyl-
P087	20818-12-0	Oxanium oxide O ₂ O ₂ , (T-4)-	P072	Thiourea, phenyl-
P087	20818-12-0	Oxanium tetraoxide	P063	Touzaphene
P088	145-73-3	7-Oxabicyclo(2,2,1)heptane-2,3-dicarboxylic acid	P123	Trichloromethanesulfoxide
P089	56-38-2	Parathion	P118	Vanadic acid, ammonium salt
P034	131-89-5	Phenol, 2-cyanoethyl-4,6-dinitro-	P119	Vanadium pentoxide V ₂ O ₅
P048	51-28-5	Phenol, 2,4-dinitro-	P120	Vanadium pentoxide
P047	534-52-1	Phenol, 2-methyl-4,6-dinitro-, & salts	P064	Vinylamine, N-methyl-N-nitroso-
P020	88-85-7	Phenol, 2-(1-methylpropyl)-4,6-dinitro-	P001	Warfarin, & salts, when present at concentrations greater than 0.3%
P009	131-74-8	Phenol, 2,4,6-trinitro-, ammonium salt (R)	P121	Zinc cyanide Zn(CN) ₂
P082	82-38-4	Phenylmercury acetate	P122	Zinc phosphide Zn ₃ P ₂ , when present at concentrations greater than 10% (R,T)
P083	103-85-5	Phenylthiourea		
P084	288-02-2	Phosazite		
P086	75-44-3	Phosgene		
P086	7803-61-2	Phosphine		

¹ CAS Number given for parent compound only.

(f) The commercial chemical products, manufacturing chemical intermediates, or off-specification commercial chemical products referred to in paragraphs (a) through (d) of this section, are identified as toxic wastes (T), unless otherwise designated and are subject to the small quantity generator exclusion defined in § 261.5 (a) and (g).

(Comment: For the convenience of the regulated community, the primary hazardous properties of these materials have been indicated by the letters T (Toxicity), R (Reactivity), I (Ignitability) and C (Corrosivity). Absence of a letter indicates that the compound is only listed for toxicity.)

These wastes and their corresponding EPA Hazardous Waste Numbers are:

Haz. waste No.	Substance
U001	Acetaldehyde (I)
U004	Acetaldehyde, trichloro-
U187	Acetamide, N-(4-ethoxyphenyl)-
U095	Acetamide, N-(2-fluoroethyl)-
U240	Acetic acid, (2,4-dichlorophenoxy)-, salts & esters
U112	Acetic acid, lead(2+) salt
U144	Acetic acid, thallium(1+) salt
U214	Acetic acid, (2,4,5-trichlorophenoxy)-
see	
F027	
U002	Acetone (I)
U003	Acetone (I, T)
U004	Acetophenone
U006	2-Acetylaminofluorene
U008	Acetyl chloride (C, R, T)
U007	Acrylamide
U008	Acrylic acid (I)
U009	Acrylonitrile
U011	Ammonia (I, T)
U012	Aniline (I, T)
U136	Aniline acid, dimethyl-
U014	Azarene
U015	492-80-8
U016	115-02-4
U010	50-07-7
U187	56-49-5
U016	225-51-4
U187	96-87-3
U192	23950-56-5
U018	56-55-3
U094	57-87-8
U012	82-53-3
U014	492-80-8
U048	3185-93-3
U063	60-11-7
U026	96-53-4
U053	106-48-0
U166	101-14-4
U222	636-21-5
U181	99-55-8
U019	71-43-2
U056	510-16-6
U030	101-55-3
U035	305-03-3
U037	106-90-7
U221	26378-45-2
U026	117-81-7
U066	84-74-2
U068	84-66-2
U102	131-11-3
U107	117-64-0
U070	95-50-1
U071	641-73-1
U072	104-
U060	7

Haz. waste No.	Chemical abstracts No.	Substance
U017	96-87-3	Benzene, (dichloromethyl)-
U223	26471-82-8	Benzene, 1,3-dioxyanilomethyl- (R, T)
U239	1330-20-7	Benzene, dimethyl- (I, T)
U201	106-46-3	1,3-Benzene-diol
U127	118-74-1	Benzene, hexachloro-
U056	110-82-7	Benzene, heptachloro-
U220	106-86-3	Benzene, methyl-
U106	121-14-2	Benzene, 1-methyl-2,4-dinitro-
U108	606-20-2	Benzene, 2-methyl-1,3-dinitro-
U055	96-82-8	Benzene, (1-methylthyl)- (I)
U169	96-93-3	Benzene, nitro-
U185	906-93-5	Benzene, pentachloro-
U185	82-66-6	Benzene, pentachloro-
U020	96-09-9	Benzene sulfonic acid chloride (C, R)
U020	96-09-9	Benzene sulfonic chloride (C, R)
U207	95-94-3	Benzene, 1,2,4,5-tetrachloro-
U061	50-29-3	Benzene, 1,1'-(2,2,2-trichloroethylidene)bis(4-chloro-
U247	72-43-5	Benzene, 1,1'-(2,2,2-trichloroethylidene)bis(4-methoxy-
U224	96-07-7	Benzene, trichloromethyl-
U021	96-35-4	Benzene, 1,3,5-tri-
U021	92-87-5	Benzidine
U202	1-81-07-2	1,2-Benzothiazol(3,2H)-one, 1,1-dioxide, & salts
U203	94-59-7	1,3-Benzothiazole, 5-(2-propenyl)-
U141	120-56-1	1,3-Benzothiazole, 5-(1-propenyl)-
U090	94-56-6	1,3-Benzothiazole, 5-propyl-
U064	189-55-9	Benzotriazole
U248	1-81-81-2	2H-1-Benzopyran-2-one, 4-hydroxy-3-(3-oxo-1-phenylbutyl)-, & salts, when present at concentration of 0.3% or less
U022	50-32-6	Benzo(a)pyrene
U197	106-51-4	p-Benzquinone
U023	94-07-7	Benzotrichloride (C, R, T)
U065	1464-53-5	2,2-Bisoxane
U021	92-87-5	[1,1'-Biphenyl]-4,4'-diamine
U073	91-94-1	[1,1'-Biphenyl]-4,4'-diamine, 3,3'-dichloro-
U091	119-90-4	[1,1'-Biphenyl]-4,4'-diamine, 3,3'-dimethoxy-
U095	119-90-7	[1,1'-Biphenyl]-4,4'-diamine, 3,3'-dimethyl-
U225	75-26-2	Bromoketone
U090	101-55-3	4-Bromophenyl phenyl ether
U128	87-86-3	1,3-Butadiene, 1,1,2,3,4-hexachloro-
U172	924-18-3	1-Butanamine, N-butyl-N-nitroso-
U031	71-36-3	1-Butanol (I)
U159	78-93-3	2-Butanone (I, T)
U160	1338-23-4	2-Butanone, peroxide (R, T)
U053	4170-30-3	2-Butenal
U074	784-41-0	2-Butenoic acid, 2-methyl-, 7-((2,3-dihydroxy-2-(1-methoxyethyl)-3-methyl-1-oxobutyl)imethyl)-, 2,3,5,7-tetrahydro-1H-pyrrolizin-1-yl ester, [1S-(1alpha,2,7(2S),3R',3R'),7alpha]]-
U143	303-34-4	n-Butyl alcohol (I)
U031	71-36-3	Carboxylic acid
U136	75-90-8	Calcium chromate
U032	13785-19-0	Carbamic acid, ethyl ester
U228	61-78-6	Carbamic acid, methyl ester
U178	615-53-2	Carbamic acid, methyl ester, dimethyl-
U097	79-44-7	Carbamic chloride, dimethyl-
U114	111-64-6	Carbamothioic acid, 1,2-ethanedithio-, salts & esters
U042	2303-16-4	Carbamothioic acid, bis(1-methylthyl)-, 5-(2,3-dichloro-2-propenyl) ester
U215	6539-73-9	Carbonic acid, dimethyl(1+) salt
U033	353-50-4	Carbonic dihalide
U166	78-22-1	Carbonochloride acid, methyl ester (I, T)
U033	393-90-4	Carbon anhydride (R, T)
U211	66-23-5	Carbon tetrachloride
U034	78-87-6	Chloral
U035	306-03-3	Chlorambucil
U008	87-74-9	Chloroethane, alpha & gamma isomers
U026	484-03-1	Chloromethane
U037	106-90-7	Chlorobenzene
U038	510-19-6	Chlorobenzene
U039	59-50-7	p-Chloro-m-cresol

Hazardous waste No.	Chemical abstracts No.	Substance
U152	126-06-7	2-Propenenitrile, 2-methyl- (I,T)
U008	78-10-7	2-Propenoic acid (I)
U113	140-88-6	2-Propenoic acid, ethyl ester (I)
U118	97-83-2	2-Propenoic acid, 2-methyl-, ethyl ester
U162	90-82-6	2-Propenoic acid, 2-methyl-, methyl ester (I,T)
U194	107-10-8	n-Propylamine (I,T)
U063	78-87-6	Propylene dichloride
U148	123-33-1	3,6-Pyridazinedione, 1,2-dihydro-
U196	110-86-1	Pyridine
U191	109-06-6	Pyridine, 2-methyl-
U237	66-75-1	2,4-(1H,3H)-Pyrimidinedione, 5-(bis(2-chloroethyl)amino)-
U164	56-04-2	4(1H)-Pyrimidinone, 2,3-dihydro-6-methyl-2-thioxo-
U180	630-55-2	Pyrrolidine, 1-nitroso-
U200	50-55-5	Reserpine
U201	108-46-3	Resorcinol
U202	61-07-2	Saccharin, & salts
U203	94-59-7	Selenite
U204	7783-00-6	Selenous acid
U204	7783-00-6	Selenium dioxide
U206	7488-56-4	Selenium sulfide
U205	7488-56-4	Selenium sulfide SeS ₂ (R,T)
U016	115-02-6	L-Serine, diazoacetate (ester)
See	93-72-1	Silvex (2,4,5-TP)
F027		
U208	16883-66-4	Streptozotocin
U103	77-78-1	Sulfonic acid, dimethyl ester
U189	1314-80-3	Sulfur phosphide (R)
See	93-78-6	2,4,6-T
F027		
U207	95-94-3	1,2,4,5-Tetrachlorobenzene
U208	630-20-6	1,1,1,2-Tetrachloroethane
U209	79-34-5	1,1,2,2-Tetrachloroethane
U210	127-18-4	Tetrachloroethylene
See	68-90-2	2,3,4,6-Tetrachlorophenol
F027		
U213	109-99-9	Tetrahydrofuran (I)
U214	563-68-8	Thallium(I) acetate
U215	6633-73-9	Thallium(I) carbonate
U216	7791-12-0	Thallium(I) chloride
U218	7791-12-0	Thallium chloride TlCl
U217	10102-45-1	Thallium(I) nitrate
U219	62-55-6	Thioacetamide
U153	74-93-1	Thiomethanol (I,T)
U244	137-26-6	Thioperonyldicarbonic diamide [(H ₂ N)C(S)] ₂ S, tetramethyl-
U219	62-56-6	Thiourea
U244	137-26-6	Thram
U220	106-86-3	Toluene
U221	25376-45-6	Toluenediamine
U223	26471-62-5	Toluene diisocyanate (R,T)
U328	95-53-4	o-Toluidine
U363	106-49-0	p-Toluidine
U222	636-21-5	o-Toluidine hydrochloride
U011	61-82-5	1H-1,2,4-Triazol-3-amine
U227	79-00-5	1,1,2-Trichloroethane
U228	79-01-6	Trichloroethylene
U121	75-69-4	Trichloromonofluoromethane
See	95-95-4	2,4,5-Trichlorophenol
F027		
See	68-06-2	2,4,6-Trichlorophenol
F027		
U234	99-35-4	1,3,5-Trinitrobenzene (R,T)
U162	123-63-7	1,3,5-Trioxane, 2,4,6-trimethyl-
U235	126-72-7	Tris(2,3-dibromopropyl) phosphite
U236	72-57-1	Trypan blue
U237	66-75-1	Uracil mustard
U176	759-73-9	Urea, N-ethyl-N-nitroso-
U177	684-93-6	Urea, N-methyl-N-nitroso-
U043	75-01-4	Vinyl chloride
U248	61-81-2	Warfarin, & salts, when present at concentrations of 0.3% or less

Attachment Number 180 NAC1

Hazardous waste No.	Chemical abstracts No.	Substance
U238	1330-20-7	Xylene (I)
U200	50-55-5	Yohimban-16-carboxylic acid, 11,17-dimethoxy-16-[(2,4,5-trimethoxybenzoyloxy)-], methyl ester, (3beta,16beta,17alpha,18beta,20alpha)-
U240	1314-84-7	Zinc phosphide Zn ₃ P ₂ , when present at concentrations of 10% or less

¹ CAS Number given for parent compound only.

(Approved by the Office of Management and Budget under control number 2050-0047) (45 FR 78529, 78541, Nov. 25, 1980)

EDITORIAL NOTE FOR FEDERAL REGISTER citations affecting § 261.33, see the List of CFR Sections Affected in the Finding Aids section of this volume.

~~APPENDIX I - REPRESENTATIVE SAMPLING METHODS~~

The methods and equipment used for sampling waste materials will vary with the form and consistency of the waste materials to be sampled. Samples collected using the sampling protocols listed below, for sampling waste with properties similar to the indicated materials, will be considered by the Agency to be representative of the waste.

Extremely viscous liquid—ASTM Standard D140-70 Crushed or powdered material—ASTM Standard D346-75 Soil or rock-like material—ASTM Standard D420-69 Soil-like material—ASTM Standard D1452-65 Fly Ash-like material—ASTM Standard D2234-76 (ASTM Standards are available from ASTM, 1916 Race St., Philadelphia, PA 19103)

Containerized liquid wastes—"COLIWASA" described in "Test Methods for the Evaluation of Solid Waste, Physical/Chemical Methods," U.S. Environmental Protection Agency, Office of Solid Waste, Washington, D.C. 20460. (Copies may be obtained from Solid Waste Information, U.S. Environmental Protection Agency, 26 W. St. Clair St., Cincinnati, Ohio 45268)

Liquid waste in pits, ponds, lagoons, and similar reservoirs—"Pond Sampler" described in "Test Methods for the Evaluation of Solid Waste, Physical/Chemical Methods,"

This manual also contains additional information on application of these protocols.

* These methods are also described in "Samplers and Sampling Procedures for Hazardous Waste Streams," EPA 600/2-80-018, January 1980.

~~APPENDIX II - EP TOXICITY TEST PROCEDURES~~

~~A. Extraction Procedure (EP)~~

1. A representative sample of the waste to be tested (minimum size 100 grams) shall be obtained using the methods specified in Appendix I or any other method capable of yielding a representative sample within the meaning of Part 260. (For detailed guidance on conducting the various aspects of the EP see "Test Methods for the Evaluation of Solid Waste, Physical/Chemical Methods" (incorporated by reference, see § 260.11).)

2. The sample shall be separated into its component liquid and solid phases using the method described in "Separation Procedure" below. If the solid residue obtained using this method totals less than 0.5% of the original weight of the waste, the residue can be discarded and the operator shall treat the liquid phase as the extract and proceed immediately to Step 8.

3. The solid material obtained from the Separation Procedure shall be evaluated for its particle size. If the solid material has a surface area per gram of material equal to, or greater than, 3.1 cm² or passes through a 9.5 mm (0.375 inch) standard sieve, the operator shall proceed to Step 4. If the surface area is smaller or the particle size larger than specified above, the solid material shall be prepared for extraction by crushing, cutting or grinding the material so that

* The percent solids is determined by drying the filter pad at 80°C until it reaches constant weight and then calculating the percent solids using the following equation:
Percent solids =

$$\frac{(\text{weight of pad + solids}) - (\text{tare weight of pad})}{\text{initial weight of sample}} \times 100$$

TABLE 1.—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES—Continued

Facility	Address	Waste description
Bonmer Industries Inc.	Landrum, SC	Wastewater treatment sludges (EPA Hazardous Waste No. F006) generated from their electroplating operations and contained in evaporation ponds #1 and #2 on August 12, 1987.
Copied Products Corp.	Harrisburg, PA	Devalved wastewater treatment sludges (EPA Hazardous Waste No. F019) generated from the chemical conversion coating of aluminum after September 12, 1986.
Copied Products Corporation	Kendall, IN	Devalved wastewater treatment sludges (EPA Hazardous Waste No. F019) generated from the chemical conversion coating of aluminum after November 17, 1986.
Chamberlain-Faucher, Inc.	Hot Springs, AR	Devalved wastewater treatment sludges (EPA Hazardous Waste No. F019) generated from the chemical conversion coating of aluminum after July 16, 1986.
Chromatol Sewer District	Chromatol, OH	Sludged bottom ash (approximately 35,000 cubic yards) contained in the South Lagoon, on September 13, 1985 which contains EPA Hazardous Waste Nos. F001, F002, F003, F004, and F005.
Conventual Can Co., Dove Corp., North Dr., El Lij and Company.	Olympia, WA Tulsa, OK Oklon, Indiana.	Devalved wastewater treatment sludges (EPA Hazardous Waste No. F019) generated from the chemical conversion coating of aluminum after September 12, 1986. Devalved wastewater treatment sludges (EPA Hazardous Waste No. F006) generated from their electroplating operations after April 28, 1986. Incinerator scrubber liquids, entering and contained in their onsite surface impoundment, and solids settling from these liquids originating from the burning of spent solvents (EPA Hazardous Waste Nos. F002, F003, and F005) contained in their onsite surface impoundment and solids retention area on August 18, 1986 and any new incinerator scrubber mist and solids retention area on August 18, 1986 and any new incinerator scrubber liquids and settled solids generated in the surface impoundment and disposed of in the retention area after August 12, 1986.
EPA's Mobile Incineration System (MSI).	Danney Farm Site, McDowell, MO.	Process wastewater, rotary kiln ash, CHEAF media, and other solids (except spent activated carbon) (EPA Hazardous Waste Nos. F020, F022, F023, F024, F027, and F028) generated during the lead demonstration of EPA's Mobile Incinerator at the Danney Farm Site in McDowell, Missouri, after July 26, 1984, so long as: (1) The incinerator is functioning properly; (2) a grab sample is taken from each tank of wastewater generated and the EP leachate values do not exceed 0.03 ppm for mercury, 0.14 ppm for selenium, and 0.56 ppm for chromium; and (3) a grab sample is taken from each drum of soil or ash generated and a core sample is collected from each CHEAF cell generated and the EP leachate values of daily composites do not exceed 0.044 ppm in ash or CHEAF media for mercury or 0.22 ppm in ash or CHEAF media for selenium. Kiln ash, cyclone ash, separator sludge, and filtered wastewater (except spent activated carbon) (EPA Hazardous Waste No. F027) generated during the treatment of hazardous materials containing 2,4,5-T and Shaver and related materials by the EPA's Mobile Incineration System at the Danney Farm Site in McDowell, Missouri after March 11, 1984, so long as: (1) The incinerator is monitored continuously and is in compliance with operating permit conditions. Should the incinerator fail to comply with the permit conditions relevant to the mechanical operation of the incinerator, RCBS must test the residues generated during the run when the failure occurred according to the requirements of Condition (2) through (5), regardless of whether or not the demonstration in Condition (6) has been made; (2) Four grab samples of wastewater must be composited from the volume of filtered wastewater collected after each eight hour run and, prior to disposal, the composable sample analyzed for the EP toxic metals, nickel, and cyanide. If arsenic, chromium, lead, and silver EP leachate level results exceed 0.44 ppm; barium levels exceed 8.8 ppm; cadmium and selenium levels exceed 4.4 ppm; or cyanide levels exceed 0.02 ppm; nickel levels exceed 4.4 ppm; or cyanide levels exceed 1.6 ppm, the wastewater must be retained to achieve these levels or must be disposed in accordance with Subtitle C of RCRA. Analyses must be performed according to SW-846 methodologies.

TABLE 1.—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES—Continued

Facility	Address	Waste description
		(3) One grab sample must be taken from each drum of kiln ash generated each eight hour run; all grab samples collected during a given eight hour run must be composited to form one composite sample. One grab sample must be taken from each drum of cyclone ash generated during each eight hour run. All samples collected during a given eight hour run must then be composited to form one composite sample. A composite sample of four grab samples of the top sludge must be collected at the end of each eight hour run. Prior to the disposal of the residues from each eight hour run, an EP leachate test must be performed on these composite samples and the leachate analyzed for the EP toxic metals, nickel, and cyanide. If arsenic, chromium, lead, and silver EP leachate level results exceed 0.44 ppm; barium levels exceed 8.8 ppm; cadmium and selenium levels exceed 4.4 ppm; or cyanide levels exceed 0.02 ppm; nickel levels exceed 4.4 ppm; or cyanide levels exceed 1.6 ppm, the waste must be retained to achieve these levels or must be disposed in accordance with Subtitle C of RCRA. Analyses must be performed according to SW-846 methodologies. (4) RCBS must be generated, prior to disposal of residues, verification data from each eight hour run for each treatment residue (i.e. kiln ash, cyclone ash, separator sludge, and filtered wastewater) to demonstrate that the maximum allowable treatment residue concentrations listed below are not exceeded. Samples for RCBS must be collected as specified in conditions (2) and (3). Analyses must be performed according to SW-846 methodologies. Any residues which exceed any of the levels listed below must be retained or must be disposed as hazardous waste and sludge concentrations must not exceed the following levels: Atrazine—0.016 ppm Benzene—0.7 ppm Benzaldehyde—0.43 ppm Benzothiazothione—1.8 ppm Chlorobenzene—0.37 ppm Chloroform—6.4 ppm Chrysenes—170 ppm Dibenz(a,h)anthracene—0.083 ppm Dibenz(b,h)anthracene—4.1 ppm Dichloromethane—2.4 ppm 2,4-Dichlorophenol—40 ppm Dichloroethane—260 ppm Dieldrin—23 ppm Endosulfan I—316 ppm Fluorene—120 ppm Indanol(1,2,3-c)-pyrene—300 ppm Inert polyethylene—210 ppm Nitrocodiphenylamine—130 ppm Phenanthrene—160 ppm Polychlorinated biphenyls—0.31 ppm Tetrahydrothiophene—66 ppm 2,4,5-TP (alkene)—110 ppm 2,4,6-Trichlorophenol—5.8 ppm And detected wastewater concentrations do not exceed the following: Acetone—35 ppm Atrazine—0.00018 ppm Benzene—0.044 ppm Benzothiazothione—0.00037 ppm Benzothiazothione—0.00018 ppm Biphenyl—15 ppm Bis-2-(4-hydroxyphenyl)propane—6.8 ppm Chloroform—0.0024 ppm Chlorobenzene—8.8 ppm Chloroform—0.052 ppm Chrysenes—0.0118 ppm 2,4-D—3.5 ppm Dibenz(a,h)anthracene—0.00006 ppm Dichloromethane—0.042 ppm 1,3-Dichlorobenzene—34 ppm 1,4-Dichlorobenzene—0.86 ppm 1,2-Dichlorobenzene—26 ppm 1,3-Dichlorobenzene—0.044 ppm 2,4-Dichlorophenol—0.86 ppm Dichloroethane—0.78 ppm Diethyl phthalate—4,400 ppm Dieldrin—0.016 ppm Endosulfan I—0.020 ppm

TABLE 1—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES—Continued

Facility	Address	Waste description
Envite Corporation	Canton, Ohio; Harvey, Ohio; Monroe, Ohio; Thomaston, Connecticut; and York, PA.	Overwatered wastewater sludges (EPA Hazardous Waste No. F008) generated from elect plating operations; spent cyanide plating solutions (EPA Hazardous Waste No. F000) generated from electroplating operations; spent cyanide plating solutions from the bottom of plate baths (EPA Hazardous Waste No. F008) generated from electroplating operations where cyanides are used in the process; spent stripping and cleaning bath solutions (EPA Hazardous Waste No. F008) generated from electroplating operations where cyanides are used in the process; spent cyanide solutions from salt bath pot cleaning (EPA Hazardous Waste No. F011) generated from metal heat treating operations; quenching wastewater treatment sludges (EPA Hazardous Waste No. F012) generated from metal heat treat where cyanides are used in the process; wastewater treatment sludges (EPA Hazardous Waste No. F019) generated from the chemical conversion coating of aluminum and stainless steel; hazardous waste sludges (EPA Hazardous Waste No. F019) generated from the chemical conversion coating of aluminum and stainless steel; hazardous waste sludges (EPA Hazardous Waste No. F019) generated from the chemical conversion coating of aluminum and stainless steel; hazardous waste sludges (EPA Hazardous Waste No. F019) generated from the chemical conversion coating of aluminum and stainless steel.
Falconer Glass Indust., Inc. Florida Production Engineering Company. General Cable Co.	Falconer, NY Daytona Beach, Florida Muncie, IN Spreveport Louisiana Elyria, OH	<p>(1) Each batch of treatment residue must be representative of the residue and tested using EPA Toxicity test for arsenic, barium, cadmium, chromium, lead, selenium, silver, zinc and nickel. If the extract concentrations for chromium, lead, arsenic, and silver are 0.315 ppm; barium levels exceed 8.3 ppm; cadmium and selenium exceed 0.003 ppm; mercury exceed 0.0128 ppm; or nickel levels exceed 2,008 ppm, the waste must be treated or managed as a hazardous waste under 40 CFR Parts 262 and 265 and the permitting standards of 40 CFR Part 270.</p> <p>(2) Each batch of treatment residue must be tested for reactive and leachable cyanide. If reactive cyanide levels exceed 250 ppm or leachable cyanide levels (using the EPA Toxicity test without acetic acid adjustment) exceed 1.26 ppm, the waste must be re-treated, managed and disposed as a hazardous waste under 40 CFR Parts 262 to 265 and the permitting standards of 40 CFR Part 270.</p> <p>(3) Each batch of waste must be tested for the total content of specific organic toxicants. The total content of arsenic exceeds 78.8 ppm, 1,2-diphényl hydrazine exceeds 0.1 ppm, methylene chloride exceeds 8.18 ppm, methyl ethyl ketone exceeds 328 ppm, nitroacetophenone exceeds 11.9 ppm, phenol exceeds 1,508 ppm, perchloroethylene exceeds 0.168 ppm, or trichloroethylene exceeds 0.582 ppm, the waste must be tested and disposed as a hazardous waste under 40 CFR Parts 262 and 265 and the permit standards of 40 CFR Part 270.</p> <p>(4) A grab sample must be collected from each batch to form one monthly composite sample which must be tested using GC/MS analysis for the compounds listed in § 261.23 as well as the remaining organics on the priority pollutant list. (See 47 FR 52 November 18, 1982, for a list of the priority pollutants.)</p> <p>(5) The data from conditions 1-4 must be kept on file at the facility for inspection purposes and must be completed, summarized, and submitted to the Administrator by certified semi-annually. The Agency will review this information and if needed will propose to modify or withdraw the exclusion.</p> <p>The organic testing described in conditions 3 and 4 above are not required until the date of promulgation. The Agency's decision to conditionally exclude treatment residue generated from the wastewater treatment systems at these facilities applies only to the wastewater and solids treatment systems as they presently are described in the delisting petition. The exclusion does not apply to the proposed modifications described in the petition as recovery including crystallization, evaporative recovery, evaporative recovery, and ion exchange.</p> <p>Wastewater treatment sludges from the filter press and magnetic drum separator (EPA Hazardous Waste No. F008) generated from electroplating operations after July 18, 1987.</p> <p>This is a one-time exclusion. Wastewater treatment sludges (EPA Hazardous Waste No. F008) generated from electroplating operations and contained in four on-site treatment tanks (EPA Hazardous Waste No. F008) generated from electroplating operations after October 1, 1987. This exclusion does not apply to sludges in any on-site impoundments as of October 1, 1987. This exclusion does not apply to sludges in any on-site impoundments as of October 1, 1987.</p> <p>Overwatered wastewater treatment sludges (EPA Hazardous Waste No. F008) and 1 Hazardous Waste No. F008) generated from electroplating operations after October 1, 1987. This exclusion does not apply to sludges in any on-site impoundments as of October 1, 1987.</p> <p>Wastewater treatment sludges (EPA Hazardous Waste No. F008) generated from electroplating operations and contained in four on-site treatment tanks (EPA Hazardous Waste No. F008) generated from electroplating operations after October 1, 1987. This exclusion does not apply to sludges in any on-site impoundments as of October 1, 1987.</p> <p>The residue generated from the use of the Chem-Tek treatment process on sludge from Hazardous Waste No. F008) generated from electroplating operations and contained in three on-site surface impoundments on November 14, 1988. To ensure that sludge incidents, the following conditions apply to this exclusion:</p>
General Electric Company. Motors Corp., Fisher Body Division.	Elyria, OH	<p>(5) RCB must generate, prior to disposal of residues, verification data from each eight hour run for each treatment residue (i.e., lin ash, cyclone ash, separator sludge, and filtered wastewater) to demonstrate that the residues do not contain lead, pentils, or hexachlorobenzene-p-dioxin or furans at levels of regulatory concern. Samples must be collected as specified in conditions (2) and (3). The TCDD equivalent levels for solids must be less than 5 ppt and for wastewater the levels must be below 0.002 ppt. Any residues with detected dioxin or furane in excess of these levels must be re-treated or must be disposed as acutely hazardous. Method 8290, a high resolution gas chromatography and high resolution mass spectroscopy (HRGC/HRMS) analytical method, must be used. For lead, pentils, and hexachlorobenzene-p-dioxin and furan homologue, the maximum practical quantitation limit must not exceed 16 ppt for solids and 120 ppt for wastewater. For hexachlorobenzene-p-dioxin and furan homologue, the maximum practical quantitation limit must not exceed 37 ppt for solids and 0.3 ppt for wastewater.</p> <p>(6) The test data from conditions (1), (2), (3), (4) and (5) must be kept on file by RCB for inspection purposes and must be completed, summarized, and submitted to the Assistant Administrator for Solid Waste and Emergency Response by certified mail on a monthly basis and when the treatment of the cancelled pesticides and related materials is concluded. The testing requirements for conditions (2), (3), (4), and (5) will continue until RCB provides the Assistant Administrator with the results of four consecutive batch analyses for the pesticides and related materials, none of which exceed the maximum allowable treatment residue concentrations listed in these conditions and the Assistant Administrator notifies RCB that the conditions have been lifted. All data submitted will be placed in the RCB docket.</p> <p>(7) RCB must provide a signed copy of the following certification statement when submitting data in response to the conditions listed above: "Under oath and under penalty of law for the making or submission of false or fraudulent statements or representations, I certify that the information contained in or accompanying this document is true, accurate, and complete. As to the (those) identified section(s) of this document for which I cannot personally verify its (their) accuracy, I certify as the Agency official having supervisory responsibility for the persons who, acting under my direct instructions, made the verification that this information is true, accurate and complete."</p>

TABLE 1—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES—Continued

Facility	Address	Waste description
Goodyear Tire and Rubber Co.	Randolm, NC	(2) One grab sample of the treated waste shall be taken each hour as it is pumped to the holding area (cell) from each water unit. At the end of each production day, the grab samples from the individual water units will be composited and the EP toxicity test will be run on each composite sample. If lead or total chromium concentrations exceed 0.315 ppm or if nickel exceeds 2.17 ppm, in the EP extract, the waste will be removed and treated or disposed of as a hazardous waste.
Gould, Inc.	McConnellsville, OH	(3) The treated waste shall be pumped into bermed cells which are constructed to assure that the treated waste is identifiable and retrievable (i.e., the material can be removed and either disposed of as a hazardous waste or retreated if conditions 1 or 2 are not met). Failure to satisfy any of these conditions would render the exclusion void. This is a one-time exclusion, applicable only to the residue generated from the use of the Chemilux treatment process on the sludge currently contained in the three on-site surface impoundments.
Harover Wire Cloth Division	Harover, Pennsylvania	Dewatered wastewater treatment sludges (EPA Hazardous Waste No. F008) generated from electroplating operations.
Hobson Army Ammunition Plant	Kingsport, Tennessee	Wastewater treatment sludge (EPA Hazardous Waste No. F008) generated from electroplating operations after November 27, 1985.
Imperial Chemicals International Minerals and Chemical Corporation	Salem, IN	Dewatered wastewater treatment sludges (EPA Hazardous Waste Nos. F003, F005, and K044) generated from the manufacturing and processing of explosives and containing spent non-halogenated solvents after November 14, 1986.
Key-Fries, Inc.	Terra Haute, Indiana	Solid resin cakes containing EPA Hazardous Waste No. F002 generated after August 27, 1985, from solvent recovery operations.
Keymark Corp.	Stoney Point, NY	Spent non-halogenated solvents and still bottoms (EPA Hazardous Waste No. F003) generated from the recovery of n-butyl alcohol after August 15, 1986.
Keymark Corp.	Fonda, NY	Biological aeration lagoon sludge and filter press sludge generated after September 21, 1984, which contain EPA Hazardous Waste Nos. F003 and F005 as well as that disposed of in a holding lagoon as of September 21, 1984.
Lederle Laboratories, Inc.	Pearl River, NY	Wastewater treatment sludge (EPA Hazardous Waste No. F019) generated from chemical conversion coating of aluminum after November 27, 1985.
Lincoln Paving Company	Lincoln, NE	Wastewater treatment sludges (EPA Hazardous Waste No. F019) generated from the chemical conversion coating of aluminum and contained in an on-site impoundment on August 12, 1987. This is a one-time exclusion.
Luzren Company	Heyll, MO	Spent non-halogenated solvents and still bottoms (EPA Hazardous Waste Nos. F003 and F005) generated from the recovery of the following solvents: Xylene, acetone, ethyl acetate, ethyl ether, methyl isobutyl ketone, n-butyl alcohol, cyclohexanone, methanol, toluene, and pyridine after August 2, 1988. Exclusion applies to primary and secondary filter press sludges and compost solids generated from these sludges.
Martha Merietta Aerospace	Martha Merietta, Wisconsin	Wastewater treatment sludges (EPA Hazardous Waste No. F008) generated from electroplating operations after November 17, 1986.
Martha Merietta Aerospace	Ocala, Florida	Dewatered wastewater treatment sludges (EPA Hazardous Waste No. F008) generated from electroplating operations after July 16, 1986.
Merc & Company, Incorporated	Eliton, Virginia	Wastewater treatment sludge (EPA Hazardous Waste No. F008) generated from electroplating operations. This exclusion was published on April 20, 1986.
Meytag Company	Newton, VA	Dewatered wastewater treatment sludges (EPA Hazardous Waste No. F008) generated from electroplating operations after January 23, 1987.
Metroplan Sewer District of Cincinnati	Cincinnati, OH	One-time exclusion for fly ash (EPA Hazardous Waste No. F002) from the incineration of wastewater treatment sludge generated from pharmaceutical production processes and stored in an on-site fly ash lagoon. This exclusion was published on May 12, 1989.
		Wastewater treatment sludges (EPA Hazardous Waste No. F008) generated from electroplating operations and wastewater treatment sludges (EPA Hazardous Waste No. F019) generated from the chemical conversion coating of aluminum November 17, 1986.
		Sludge bottom ash sludge (approximately 25,000 cubic yards), contained in the North Lagoon on September 21, 1984, which contains EPA Hazardous Waste Nos. F001, F002, F003, F004, and F005.

Facility	Address	Waste description
Michelin Tire Corp.	Sandy Springs, South Carolina	Dewatered wastewater treatment sludge (EPA Hazardous Waste No. F008) generated from electroplating operations after November 14, 1986.
Monroe Auto Equipment	Paragould, AR	Wastewater treatment sludge (EPA Hazardous Waste No. F008) generated from electroplating operations after November 27, 1985. This exclusion does not apply to the sludge contained in the on-site impoundment.
North American Philips Consumer Electronics Corporation	Greenville, Tennessee	Wastewater treatment sludges (EPA Hazardous Waste No. F008) generated from electroplating operations. This exclusion was published on April 30, 1986.
Parnor C, Inc.	Las Piedra, PR	Dewatered wastewater treatment sludges (EPA Hazardous Waste No. F008) generated from electroplating operations after October 17, 1986.
Phasione Supply Company	Portageville, Missouri	Dewatered wastewater treatment sludges (EPA Hazardous Waste No. F008) generated from electroplating operations after August 15, 1986.
Reynolds Metals Company	Sheffield, AL	Dewatered wastewater treatment sludges (EPA Hazardous Waste No. F019) generated from the chemical conversion coating of aluminum after August 16, 1986.
Siegel-Robert, Inc.	St. Louis, MO	Wastewater treatment sludge (EPA Hazardous Waste No. F008) generated from electroplating operations after November 27, 1986.
Square D Company	Orford, Ohio	Dewatered filter press sludge (EPA Hazardous Waste No. F008) generated from electroplating operations after August 15, 1986.
Synlab Agrisure	Springfield, MO	Mix ash, cyclone ash, separator sludge, and filtered wastewater (except spent activated carbon) (EPA Hazardous Waste No. F020) generated during the treatment of wastewater treatment sludge by the EPA's Mobile Incineration System at the Denney Farm site in McDonald, Missouri after June 2, 1988, so long as: (1) The incinerator is monitored continuously and is in compliance with operating permit conditions. Should the incinerator fail to comply with the permit conditions referred to in the run when the failure occurred according to the requirements of Condition (2) from mechanical operation of the incinerator. Synlab must test the residue generated during the run to determine if it meets the requirements of Condition (7) has been met. (2) Regardless of whether or not the demonstration in Condition (7) has been met, four grab samples of wastewater must be composited from the volume of the wastewater collected after each eight hour run and, prior to disposal, the composite samples must be analyzed for the EP toxic metals, nickel, and cyanide. If any of the composite samples exceed 0.61 ppm; cadmium and selenium levels exceed 0.12 ppm; mercury levels exceed 12 ppm; chromium, lead, and silver EP leachate test results exceed 0.61 ppm; barium level exceed 0.02 ppm; nickel levels exceed 6.1 ppm; or cyanide levels exceed 2.4 ppm, the wastewater must be retreated to achieve these levels or must be disposed in accordance with all applicable hazardous waste regulations. Analyses must be performed according to SW-846 methodologies. (3) One grab sample must be taken from each drum of lily and cyclone ash generated during each eight hour run; all grab collected during a given eight hour run must then be composited to form one composite sample. A composite sample of four grab samples collected from the separator sludge must be collected at the end of each eight hour run. Prior to disposal of the residue from each eight hour run, an EP leachate test must be performed on these composite samples and the leachate analyzed for the EP toxic metals, nickel and cyanide (using a distilled water extraction for the cyanide extraction) to determine if the following maximum allowable treatment residue concentrations listed below are not exceeded. Analyses must be performed according to SW-846 methodologies. Residues which exceed any of the levels listed below must be retreated to achieve the levels or must be disposed in accordance with all applicable hazardous waste regulations. Maximum Allowable Solids Treatment Residue EP Leachate Concentrations (pp/L) Arsenic—1.8 Barium—32 Cadmium—0.32 Chromium—1.8 Lead—1.8 Mercury—0.046 Nickel—18 Selenium—0.32 Silver—1.8 Cyanide—6.8

TABLE 1—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES—Continued

TABLE 1—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES—Continued

Facility	Address	Waste description	Facility	Address	Waste description
		<p>(4) — If Synlex stabilizes any of the ltn and cyclone ash or separator sludge, a Portland cement-type stabilization process must be used and Synlex must collect a composite sample of four grab samples from each batch of stabilized waste. An MEP leachate test must be performed on these composite samples and the leachate analyzed for the EPA toxic metals, nickel, and cyanide (using a distilled water extraction for the cyanide leachate analysis) to demonstrate that the maximum allowable treatment residue concentrations listed in Condition (3) are not exceeded during any run of the MEP extraction. Analyses must be performed according to SW-846 methodologies. Any residues which exceed any of the levels listed in Condition (3) must be retained to achieve these levels or must be disposed in accordance with all applicable hazardous waste regulations. If the residues are stabilized, the analyses required in the condition supersede the analyses required in Condition (3).</p> <p>(5) Synlex must generate, prior to disposal of residues, verification data from each eight hour run from each treatment residue (i.e., ltn and cyclone ash, separator sludge, and filtered wastewater) to demonstrate that the maximum allowable treatment residue concentrations listed below are not exceeded. Samples must be collected as specified in Conditions (2) and (3). Analyses must be performed according to SW-846 methodologies. Any solid or liquid residues which exceed any of the levels listed below must be retained to achieve these levels or must be disposed in accordance with Subtitle C of RCRA.</p> <p>Maximum Allowable Wastewater Concentrations (ppm):</p> <p>Benz(a)anthracene—1x10⁻⁴ Benzofluoranthene—4x10⁻⁶ Benzofluoranthene—2x10⁻⁴ Chloroform—0.07 Chrysene—0.002 Dibenz(a,h)anthracene—8x10⁻⁸ 1,2-Dichloroethane—0.06 Dichloromethane—0.06 Indenol,1,2,3-cd-pyrene—0.002 Polychlorinated biphenyls—1x10⁻⁴ 1,2,4,5-Tetrachlorobenzene—0.13 2,3,4,6-Tetrachlorobenzene—12 Toluene—120 Trichloroethylene—0.04 2,4,5-Trichlorophenol—8 2,4,6-Trichlorophenol—0.02 Maximum Allowable Solid Treatment Residue Concentrations (ppm):</p> <p>Benz(a)anthracene—1.1 Benzofluoranthene—0.43 Benzofluoranthene—1.8 Chloroform—5.4 Chrysene—170 Dibenz(a,h)anthracene—0.0633 Dichloromethane—2.4 1,2-Dichloroethane—4.1 Indenol,1,2,3-cd-pyrene—330 Polychlorinated biphenyls—0.31 1,2,4,5-Tetrachlorobenzene—720 Trichloroethylene—8 2,4,6-Trichlorophenol—3.9</p> <p>(6) Synlex must generate, prior to disposal of residues, verification data from each eight hour run for each treatment residue (i.e., ltn and cyclone ash, separator sludge, and filtered wastewater) to demonstrate that the residues do not contain ltns, pentas-, or hexachloro-dibenzop-dioxins or ltns at levels of regulatory concern. Samples must be collected as specified in Conditions (2) and (3). The TCDD equivalent levels for wastewaters must be less than 2 ppb and less than 5 ppb for the solid treatment residues. Any residues with detected dioxins or ltns in excess of these levels must be retained or must be disposed as acutely hazardous. Method 8280, a high resolution gas chromatography and high resolution mass spectroscopy (HRGC/HRMS) analytical method, must be used. For ltns, and pentachlorinated dioxin and ltns homologs, the maximum practical quantitation limit must not exceed 16 ppb for solids and 120 ppb for wastewaters. For hexachlorodioxin, the maximum practical quantitation limit must not exceed 37 ppb for solids and 300 ppb for wastewaters.</p> <p>(7)(A) The test data from Conditions (1), (2), (3), (4), (5) and (6) must be kept on file by Synlex for inspection purposes and must be compiled, summarized, and submitted to the Region Chief, Variance Section, PSD/O/SW (WH-540), US EPA, 401 M Street, S.W., Washington, D.C. 20460 by certified mail on a monthly basis and when the treatment of the lagoon sludge is concluded. All data submitted will be placed in the RCRA docket.</p>	SR of Tennessee, Tennessee Electric, Inc.	Fltger, TN	
			Texas Instruments, Inc.	Dallas, TX	
			TCI Environmental Systems, Inc.	Holland, Ohio	
					<p>(8) The testing requirements for Conditions (2), (3), (4), (5), and (6) will continue until Synlex provides the Region Chief, Variance Section, with the results of four consecutive batch analyses for the petitioned wastes, none of which exceed the maximum allowable treatment residue concentrations listed in these conditions and the Region Chief, Variance Section, notifies Synlex that the conditions have been lifted.</p> <p>(9) Synlex must provide a signed copy of the following certification statement when submitting data in response to the conditions listed above: "Under oath and criminal penalty of law for the making or submission of false or fraudulent statements or representations, I certify that the information contained in it accompanying this document is true, accurate, and complete. As to the (those) identified sections of the document for which I cannot personally verify its (their) accuracy, I certify as the company official having supervisory responsibility for the persons who, acting under my direct instructions, made the verification that the information is true, accurate and complete."</p> <p>Designated wastewater treatment sludge (EPA Hazardous Waste No. F006) generated from the copper, nickel, and chromium electroplating of plastic parts after November 17, 1986, designated wastewater treatment sludge (EPA Hazardous Waste No. F006) generated from electroplating operations after November 17, 1986. To ensure chromium levels do not exceed the regulatory standards there must be continuous batch testing of the filter press sludge for chromium for 45 days after the exclusion is granted. Each batch of treatment residue must be representatively sampled and tested using the EP toxicity test for chromium. This data must be kept on file at the facility for inspection purposes. If the extract levels exceed 0.622 ppm of chromium the waste must be managed and disposed as a hazardous waste. If these conditions are not met, the exclusion does not apply. This exclusion does not apply to sludges in any on-site impoundments as of the date Wastewater Treatment Sludge (EPA Hazardous Waste No. F006 and F019) generated after August 27, 1985, from their electroplating operations that have been batch tested for cadmium using the EP toxicity procedure and have been found to contain less than 0.20 ppm cadmium in the EP extract. Wastewater treatment sludges that exceed this level will be considered a hazardous waste.</p> <p>Designated wastewater treatment sludge (EPA Hazardous Waste No. F006) generated from electroplating operations after November 17, 1986. To ensure that hazardous constituents are not present in the waste at levels of regulatory concern, the facility must implement a contingency testing program for the petitioned wastes. This testing program must meet the following conditions for the exclusion to be valid:</p> <p>(1) Each batch of treatment residue must be representatively sampled and tested using the total oil and grease test and the EP Toxicity Test (or the City Waste EP test, if the oil and grease content of the waste exceeds one percent) for arsenic, barium, bismuth, cadmium, chromium, lead, selenium, silver, mercury, and nickel. If the extract concentrations for chromium, lead, selenium, silver, mercury, and nickel exceed 0.013 ppm; chromium and selenium levels exceed 0.043 ppm; mercury levels exceed 0.013 ppm; or cadmium levels exceed 2.2 ppm, the waste will be retained or managed and disposed as a hazardous waste under 40 CFR Part 262 to 266 and the permitting standards of 40 CFR Part 270.</p> <p>(2) Each batch of treatment residue must be tested for reactive and leachable cyanide. If the reactive cyanide levels exceed 350 ppm or leachable cyanide level (using the EP Toxicity Test without sonic acid equipment) exceed 1.26 ppm, the waste must be re-treated or managed and disposed as a hazardous waste under 40 CFR Parts 262 to 266 and the permitting standards of 40 CFR Part 270.</p> <p>(3) Each batch of the waste must be tested for the total content of the following organic nutrients. If the total content of any of the constituents exceeds the maximum levels shown, the waste must be managed and disposed as a hazardous waste under 40 CFR Parts 262 to 266 and the permitting standards of 40 CFR Part 270.</p> <p>Compound and Maximum Allowable Levels (ppm)</p> <p>Acetone, 54.8 Anthracene, 78.8 Benzene, 0.108 p-Chloro-m-cresol, 133 1,1-Dichloroethane, 0.01 Fluorene, 10.4 Methylen chloride, 8.2 Methyl ethyl ketone, 326 n-Hexachlorocyclopentadiene, 11.9 Phenanthrene, 14 Trichloroethylene, 0.166 Toluene, 0.56 Chloroform, 0.013 1,2-Dichloroethane, 0.0063 1,2,4-trimethylbenzene, 231 2,4-Dinitrophenol, 12.5 Vinyl chloride, 0.18</p>

Facility	Address	Waste description
Trid Environmental Systems, Inc.	Nashville, Tennessee	<p>(4) A grab sample must be collected from each batch to form one monthly composite sample, which must be tested using GC/MS analysis for the compounds shown above as well as the remaining organics on the priority pollutant list. (See 47 FR 52008, November 19, 1982, for a list of the priority pollutants.)</p> <p>(5) The test data from conditions 1-4 must be kept on file at the facility for inspection purposes and must be compiled, summarized, and submitted to the Administrator by certified mail on a semiannual basis. The Agency will review this information and if needed, will propose to modify or withdraw the exclusion. The organics testing described in conditions 3 and 4 above is not required until May 18, 1987. The Agency's decision to conditionally exclude the treatment residue generated from the wastewater treatment system at the facility applies only to the wastewater treatment residue as described in the petition.</p> <p>Dewatered wastewater treatment sludges (EPA Hazardous Waste No. F019) generated from chemical conversion coating of aluminum after November 17, 1986. To ensure that hazardous constituents are not present in the waste at levels of regulatory concern, the facility must implement a contingency testing program for the petitioned wastes. The testing program must meet the following conditions for the exclusion to be valid:</p> <p>(1) Each batch of treatment residue must be representatively sampled and tested using the total oil and grease test and the EP Toxicity test (or the City Waste EP test, if the oil and grease content of the waste exceeds one percent) for arsenic, barium, cadmium, chromium, lead, selenium, silver, mercury, and nickel. If the extract concentrations for chromium, lead, selenium, silver, mercury, and nickel exceed 0.044 ppm; or cadmium and selenium levels exceed 0.22 ppm; mercury levels exceed 0.044 ppm; or nickel levels exceed 7.8 ppm, the waste will be re-treated or managed and disposed as a hazardous waste under 40 CFR Parts 263 to 265 and the permitting standards of 40 CFR Part 270.</p> <p>(2) Each batch of treatment residue must be tested for reactive and leachable cyanide. If the reactive cyanide levels exceed 250 ppm or leachable cyanide levels (using the EP Toxicity test without acidic acid adjustment) exceed 4.4 ppm, the waste must be re-treated or managed and disposed as a hazardous waste under 40 CFR Parts 263 to 265 and the permitting standards of 40 CFR Part 270.</p> <p>(3) Each batch of the waste must be tested for the total content of the following organic toxicants. If the total content of any of the constituents exceeds the maximum levels shown, the waste must be managed and disposed as a hazardous waste under 40 CFR Parts 263 to 265 and the permitting standards of 40 CFR Part 270.</p> <p style="text-align: center;">Compound and Maximum Acceptable Levels (ppm)</p> <p>Acrolein, 363 Anthracene, 492 Benzene, 0.68 p-Chloro-m-cresol, 848 1,1-Dichloroethane, 0.068 Fluorene, 66.7 Methylene chloride, 52.4 m-Nitroodiphenylamine, 76.1 Phenanthrene, 89 Tetrahydrothiophene, 1.2 Trichloroethylene, 3.78 Chloroform, 0.081 1,2-Dichloroethane, 0.053 2,4-Dimethylphenol, 79.7 Vinyl chloride, 1.16 1,2-Diphenylhydrazine, 0.005</p> <p>(4) A grab sample must be collected from each batch to form one monthly composite sample, which must be tested using GC/MS analysis for the compounds shown above as well as the remaining organics on the priority pollutant list. (See 47 FR 52008, November 19, 1982, for a list of the priority pollutants.)</p> <p>(5) The test data from conditions 1-4 must be kept on file at the facility for inspection purposes and must be compiled, summarized, and submitted to the Administrator by certified mail on a semiannual basis. The Agency will review this information and if needed, will propose to modify or withdraw the exclusion. The organics testing described in conditions 3 and 4 above is not required until May 18, 1987. The Agency's decision to conditionally exclude the treatment residue generated from the wastewater treatment system at the facility applies only to the wastewater treatment residue as described in the petition.</p> <p>Dewatered wastewater treatment sludges (EPA Hazardous Waste No. F008) generated from electroplating operations after November 17, 1986. To ensure that hazardous constituents are not present in the waste at levels of regulatory concern, the facility must implement a contingency testing program for the petitioned wastes. The testing program must meet the following conditions for the exclusion to be valid:</p>
United Technologies Automotive, Inc.	Decatur, Alabama	<p>(1) Each batch of treatment residue must be representatively sampled and tested using the total oil and grease test and the EP Toxicity test (or the City Waste EP test, if the oil and grease content of the waste exceeds one percent) for arsenic, barium, cadmium, chromium, lead, selenium, silver, mercury, and nickel. If the extract concentrations for chromium, lead, selenium, silver, mercury, and nickel exceed 0.013 ppm; or cadmium and selenium levels exceed 0.063 ppm; mercury levels exceed 0.013 ppm; or nickel levels exceed 2.3 ppm, the waste will be re-treated or managed and disposed as a hazardous waste under 40 CFR Parts 263 to 265 and the permitting standards of 40 CFR Part 270.</p> <p>(2) Each batch of treatment residue must be tested for reactive and leachable cyanide. If the reactive cyanide levels exceed 250 ppm or leachable cyanide levels (using the EP Toxicity test without acidic acid adjustment) exceed 1.28 ppm, the waste must be re-treated or managed and disposed as a hazardous waste under 40 CFR Parts 263 to 265 and the permitting standards of 40 CFR Part 270.</p> <p>(3) Each batch of the waste must be tested for the total content of the following organic toxicants. If the total content of any of the constituents exceeds the maximum levels shown, the waste must be managed and disposed as a hazardous waste under 40 CFR Parts 263 to 265 and the permitting standards of 40 CFR Part 270.</p> <p style="text-align: center;">Compound and Maximum Acceptable Levels (ppm)</p> <p>Acrolein, 54.8 Anthracene, 76.8 Benzene, 0.108 p-Chloro-m-cresol, 133 1,1-Dichloroethane, 0.01 Fluorene, 10.4 Methylene chloride, 8.2 Methyl ethyl ketone, 326 n-Nitroodiphenylamine, 11.9 Phenanthrene, 14 Tetrahydrothiophene, 0.168 Trichloroethylene, 0.68 Chloroform, 0.013 1,2-Dichloroethane, 0.0083 1,2-Dioxo-Dichloroethylene, 231 2,4-Dimethylphenol, 12.5 Vinyl chloride, 0.18</p> <p>(4) A grab sample must be collected from each batch to form one monthly composite sample, which must be tested using GC/MS analysis for the compounds shown above as well as the remaining organics on the priority pollutant list. (See 47 FR 52008, November 19, 1982, for a list of the priority pollutants.)</p> <p>(5) The test data from conditions 1-4 must be kept on file at the facility for inspection purposes and must be compiled, summarized, and submitted to the Administrator by certified mail on a semiannual basis. The Agency will review this information and if needed, will propose to modify or withdraw the exclusion. The organics testing described in conditions 3 and 4 above is not required until May 18, 1987. The Agency's decision to conditionally exclude the treatment residue generated from the wastewater treatment system at the facility applies only to the wastewater treatment residue as described in the petition.</p> <p>Dewatered wastewater treatment sludge (EPA Hazardous Waste No. F019) generated from the chemical conversion of aluminum after April 28, 1986.</p>
Jeffersonville, IN.	Jeffersonville, IN.	<p>Wastewater Treatment sludges (EPA Hazardous Waste No. F008) generated from electroplating operations and contained in two on-site lagoons on August 18, 1985. This is one-time exclusion from the incineration of Vertac till bottoms. This exclusion was published on June 26, 1989.</p>
U.S. EPA Combustion Research Facility.	Decatur, Alabama	<p>Retreated wastewater treatment sludges (EPA Hazardous Waste No. F008) previously generated from electroplating operations and currently contained in an on-site surface impoundment after September 26, 1985. This is a one-time exclusion for the residue wastes only. This exclusion does not relieve the waste unit from regulatory compliance under Subtitle C.</p>
U.S. Nameplate Company, Inc.	Mount Vernon, Iowa	<p>Wastewater treatment sludge filter cake (EPA Hazardous Waste No. F019) generated from the chemical conversion coating of aluminum. This exclusion was published on February 1, 1989.</p>
VAW of America Incorporated.	St. Augustine, Florida	<p>Wastewater treatment sludges (EPA Hazardous Waste No. F008) generated from electroplating operations after November 17, 1986. To ensure that hazardous constituents are not present in the waste at levels of regulatory concern, the facility must implement a contingency testing program for the petitioned wastes. The testing program must meet the following conditions for the exclusion to be valid:</p>

TABLE 1—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES—Continued

Facility	Address	Waste description
Vermont American Corp	Newark, OH	Wastewater treatment sludge (EPA Hazardous Waste No. F006) generated from electroplating operations after November 27, 1985.
Watwood Industries	Pocahontas, AR	Wastewater treatment sludges (EPA Hazardous Waste No. F006) generated from electroplating operations after dewatering and held on-site on July 17, 1986 and any such sludge generated (after dewatering) after July 17, 1986.
Watershed Arsenal	Watershed, NY	Wastewater treatment sludges (EPA Hazardous Waste No. F006) generated from electroplating operations after January 10, 1986.
William L. Bonnell Co.	Carthage, TN	Dewatered wastewater treatment sludges (Vacuum filter sludge) (EPA Hazardous Waste No. F019) currently generated from the chemical conversion coating of aluminum after October 17, 1986. This exclusion does not apply to sludges in the on-site storage impoundments.
William L. Bonnell Co.	Newnan, Georgia	Dewatered wastewater treatment sludges (EPA Hazardous Waste No. F019) generated from the chemical conversion coating of aluminum after November 14, 1986. This exclusion does not include sludges contained in Bonnell's on-site surface impoundments.
Windsor Plastics, Inc.	Evansville, IN	Spent non-halogenated solvents and still bottoms (EPA Hazardous Waste No. F003) generated from the recovery of acetone after November 17, 1986.

TABLE 2—WASTES EXCLUDED FROM SPECIFIC SOURCES

Facility	Address	Waste description
American Cyanamid	Hannibal, Missouri	Wastewater and sludge (EPA Hazardous Waste No. K019) generated from the washing and stripping of phosphate production and contained in on-site lagoons on May 8, 1987, and such wastewater and sludge generated after May 8, 1987.
Amoco Oil Co.	Wood River, IL	150 million gallons of DAF from petroleum refining contained in four surge ponds after treatment with the Chemtrix stabilization process. This waste contains EPA Hazardous Waste No. K048. This exclusion applies to the 150 million gallons of waste after chemical stabilization as long as the mixing ratio of the reagent with the waste are monitored continuously and do not vary outside of the limits presented in the demonstration samples. One grab sample is taken each hour from each treatment unit, composited, and EP toxicity tests performed on each sample. If the waste that was processed during the composting period is the EP extract, then the waste that was processed during the composting period is considered hazardous; the treatment residue shall be pumped into bermed cells to ensure that the waste is identifiable in the event that removal is necessary.
Bethlehem Steel Corp.	Steeltown, PA	Uncured and cured chemically stabilized electric arc furnace dust/sludge (CSEAFD) treatment residue (K061) generated from the primary production of steel after May 22, 1988. This exclusion is conditioned upon the data obtained from Bethlehem's full-scale CSEAFD treatment facility because Bethlehem's original data were obtained from a laboratory-scale CSEAFD treatment process. To ensure that hazardous constituents are not present in the waste at levels of regulatory concern once the full-scale treatment facility is in operation, Bethlehem must implement a testing program for the exclusion. This testing program must meet the following conditions for the exclusion to be valid: (1) <i>Testing:</i> (A) <i>Initial Testing:</i> During the first four weeks of operation of the full-scale treatment system, Bethlehem must collect representative grab samples of each treated batch of the CSEAFD and composite the grab samples daily. The daily composites, prior to disposal, must be analyzed for the EP leachate concentrations of all the EP toxic metals, nickel and cyanide (using distilled water in the cyanide extractions), and the total constituent concentrations of reactive sulfide and reactive cyanide. Analyses must be performed according to SW-846 methodologies. Bethlehem must report the analytical test data obtained during the initial period no later than 90 days after the treatment of the first full-scale batch. (B) <i>Subsequent Testing:</i> Bethlehem must collect representative grab samples from every treated batch of CSEAFD generated daily and composite all of the grab samples to produce a weekly composite sample. Bethlehem then must analyze each weekly composite sample for the EP leachate concentrations of all the EP toxic metals and nickel. Analyses must be performed according to SW-846 methodologies. The analytical data, including all quality control information, must be compiled and maintained on site for a minimum of three years. These data must be furnished upon request and made available for inspection by any employee or representative of EPA or the State of Pennsylvania. (2) <i>Dewatering levels:</i> If the EP extract concentrations resulting from the testing in condition (1)(A) or (1)(B) for chromium, lead, arsenic, or silver exceed 0.315 mg/l for barium exceeds 6.3 mg/l for cadmium or selenium exceed 0.065 mg/l, for mercury exceeds 0.0126 mg/l or for nickel exceeds 0.0126 mg/l, for cyanide exceeds 1.26 mg/l, or total reactive cyanide or total reactive sulfide levels exceed 250 mg/kg and 600 mg/kg, respectively, the waste must either be re-treated or managed and disposed in accordance with Subtitle C of RCRA.

TABLE 2—WASTES EXCLUDED FROM SPECIFIC SOURCES—Continued

Facility	Address	Waste description
Bethlehem Steel Corp.	Johnstown, PA	(3) <i>Data submission:</i> Within one week of system start-up, Bethlehem must notify the Section Chief, Variance Section (see address below) when their full-scale stabilization system is on-line and waste treatment has begun. All data obtained through the initial testing condition (1)(A) must be submitted to the Section Chief, Variance Section, PSPD/O&W (OS-343), U.S. EPA, 401 M Street, S.W., Washington, DC 20460 within the time period specified in condition (1)(A). At the Section Chief's request, Bethlehem must submit analytical data obtained through condition (1)(B) to the above address, within the time period specified by the Section Chief. Failure to submit the required data obtained from either condition (1)(A) or (1)(B) within the specified time periods will be considered by the Agency sufficient basis to revoke Bethlehem's exclusion to the extent directed by EPA. A data submission must be accompanied by the following certification statement: "I, _____, an authorized representative of Bethlehem Steel Corporation, certify that the information furnished to you for the making or submission of false or fraudulent statements or representations pursuant to the applicable provisions of the Federal Code of Regulations, which include, but may not be limited to, 18 U.S.C. 6929, 1. I certify that the information contained in or accompanying this document is true, accurate and complete. "As to the (those) identified section(s) of this document for which I cannot personally verify the information is true, accurate and complete, I certify as the company official having supervisory responsibility for the persons who, acting under my direct instructions, made the verification that the information is true, accurate and complete. "In the event that any of the information is determined by EPA in its sole discretion to be false, inaccurate or incomplete, and upon conveyance of the fact to the company, I recognize and agree that this exclusion of wastes will be void as if it never had effect to the extent directed by EPA and that the company will be liable for any actions taken in contravention of the company's RCRA and CERCLA obligations premised upon the company's reliance on the void exclusion." Uncured and cured chemically stabilized electric arc furnace dust/sludge (CSEAFD) treatment residue (K061) generated from the primary production of steel after May 22, 1988. This exclusion is conditioned upon the data obtained from Bethlehem's full-scale CSEAFD treatment facility because Bethlehem's original data were obtained from a laboratory-scale CSEAFD treatment process. To ensure that hazardous constituents are not present in the waste at levels of regulatory concern once the full-scale treatment facility is in operation, Bethlehem must implement a testing program for the exclusion. This testing program must meet the following conditions for the exclusion to be valid: (1) <i>Testing:</i> (A) <i>Initial Testing:</i> During the first four weeks of operation of the full-scale treatment system, Bethlehem must collect representative grab samples of each treated batch of the CSEAFD and composite the grab samples daily. The daily composites, prior to disposal, must be analyzed for the EP leachate concentrations of all the EP toxic metals, nickel and cyanide (using distilled water in the cyanide extractions), and the total constituent concentrations of reactive sulfide and reactive cyanide. Analyses must be performed according to SW-846 methodologies. Bethlehem must report the analytical test data obtained during the initial period no later than 90 days after the treatment of the first full-scale batch. (B) <i>Subsequent Testing:</i> Bethlehem must collect representative grab samples from every treated batch of CSEAFD generated daily and composite all of the grab samples to produce a weekly composite sample. Bethlehem then must analyze each weekly composite sample for the EP leachate concentrations of all the EP toxic metals and nickel. Analyses must be performed according to SW-846 methodologies. The analytical data, including all quality control information, must be compiled and maintained on site for a minimum of three years. These data must be furnished upon request and made available for inspection by any employee or representative of EPA or the State of Pennsylvania. (2) <i>Dewatering levels:</i> If the EP extract concentrations resulting from the testing in condition (1)(A) or (1)(B) for chromium, lead, arsenic, or silver exceed 0.315 mg/l, for barium exceeds 6.3 mg/l for cadmium or selenium exceed 0.065 mg/l, for mercury exceeds 0.0126 mg/l or for nickel exceeds 0.0126 mg/l, for cyanide exceeds 1.26 mg/l, or total reactive cyanide or total reactive sulfide levels exceed 250 mg/kg and 600 mg/kg, respectively, the waste must either be re-treated or managed and disposed in accordance with Subtitle C of RCRA. (3) <i>Data submission:</i> Within one week of system start-up, Bethlehem must notify the Section Chief, Variance Section (see address below) when their full-scale stabilization system is on-line and waste treatment has begun. All data obtained through the initial testing condition (1)(A) must be submitted to the Section Chief, Variance Section, PSPD/O&W (OS-343), U.S. EPA, 401 M Street, S.W., Washington, DC 20460 within the time period specified in condition (1)(A). At the Section Chief's request, Bethlehem must submit analytical data obtained through condition (1)(B) to the above address, within the time period specified by the Section Chief. Failure to submit the required data obtained from either condition (1)(A) or (1)(B) within the specified time periods will be considered by the Agency sufficient basis to revoke Bethlehem's exclusion to the extent directed by EPA. Data submission must be accompanied by the following certification statement:

Facility	Address	Waste description
<p>Enville Corporation</p>	<p>Canton, Ohio; Harvey, Illinois; Thomaston, Connecticut, and York, PA.</p>	<p>Spent pickle liquor (EPA Hazardous Waste No. K062) generated from steel finishing operations of facilities within the iron and steel industry (ISIC Code 331) and 3327 wastewater treatment sludge (EPA Hazardous Waste No. K002) generated from the production of chrome yellow and orange pigments; wastewater treatment sludge (EPA Hazardous Waste No. K002) generated from the production of methylene orange pigments; wastewater treatment sludge (EPA Hazardous Waste No. K004) generated from the production of zinc yellow pigments; wastewater treatment sludge (EPA Hazardous Waste No. K005) generated from the production of chrome green pigments; wastewater treatment sludge (EPA Hazardous Waste No. K006) generated from the production of iron blue pigment chrome oxide green pigments (anhydrous and hydrated); wastewater treatment sludge (EPA Hazardous Waste No. K008) generated from the production of iron blue pigment chrome oxide green pigments after November 14, 1986. To ensure that hazardous constituents are not present in the waste at levels of regulatory concern, the facility must implement a contingency testing program for the petitioned wastes. This testing program must meet the following conditions for the exclusion to be valid:</p> <ul style="list-style-type: none"> (1) Each batch of treatment residue must be representative of the full-scale treatment residue (EPA Toxicity test for arsenic, barium, cadmium, chromium, lead, selenium, silver, mercury and nickel). If the extract concentrations for chromium, lead, arsenic, and silver exceed 0.315 ppm; barium levels exceed 6.3 ppm; cadmium and selenium exceed 0.053 ppm; mercury exceeds 0.0126 ppm; or nickel levels exceed 2,206 ppm, the waste must be treated or managed and disposed as a hazardous waste under 40 CFR Parts 262 to 265 and the permitting standards of 40 CFR Part 270. (2) Each batch of treatment residue must be tested for reactive and leachable cyanide. If reactive cyanide levels exceed 260 ppm; or leachable cyanide levels (using the E Toxity test without scaling acid adjustment) exceed 1.26 ppm, the waste must be treated or managed and disposed as hazardous waste under 40 CFR Parts 262 to 265 and the permitting standards of 40 CFR Part 270. (3) Each batch of waste must be tested for the total content of specific organic toxicants, and the total content of anthracene exceeds 76.9 ppm, 1,2-diphenyl ethane exceeds 0.0 ppm, methylene chloride exceeds 9.18 ppm, methyl ethyl ketone exceeds 328 ppm, nitrophenol/amine exceeds 11.8 ppm, phenol exceeds 1,668 ppm, benzotrithiopyrene exceeds 0.188 ppm, or nitrobenzene exceeds 0.592 ppm, the waste must be treated and disposed as a hazardous waste under 40 CFR Parts 262 to 265 and the permitting standards of 40 CFR Part 270. (4) A grab sample must be collected from each batch to form one monthly composite sample which must be tested using GC/MS analysis for the compounds listed in 40 CFR Part 261.102, for a list of the priority pollutants. (See 47 FR 823 November 19, 1982, for a list of the priority pollutants.) (5) The data from conditions 1-4 must be kept on file at the facility for inspection purposes and must be compiled, summarized, and submitted to the Administrator by certified semi-annually. The Agency will review the information and if needed will propose a modification or withdrawal of the exclusion. The organic testing described in conditions 3 and above is not required until six months from the date of promulgation. The Agency decision to conditionally exclude the treatment residue generated from the wastewater treatment systems at these facilities applies only to the wastewater and solids treatment systems as they presently exist as described in the delisting petition. The exclusion does not apply to the proposed process additions described in the petition as recovery including crystallization, electrolytic metal recovery, evaporative recovery, and ion change.
<p>LCP Chemical</p>	<p>Orrington, ME</p>	<p>Brine purification muds and wastewater treatment sludges generated after August 27, 1987 from their chlor-alkali manufacturing operations (EPA Hazardous Waste Nos. K071 and K106) that have been batch tested for mercury using the EPA toxicity procedures and found to contain less than 0.05 ppm mercury in the EP extract. Brine purification muds and wastewater treatment sludges that exceed this level will be considered hazardous waste.</p>
<p>Meal Corp</p>	<p>Peekskill, NY</p>	<p>Wastewater treatment sludge (EPA Hazardous Waste Nos. K006 and K007) generated from the production of chrome oxide green and iron blue pigments after November 27, 1986. Brine purification muds (EPA Hazardous Waste No. K071) generated from the mercury processes in chlorine production, where separately pretreated brine is not used after August 15, 1986.</p>
<p>Monanto Industrial Chemicals Company</p>	<p>Saugus, Illinois</p>	<p>Wastewater treatment sludge (EPA Hazardous Waste No. K008) generated from the production of chrome oxide green and iron blue pigments after November 27, 1986.</p>
<p>CF&I Steel Corporation</p>	<p>Pueblo, Colorado</p>	<p>"Under civil and criminal penalty of law for the making or submission of false or fraudulent statements or representations (pursuant to the applicable provisions of the Federal Code which include, but may not be limited to, 18 U.S.C. 892B), I certify that the information contained in or accompanying the document is true, accurate and complete.</p> <p>"As to the (those) identified section(s) of this document for which I cannot personally verify its (their) truth and accuracy, I certify as the company official having supervisory responsibility for the persons who, acting under my direct instructions, made the verification that the information is true, accurate and complete.</p> <p>"In the event that any of this information is determined by EPA in its sole discretion to be false, inaccurate or incomplete, and upon conveyance of this fact to the company, I recognize and agree that this exclusion of wastes will be void as if it never had effect to the extent directed by EPA and that the company will be liable for any actions taken in contravention of the company's RCRA and CERCLA obligations premised upon the company's reliance on the void exclusion."</p> <p>(1) Testing:</p> <p>(A) Initial Testing: During the first four weeks of operation of the full-scale treatment system, CF&I must collect representative grab samples of each treated batch of the CSEAFD and composite the grab samples daily. The daily composites, prior to disposal, must be analyzed for the EP leachate concentrations of all the EP toxic metals, nickel, and cyanide (using distilled water in the cyanide extractions), and the total constituent concentrations of reactive sulfide and reactive cyanide. Analyses must be performed according to SW-648 methodologies. CF&I must report the analytical test data obtained during this initial period no later than 90 days after the treatment of the first full-scale batch.</p> <p>(B) Subsequent Testing: CF&I must collect representative grab samples from every treated batch of CSEAFD generated daily and composite all of the grab samples to produce weekly composite samples. CF&I then must analyze each weekly composite sample for the EP leachate concentrations of all of the EP toxic metals and nickel. Analyses must be performed according to SW-648 methodologies. The analytical data, including all quality control information, must be compiled and maintained on site for a minimum of three years. These data must be furnished upon request and made available for inspection by any employee or representative of EPA or the State of Colorado.</p> <p>(2) Delisting levels: If the EP extract concentrations determined in conditions (1)(A) or (1)(B) for chromium, lead, arsenic, or silver exceed 0.315 mg/l; for barium exceeds 6.3 mg/l; for cadmium or selenium exceeds 0.083 mg/l; for mercury exceeds 0.0126 mg/l; or nickel exceeds 3.15 mg/l; or for cyanide exceeds 4.42 mg/l, or total reactive cyanide or total reactive sulfide levels exceed 250 mg/kg and 500 mg/kg, respectively, the waste must either be re-treated or managed and disposed in accordance with Subtitle C of RCRA.</p> <p>(3) Data submittals: Within one week of system start-up, CF&I must notify the Section Chief, Variance Section (see address below) when their full-scale stabilization system is on-line and waste treatment has begun. All data obtained through the initial testing condition (1)(A), must be submitted to the Section Chief, Variance Section, PSPD/OSW, (OS-343), U.S. EPA, 401 M Street, SW, Washington, DC 20460 within the time period specified in condition (1)(A). At the Section Chief's request, CF&I must submit analytical data obtained through condition (1)(B) to the above address, within the time period specified by the Section Chief. Failure to submit the required data obtained from either condition (1)(A) or (1)(B) within the specified time periods will be considered by the Agency sufficient basis for the revocation of CF&I's exclusion to the extent directed by EPA. All data must be accompanied by the following certification statement: "Under civil and criminal penalties (pursuant to the making of submission of false or fraudulent statements or representations (pursuant to the applicable provisions of the Federal Code which include, but may not be limited to, 18 U.S.C. 892B), I certify that the information contained in or accompanying this document is true, accurate and complete. As to the (those) identified section(s) of this document for which I cannot personally verify its (their) truth and accuracy, I certify as the company official having supervisory responsibility for the persons who, acting under my direct instructions, made the verification that this information is true, accurate and complete. In the event that any of this information is determined by EPA in its sole discretion to be false, inaccurate or incomplete, and upon conveyance of this fact to the company, I recognize and agree that this exclusion of wastes will be void as if it never had effect to the extent directed by EPA and that the company will be liable for any actions taken in contravention of the company's RCRA and CERCLA obligations premised upon the company's reliance on the void exclusion."</p>

TABLE 2—WASTES EXCLUDED FROM SPECIFIC SOURCES—Continued

Facility	Address	Waste description
Roanoke Electric Steel Corp.	Roanoke, VA.	Fully-cured chemically stabilized electric arc furnace dust/skudge (CSEAFD) treatment residue (EPA Hazardous Waste No. K061) generated from the primary production of steel after March 22, 1989. This exclusion is conditioned upon the data obtained from Roanoke's full-scale CSEAFD treatment facility because Roanoke's original data were obtained from a laboratory-scale CSEAFD treatment process. To ensure that hazardous constituents are not present in the waste at levels of regulatory concern once the full-scale treatment facility is in operation, Roanoke must implement a testing program for the petitioned waste. This testing program must meet the following conditions for the exclusion to be valid: (1) <i>Testing:</i> (A) <i>Initial testing:</i> During the first four weeks of operation of the full-scale treatment system, Roanoke must collect representative grab samples of each treated batch of the CSEAFD and composite the grab samples daily. The daily composites, prior to disposal, must be analyzed for the EP leachate concentrations of all the EP toxic metals, nickel and cyanide (using distilled water in the cyanide extractions), and the total constituent concentrations of reactive sulfide and reactive cyanide. Analyses must be performed according to SW-846 methodologies. Roanoke must report the analytical test data obtained during this initial period no later than 90 days after the treatment of the first full-scale batch. (B) <i>Subsequent testing:</i> Roanoke must collect representative grab samples from every treated batch of CSEAFD generated daily and composite all of the grab samples to produce a weekly composite sample. Roanoke then must analyze each weekly composite sample for all of the EP toxic metals and nickel. Analyses must be performed according to SW-846 methodologies. The analytical data, including all quality control information, must be compiled and maintained on site for a minimum of three years. These data must be furnished upon request and made available for inspection by any employee or representative of EPA or the State of Virginia. (2) <i>DeListing levels:</i> If the EP extract concentrations for chromium, lead, arsenic, or silver exceed 0.315 mg/l; for barium exceeds 6.3 mg/l; for cadmium or selenium exceed 0.063 mg/l; for mercury exceeds 0.0126 mg/l; for nickel exceeds 3.15 mg/l; or for cyanide exceeds 1.26 mg/l, or total reactive cyanide or total reactive sulfide levels exceed 250 mg/kg and 500 mg/kg, respectively, the waste must either be re-treated or managed and disposed in accordance with Subtitle C of RCRA. (3) <i>Data submittals:</i> Within one week of system start-up, Roanoke must notify the Section Chief, Variances Section (see address below) when their full-scale stabilization system is on-line and waste treatment has begun. All data obtained through the initial testing condition (1)(A), must be submitted to the Section Chief, Variances Section, PSPO/OSW, (OS-343), U.S. EPA, 401 M Street, SW, Washington, DC 20460 within the time period specified in condition (1)(A). Failure to submit the required data or keep the required records will be considered by the Agency, at its discretion, sufficient basis to revoke Roanoke's exclusion. All data must be accompanied by the following certification statement: "Under civil and criminal penalty of law for the making or submission of false or fraudulent statements or representations (pursuant to the applicable provisions of the Federal Code which include, but may not be limited to, 18 USC 8928), I certify that the information contained in or accompanying this document is true, accurate and complete. As to the (those) identified section(s) of this document for which I cannot personally verify its (their) truth and accuracy, I certify as the company official having supervisory responsibility for the persons who, acting under my direct instructions, made the verification that the information is true, accurate and complete. In the event that any of this information is determined by EPA in its sole discretion to be false, inaccurate or incomplete, and upon conveyance of this fact to the company, I recognize and agree that this exclusion of wastes will be void as if it never had effect or to the extent directed by EPA and that the company will be liable for any actions taken in contravention of the company's RCRA and CERCLA obligations premised upon the company's reliance on the void exclusion." Brine purification muds generated from their chlor-alkali manufacturing operations (EPA Hazardous Waste No. K071) and disposed of in brine mud pond HWTF: 5 EP-201.
Stauffer Chemical Co.	Aux, AL	Brine purification muds, which have been washed and vacuum filtered, generated after August 27, 1985 from their chlor-alkali manufacturing operations (EPA Hazardous Waste No. K071) that have been batch tested for mercury using the EP toxicity procedure and have been found to contain less than 0.05 ppm in mercury in the EP extract. Brine purification muds that exceed this level will be considered a hazardous waste.
Stauffer Chemical Co.	St. Gabriel, LA	Spent pickle liquor (EPA Hazardous Waste No. K062) generated by steel finishing operations of facilities within the iron and steel industry (SIC Codes 331 and 332) after November 17, 1986. To ensure that hazardous constituents are not present in the waste at levels of regulatory concern, the facility must implement a contingency testing program for the petitioned wastes. This testing program must meet the following conditions for the exclusion to be valid:

TABLE 2—WASTES EXCLUDED FROM SPECIFIC SOURCES—Continued

Facility	Address	Waste description
Tncl Environmental System, Inc.	Muskegon, Michigan.	(1) Each batch of treatment residue must be representatively sampled and tested using the total oil and grease test and the EP Toxicity test (or the City Waste EP test, if the oil and grease content of the waste exceeds one percent) for arsenic, barium, cadmium, chromium, lead, mercury, selenium, silver and nickel. If the extract concentrations for chromium, lead, arsenic, barium, and silver exceed 6.3 ppm; cadmium and selenium exceed 0.063 ppm; mercury levels exceed 0.013 ppm; or nickel levels exceed 2.2 ppm, the waste will be re-treated or managed and disposed as a hazardous waste under 40 CFR Parts 262 to 265 and the permitting standards of 40 CFR 270. (2) Each batch of treatment residue must be tested for reactive and leachable cyanide. If the reactive cyanide levels exceed 250 ppm; or leachable cyanide levels (using the EP Toxicity test without acetic acid adjustment) exceed 1.26 ppm, the waste must be re-treated or managed and disposed as hazardous waste under 40 CFR Parts 262 to 265 and the permitting standards of 40 CFR Part 270. (3) Each batch of waste must be tested for the total content of the following organic toxicants. If the total content of any of the constituents exceeds the maximum levels shown, the waste must be managed and disposed as a hazardous waste under 40 CFR Parts 262 and 265 and the permitting standards of 40 CFR Part 270. Compound and Maximum Acceptable Levels (ppm) Acroten, 56.8 Anthracene, 76.8 Benzene, 0.106 p-Chloro-m-cresol, 133 1,1-Dichloroethane, 0.01 Fluorene, 10.4 Methylenechloride, 8.2 Methyl ethyl ketone, 326 n-Nitrodiphenylamine, 11.9 Phenanthrene, 14 Tetrachloroethylene, 0.186 Trichloroethylene, 0.59 Chloroform, 0.013 1,2-Dichloroethane, 0.0063 1,2-trans-Dichloroethylene, 231 2,4-Dimethylphenol, 12.5 Vinyl chloride, 0.18 1,2-Diphenyl hydrazine, 0.001 (4) A grab sample must be collected from each batch to form one monthly composite sample, which must be tested using GC/MS analysis for the organic compounds shown above, as well as the remaining organics on the priority pollutant list (see 47 FR 52309, November 19, 1982, Appendix A-126 Priority Pollutants). (5) The test data from conditions 1-4 must be kept on file at the facility for inspection purposes and must be compiled, summarized, and submitted to the Administrator by certified mail on a semiannual basis. The Agency will review the information and if needed, will propose to modify or withdraw the exclusion. The organic testing described in conditions 3 and 4 above is not required until May 18, 1987. The Agency's decision to conditionally exclude the treatment residue generated from the wastewater treatment system at this facility applies only to the wastewater treatment residue described in this petition. Spent pickle liquor (EPA Hazardous Waste No. K062) generated by steel finishing operations of facilities within the iron and steel industry (SIC Codes 331 and 332) after November 17, 1986. To ensure that hazardous constituents are not present in the waste at levels of regulatory concern, the facility must implement a contingency testing program for the petitioned wastes. This testing program must meet the following conditions for the exclusion to be valid: (1) Each batch of treatment residue must be representatively sampled and tested using the total oil and grease test and the EP Toxicity test (or the City Waste EP test, if the oil and grease content of the waste exceeds one percent) for arsenic, barium, cadmium, chromium, lead, mercury, selenium, silver and nickel. If the extract concentrations for chromium, lead, arsenic, barium, and silver exceed 6.3 ppm; cadmium and selenium exceed 0.063 ppm; mercury levels exceed 0.013 ppm; or nickel levels exceed 2.2 ppm, the waste will be re-treated or managed and disposed as a hazardous waste under 40 CFR Parts 262 to 265 and the permitting standards of 40 CFR 270. (2) Each batch of treatment residue must be tested for reactive and leachable cyanide. If the reactive cyanide levels exceed 250 ppm; or leachable cyanide levels (using the EP Toxicity test without acetic acid adjustment) exceed 1.26 ppm, the waste must be re-treated or managed and disposed as hazardous waste under 40 CFR Parts 262 to 265 and the permitting standards of 40 CFR Part 270.

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TABLE 2—WASTES EXCLUDED FROM SPECIFIC SOURCES—Continued

Facility	Address	Waste description
		(3) Each batch of waste must be tested for the total content of the following organic toxicants. If the total content of any of the constituents exceeds the maximum levels shown, the waste must be managed and disposed as a hazardous waste under 40 CFR Parts 262 and 266 and the permitting standards of 40 CFR Part 270: Compound and Maximum Acceptable Levels (ppm) Acrolein, 56.8 Anthracene, 76.8 Benzene, 0.106 p-Chloro-m-cresol, 133 1,1-Dichloroethane, 0.01 Fluorene, 10.4 Methylenechloride, 6.2 Methyl ethyl ketone, 326 n-Nitrosodiphenylamine, 11.9 Phenanthrene, 14 Tetrachloroethylene, 0.188 Trichloroethylene, 0.59 Chloroform, 0.013 1,2-Dichloroethane, 0.0063 1,2-Trans-Dichloroethylene, 231 2,4-Dimethylphenol, 12.5 Vinyl chloride, 0.18 1,2-Diphenyl hydrazine, 0.001
Vulcan Materials Company.	Port Edwards, WI.	(4) A grab sample must be collected from each batch to form one monthly composite sample, which must be tested using GC/MS analysis for the organic compounds shown above, as well as the remaining organics on the priority pollutant list (see 47 FR 52306, November 19, 1982, Appendix A-126 Priority Pollutants). (5) The test data from conditions 1-4 must be kept on file at the facility for inspection purposes and must be compiled, summarized, and submitted to the Administrator by certified mail on a semiannual basis. The Agency will review the information and if needed, will propose to modify or withdraw the exclusion. The organics testing described in conditions 3 and 4 above is not required until May 18, 1987. The Agency's decision to conditionally exclude the treatment residue generated from the wastewater treatment system at the facility applies only to the wastewater treatment residue described in this petition. Brine purification muds (EPA Hazardous Waste No. K071) generated from the mercury cell process in chlorine production, where separately prepared brine is not used after November 17, 1986. To assure that mercury levels in this waste are maintained at acceptable levels, the following conditions apply to this exclusion: Each batch of treated brine clarifier muds and saturator insolubles must be tested (by the extraction procedure) prior to disposal and the leachate concentration of mercury must be less than or equal to 0.0129 ppm. If the waste does not meet this requirement, then it must be re-treated or disposed of as hazardous. This exclusion does not apply to wastes for which either of these conditions is not satisfied.

TABLE 3—WASTES EXCLUDED FROM COMMERCIAL CHEMICAL PRODUCTS, OFF-SPECIFICATION SPECIES, CONTAINER RESIDUES, AND SOIL RESIDUES THEREOF

Facility	Address	Waste description
Union Carbide Corp.	Taft, LA	Contaminated soil (approximately 11,000 cubic yards), which contains acrolein in concentrations of less than 9 ppm.

(49 FR 37070, Sept. 21, 1984)

EDITORIAL NOTE: FOR FEDERAL REGISTER citations affecting Appendix IX of Part 261, see the List of CFR Sections Affected in the Finding Aids section of this volume.

~~APPENDIX X—METHOD OF ANALYSIS FOR CHLORINATED DIBENZO-P-DIOXINS AND -DIBENZOFURANS 1, 2, 3, 4~~

~~Method 8280~~

~~1. Scope and Application~~

~~This method is appropriate for the analysis of tetra-, penta-, and hexachlorinated dibenzo-p-dioxins and dibenzofurans.~~

~~Analytical protocol for determination of TCDDs in phenolic chemical wastes and soil samples obtained from the proximity of chemical dumps. T.O. Tierman and M. Taylor, Brehm Laboratory, Wright State University, Dayton, OH 45435.~~

~~Continued~~

1.1 This method measures the concentration of chlorinated dibenzo-p-dioxins and chlorinated dibenzofurans in chemical wastes including still bottoms, filter aids, sludges, spent carbon, and reactor residues, and in soils.

1.2 The sensitivity of this method is dependent upon the level of interferences.

1.3 This method is recommended for use only by analysts experienced with residue analysis and skilled in mass spectral analytical techniques.

1.4 Because of the extreme toxicity of these compounds, the analyst must take necessary precautions to prevent exposure to himself, or to others, of materials known or believed to contain CDDs or CDFs.

2. Summary of the Method

2.1 This method is an analytical extraction cleanup procedure, and capillary column gas chromatograph-low resolution mass spectrometry method, using capillary column GC/MS conditions and internal standard techniques, which allow for the measurement of PCDDs and PCDFs in the extract.

2.2 If interferences are encountered, the method provides specific general purpose cleanup procedures to aid the analyst in their elimination.

3. Interferences

3.1 Solvents, reagents, glassware, and other sample processing hardware may yield discrete artifacts and/or elevated baselines causing misinterpretation of gas chromatograms. All of these materials must be demonstrated to be free from interferences

Analytical protocol for determination of chlorinated dibenzo-p-dioxins and chlorinated dibenzofurans in river water. T.O. Tierman and M. Taylor, Brehm Laboratory, Wright State University, Dayton, OH 45435.

In general, the techniques that should be used to handle these materials are those which are followed for radioactive or infectious laboratory materials. Assistance in evaluating laboratory practices may be obtained from industrial hygienists and persons specializing in safe laboratory practices. Typical infectious waste incinerators are probably not satisfactory devices for disposal of materials highly contaminated with CDDs or CDFs. Safety instructions are outlined in EPA Test Method 613(4.0)

See also: (1) "Program for monitoring potential contamination in the laboratory following the handling and analyses of chlorinated dibenzo-p-dioxins and dibenzofurans" by F. D. Hileman et al., In: Human and Environmental Risks of Chlorinated Dioxins and Related Compounds, R.E. Tucker, et al., eds., Plenum Publishing Corp., 1983. (2) Safety procedures outlined in EPA Method 613, Federal Register volume 44, No. 233, December 3, 1979.

under the conditions of analysis by running method blanks. Specific selection of reagents and purification of solvents by distillation in all-glass systems may be required.

3.2 Interferences co-extracted from the samples will vary considerably from source to source, depending upon the diversity of the industry being sampled. PCDD is often associated with other interfering chlorinated compounds such as PCB's which may be at concentrations several orders of magnitude higher than that of PCDD. While general cleanup techniques are provided as part of this method, unique samples may require additional cleanup approaches to achieve the sensitivity stated in Table 1.

TABLE 1—GAS CHROMATOGRAPHY OF TCDD

Column	Retention time (min.)	Detection limit (µg/kg)
Glass capillary	9.5	0.003

Detection limit for liquid samples is 0.003 µg/l. This is calculated from the minimum detectable GC response being equal to five times the GC background noise assuming a 1 ml effective final volume of the 1 liter sample extract, and a GC injection of 8 microliters. Detection levels apply to both electron capture and GC/MS detection. For further details see 44 FR 80626 (December 3, 1979).

3.3 The other isomers of tetrachlorodibenzo-p-dioxin may interfere with the measurement of 2,3,7,8-TCDD. Capillary column gas chromatography is required to resolve those isomers that yield virtually identical mass fragmentation patterns.

4. Apparatus and Materials

4.1. Sampling equipment for discrete or composite sampling.

4.1.1 Grab sample bottle—amber glass, 1-liter or 1-quart volume. French or Boston Round design is recommended. The container must be washed and solvent rinsed before use to minimize interferences.

4.1.2. Bottle caps—threaded to screw on to the sample bottles. Caps must be lined with Teflon. Solvent washed foil, used with the shiny side towards the sample, may be substituted for the Teflon if sample is not corrosive.

4.1.3. Compositing equipment—automatic or manual compositing system. No nylon or rubber tubing may be used, and the system must incorporate glass sample containers for the collection of a minimum of 250 ml. Sample containers must be kept refrigerated after sampling.

4.2 Water bath—heated, with concentric ring cover, capable of temperature control (±2 °C). The bath should be used in a hood.

4.3 Gas chromatograph/mass spectrometer data system.

4.3.1 Gas chromatograph: An analytical system with a temperature programmable

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ATTACHMENT 1-2

10 CFR Chapter I, Part 71, Subpart A, Section 71.4

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PART 71 • PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

to other authorized place of use. No provision of this part authorizes possession of licensed material.

(d) Exemptions from the requirement for license in § 71.3 are specified in § 71.10. General licenses for which no NRC package approval is required are issued in §§ 71.14-71.24. The general license in § 71.12 requires that an NRC certificate of compliance or other package approval be issued for the package to be used under the general license. Application for package approval must be completed in accordance with Subpart D of this part demonstrating that the design of the package to be used satisfies the package approval standards contained in Subpart E of this part as related to the tests of Subpart F of this part. The transport of licensed material or delivery of licensed material to a carrier for transport is subject to the operating controls and procedures requirements of Subpart G of this part, to the quality assurance requirements of Subpart H of this part, and to the general provisions of Subpart A of this part, including DOT regulations referenced in § 71.5.

§ 71.1 Communications and records.

(a) All communications concerning the regulations in this part should be addressed to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20545, or may be delivered in person at the Commission Office at 2120 L Street, NW, Washington, DC, or its Offices at 11555 Rockville Pike, Rockville, Maryland.

(b) Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

§ 71.2 Interpretations.

Only written interpretations of the regulations in this part by the Commission's General Counsel are binding upon the Commission.

§ 71.3 Requirement for license.

A licensee subject to the regulations in this part may not (a) deliver any

licensed material to a carrier for transport or (b) transport licensed material except as authorized in a general license or a specific license issued by the Commission, or as exempted in this part.

§ 71.4 Definitions.

The following terms are as defined here for the purpose of this part. Throughout this part, the standards are expressed in metric units; the approximate English equivalents presented in parentheses are for information only.

A₁ means the maximum activity of special form radioactive material permitted in a Type A package. *A₂* 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 Appendix A of this part, Table A-1, or may be derived in accordance with the procedure prescribed in Appendix A of this part.

Carrier means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

Close reflection by water means immediate contact by water of sufficient thickness for maximum reflection of neutrons.

Containment system means the components of the packaging intended to retain the radioactive material during transport.

Conveyance means any vehicle, aircraft, vessel, freight container, or hold, compartment, or defined deck area of an inland waterway craft or seagoing vessel.

Exclusive use (also referred to in other regulations as "sole use" or "full load") means the sole use of a conveyance by a single consignor and for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee.

Fissile classification means the categorization of fissile material packages into one of the following three classes according to the controls needed to provide nuclear criticality safety during transportation:

(1) *Fissile Class I*: A package which may be transported in unlimited numbers and in any arrangement, and which requires no nuclear criticality safety controls during transportation. A transport index is not assigned for purposes of nuclear criticality safety but may be required because of external radiation levels.

(2) *Fissile Class II*: A package which may be transported together with other packages in any arrangement but for criticality control, in numbers which do not exceed an aggregate transport index of 50. These shipments require no other nuclear criticality safety control during

transportation. Individual packages may have a transport index not less than 0.1 and not more than 10.

(3) *Fissile Class III*: A shipment of packages which is controlled in transportation by specific arrangements between the shipper and the carrier to provide nuclear criticality safety.

Fissile material and fissile radionuclides: "Fissile material" means any material consisting of or containing one or more fissile radionuclides. Fissile radionuclides are plutonium-238, plutonium-239, plutonium-241, uranium-233, and uranium-235. Neither natural nor depleted uranium is fissile material. Fissile materials are classified in this section according to the controls needed to provide nuclear criticality safety during transportation. Certain exclusions are provided in § 71.53.

Low specific activity material means any of the following:

(1) Uranium or thorium ores and physical or chemical concentrates of those ores;

(2) Unirradiated natural or depleted uranium or unirradiated natural thorium;

(3) Tritium oxide in aqueous solutions provided the concentration does not exceed 5.0 millicuries per milliliter;

(4) Material in which the radioactivity is essentially uniformly distributed and in which the estimated average concentration per gram of contents does not exceed:

(i) 0.0001 millicurie of radionuclides for which the *A₂* quantity in Appendix A of this part is not more than 0.05 curie;

(ii) 0.005 millicurie of radionuclides for which the *A₂* quantity in Appendix A of this part is more than 0.05 curie, but not more than 1 curie; or

(iii) 0.1 millicurie of radionuclides for which the *A₂* quantity in Appendix A of this part is more than 1 curie.

(5) Objects of nonradioactive material externally contaminated with radioactive material, provided that the radioactive material is not readily dispersible and the surface contamination, when averaged over an area of 1 square meter, does not exceed 0.0001 millicurie (220,000 disintegrations per minute) per square centimeter of radionuclides for which the *A₂* quantity in Appendix A of Part 71 is not more than 0.05 curie, or 0.001 millicurie (2,200,000 disintegrations per minute) per square centimeter for other radionuclides.

Maximum normal operating pressure means the maximum gauge pressure that would develop in the containment system in a period of one year under the heat test specified in § 71.71(c)(1), in the absence of venting, external cooling by an ancillary system, or operational controls during transport.

Natural thorium means thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).

PART 71 • PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

Normal form radioactive material means radioactive material which has not been demonstrated to qualify as "special form radioactive material."

Optimum interspersed hydrogenous moderation means the presence of hydrogenous material between packages to such an extent that the maximum nuclear reactivity results.

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

(1) Fissile material package means a fissile material packaging together with its fissile contents.

(2) Type B package means a Type B package together with its radioactive contents. On approval, a Type B package design is designated by NRC as B(U) unless the package has a maximum normal operating pressure of more than 700 kilopascal (100 lb/in²) gauge or a pressure relief device which would allow the release of radioactive material to the environment under the tests specified in § 71.73 (hypothetical accident conditions), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see DOT regulations in 49 CFR Part 173. A Type B package approved prior to September 8, 1983, was designated only as Type B. Limitations on its use are specified in § 71.13.

Packaging means the assembly of components necessary to ensure compliance with the packaging requirements of this part. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

Special form radioactive material means radioactive material which satisfies the following conditions:

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

(2) The piece or capsule has at least one dimension not less than 5 millimeters (0.197 inch); and

(3) It satisfies the test requirements of § 71.74.

A special form encapsulation designed in accordance with the requirements of § 71.4(o) of this part in effect on June 30, 1983, and constructed prior to July 1, 1985 may continue to be used. A special form encapsulation either designed or constructed after June 30, 1985 must meet requirements of this paragraph

applicable at the time of its design or construction.

Specific activity of a radionuclide means the radioactivity of the radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

State means the several States of the Union, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the trust Territory of the Pacific Islands, and the Commonwealth of the Northern Mariana Islands.

Transport index means the dimensionless number (rounded up to the first decimal place) placed on the label of a package to designate the degree of control to be exercised by the carrier during transportation. The transport index is determined as follows:

(1) The number expressing the maximum radiation level in millirem per hour at 1 meter from the external surface of the package; or

(2) For Fissile Class II packages, the number expressing the maximum radiation level in millirem per hour at 1 meter from the external surface of the package, or the number obtained by dividing 50 by the allowable number of the packages which may be transported together as determined under § 71.59, whichever number is larger.

Type A quantity means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A₁ for special form radioactive material or A₂ for normal form radioactive material, where A₁ and A₂ are given in Appendix A of this part or may be determined by procedures described in Appendix A of this part.

Type B quantity means a quantity of radioactive material greater than a Type A quantity

Uranium—natural depleted enriched

(1) Natural uranium means uranium with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-235, and the remainder essentially uranium-238).

(2) Depleted uranium means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

(3) Enriched uranium means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

§ 71.5—Transportation of licensed material

(a) Each licensee who transports licensed material outside of the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the regulations appropriate to the mode of transport of DOT in 49 CFR Parts 170 through 180.

(1) The licensee shall particularly note DOT regulations in the following areas:

(i) Packaging—49 CFR Part 173, Subparts A and B and §§ 173.401-173.478.

(ii) Marking and labeling—49 CFR Part 172, Subpart D and §§ 172.400-172.407; 172.436-172.440.

(iii) Placarding—49 CFR Part 172.500-172.519, 172.556 and Appendices B and C.

(iv) Monitoring—49 CFR Part 172, Subpart C.

(v) Accident reporting—49 CFR Part 171.15 and 171.16.

(vi) Shipping papers—49 CFR Part 172, Subpart C.

(2) The licensee shall also note DOT regulations pertaining to the following modes of transportation:

(i) Rail—49 CFR Part 174, Subparts A-D and K.

(ii) Air—49 CFR Part 176, Subparts A-D and M.

(iii) Vessel—49 CFR Part 178, Subparts A-D and M.

(iv) Public Highway—49 CFR Part 177.

(b) If DOT regulations are not applicable to a shipment of licensed material by rail, highway, or water because the shipment of the transportation of the shipment is not in interstate or foreign commerce, or to a shipment of licensed material by air because the shipment is not transported in civil aircraft, the licensee shall conform to the standards and requirements of the DOT specified in paragraph (a) of this section to the same extent as if the shipment or transportation were in interstate or foreign commerce or in civil aircraft. 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, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

§ 71.8 Information collection requirements: OMB approval

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements contained in this part under control number 3150-0008.

(b) The approved information collection requirements contained in this part appear in §§ 71.5, 71.12, 71.31, 71.33, 71.35, 71.37, 71.85, 71.87, 71.89, 71.91, 71.93, 71.96, 71.97, 71.101, 71.103, 71.105, 71.107, 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123, 71.125, 71.127, 71.129, 71.131, 71.133, 71.135, and 71.137.

EFFECTIVE DATE
JULY 22, 2001

NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

180 NAC 2

TITLE 180 CONTROL OF RADIATION

CHAPTER 2 REGISTRATION OF RADIATION GENERATING EQUIPMENT FACILITIES AND SERVICES

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FORMS

- Form NRH-4 Application for Registration of Radiation Generating Equipment
- Form NRH-4a (Additional Machines)
- Form NRH 9 Application for Registration of Services for Radiation Sources

ATTACHMENT

Attachment Number 2-1 21 CFR 1020.30(d)

EFFECTIVE DATE
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180 NAC 2

TITLE 180 CONTROL OF RADIATION

CHAPTER 2 REGISTRATION OF RADIATION GENERATION EQUIPMENT FACILITIES AND SERVICES

PE AND AUTHORITY

2-001.01 180 NAC 2 provides for the registration of radiation generating equipment facilities and for the registration of persons providing radiation generating equipment installation, servicing of radiation sources, radiation measurements and other services. The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Rev. Stat. section 71-3501 to 71-3519.

2-001.02 In addition to the requirements of 180 NAC 2, all registrants are subject to the applicable provisions of 180 NAC 1, 4, 5, 6, 8, 9, 10, 15, 16, 17, and 18.

2-002 DEFINITIONS: For purposes of 180 NAC 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.

2-003 EXEMPTIONS

2-003.01 Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this part, providing dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5 mrem (5 μ Sv) 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.

2-003.02 Radiation generating equipment while in transit or storage incident thereto are exempt from the requirements of 180 NAC 2.

2-003.03 Domestic television receivers are exempt from the requirements of 180 NAC 2.

2-004 APPLICATION FOR REGISTRATION OF RADIATION GENERATING EQUIPMENT FACILITIES: Each person having a radiation generating equipment facility shall:

2-004.01 Apply for registration of such facility with the Agency within thirty (30) days following the commencement of the operation of a radiation generating equipment facility. Application for registration shall be completed on form NRH-4 furnished by the Agency and shall contain all the information required by the form

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NRH-4 and accompanying instructions; and submit the appropriate fee as specified in 180 NAC 18.

2-004.02 Designate on the application form an individual to be responsible for radiation protection.

2-004.03 Each registrant shall prohibit any person from furnishing radiation generating equipment servicing or services as described in 180 NAC 2-005.04 to his radiation generating equipment facility until such person provides evidence that he has been registered with the Agency as a provider of services in accordance with 180 NAC 2-005. A list of these registrants shall be available for distribution by the Agency.

2-005 APPLICATION FOR REGISTRATION OF SERVICING AND SERVICES

2-005.01 Each person who is engaged in the business of installing or offering to install radiation generating equipment or is engaged in the business of furnishing or offering to furnish radiation generating equipment servicing, radiation source servicing, radiation measurements, and/or other services in this State shall apply for registration of such services with the Agency within 30 days following January 1, 1974 or thereafter prior to furnishing or offering to furnish any such services.

2-005.02 Application for registration shall be completed on form NRH-9 furnished by the Agency and shall contain all information required by the Agency as indicated on the forms and accompanying instructions; and

1. Submit the appropriate fee as specified in 180 NAC 18.

2-005.03 Each person applying for registration under 180 NAC 2 shall specify:

1. That he has read and understands the requirements of 180 NAC 2; and
2. The services for which he is applying for registration; and
3. The training and experience that qualify him to discharge the services for which he is applying for registration. (See 180 NAC 15); and
4. The type of measurement instrument to be used, frequency of calibration, and calibration source; and
5. The type of personnel dosimeters supplied, frequency of reading, and replacement or exchange schedule.

2-005.04 For the purpose of 180 NAC 2-005, services may include but shall not be limited to:

1. Installation and/or servicing of radiation generating equipment and associated radiation generating equipment components. Services shall include those adjustments and measurements necessary for proper operation of radiation generating equipment. (See 180 NAC 15-033);
2. Calibration of radiation generating equipment or radiation measurement instruments or devices (See qualified expert training and experience qualifications in See 180 NAC 15-013.03);

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3. Radiation protection or health physics consultations, radiation measurements, or surveys (See qualified expert training and experience qualifications in 180 NAC 15-013.03);
4. Personnel dosimetry services. (See 180 NAC 15-034); and
5. Operation of radiation generating equipment by an individual (180 NAC 16).

2-005.05 No individual shall perform services which are not specifically stated for that individual on the certificate of registration issued by the Agency.

2-006 ISSUANCE OF CERTIFICATE OF REGISTRATION (NRH-4 AND/OR NRH-9)

2-006.01 Upon a determination that an applicant meets the requirements of the regulations, the agency shall issue a Certificate of Registration.

2-006.02 The Agency may incorporate in the Certificate of Registration at the time of registration or thereafter by rule, regulation or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use and transfer of radiation generating equipment, radiation source servicing, radiation measurements and/or services it deems appropriate or necessary.

2-007 EXPIRATION OF CERTIFICATE OF REGISTRATION: Except as provided by 180 NAC 2-008.02, each certificate of registration shall expire annually on the anniversary of the date issued

2-008 RENEWAL OF CERTIFICATE OF REGISTRATION

2-008.01 Application for renewal of Registration shall be filed in accordance with 180 NAC 2-004 or 180 NAC 2-005.

2-008.02 In any case in which a registration not less than 30 days prior to the expiration of his existing certificate of registration has filed an application in proper form for renewal, such existing certificate of registration shall not expire until the application status has been finally determined by the Agency.

2-009 REPORT OF CHANGES: The registrant shall notify the Agency in writing within thirty (30) days of any change which would render the information contained in the application for registration no longer accurate

2-010 APPROVAL NOT IMPLIED: No person, in any advertisement, shall refer to the fact that he or his facility is registered with the Agency pursuant to the provisions of 180 NAC 2-004 or 180 NAC 2-005, and no person shall state or imply that any activity under such registration has been approved by the Agency.

2-011 ASSEMBLER AND/OR TRANSFER OBLIGATION¹

¹In the case of diagnostic x-ray systems which contain certified components, a copy of the assembler's report (Form FDA 2579) prepared in compliance with requirements of 21 CFR Chapter 1, Section 1020.30(d) attached hereto as pages 466-468, except the stricken text of Attachment Number 2-1 and incorporated herein by this reference, shall suffice in lieu of any other report by the assembler.

2-011.01 Any person who sells, leases, transfers, lends, disposes, assembles, or installs radiation generating equipment in this State shall notify the Agency within 15 days of:

1. The name and address of persons who have received this equipment;
2. The manufacturer, model, and serial number of each radiation generating equipment transferred; and
3. The date of transfer of each radiation generating equipment.

2-011.02 No person shall make, sell, lease, transfer, lend, assemble, or install radiation generating equipment or the components used in connection with such equipment unless such components and equipment when properly placed in operation and used shall meet the requirements of 180 NAC 2.

2-012 OUT-OF-STATE RADIATION GENERATING EQUIPMENT

2-012.01 Whenever any radiation generating equipment which is registered in another state or by the federal government is to be brought into the State, for any temporary use, the person proposing to bring such equipment into the State shall give written notice to the Agency (at least 2 working days) before such equipment is to be used in the State. The notice shall include:

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

2-012.02 If, for a specific case, the (two working-day) period would impose an undue hardship on the person, upon application to the Agency, permission to proceed sooner may be granted.

2-012.03 The person referred to in 180 NAC 2-012 .01 shall:

1. Comply with all applicable regulations of the Agency;
2. Supply the Agency with such other information as the Agency may reasonably request; and

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3. Not operate within the State on a temporary basis in excess of 180 calendar days per year.
4. Submit the appropriate fee as specified in 180 NAC 18.

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NEBRASKA HEALTH AND HUMAN SERVICES SYSTEM
DEPARTMENT OF REGULATION AND LICENSURE
DIVISION OF PUBLIC HEALTH ASSURANCE
X-RAY PROGRAM

For Agency Use Only
Regist. No. _____
State _____ Co. _____
Priority _____ Fee Det. No. _____

APPLICATION FOR REGISTRATION OF RADIATION GENERATING EQUIPMENT

Instructions: Type or Print except where indicated. Retain one copy for your files and submit original application to: Nebraska Dept. of Health and Human Services Regulation and Licensure, Division of Public Health Assurance, 301 Centennial Mall South, P O Box 95007, Lincoln, NE 68509-5007.

<p>1.a <u>Legal Name and Street address of Applicant (Institution, Firm, Person, etc.)</u></p> <p>Applicant Name: _____</p> <p>Address: _____</p> <p>City, State Zip: _____</p> <p>Telephone #: _____</p> <p>FAX #: _____</p> <p>eMail Address: _____</p>	
<p>1.b <u>Street address(es) at which Radiation Generating Equipment will be used. (If different than 1.a)</u></p> <p>(1) <u>Permanent</u> Address: _____</p> <p>_____</p> <p>City, State Zip: _____</p> <p>(2) <u>Temporary Job Sites Throughout Nebraska?</u> <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>2. Billing Information</p> <p>Address(if different than 1.a):</p> <p>_____</p> <p>_____</p> <p>Person to Contact: _____</p> <p>Telephone #: _____</p>	<p>3. Person Responsible for Radiation Protection</p> <p>_____</p> <p>Title: _____</p> <p>Telephone #: _____</p>
<p>4. Type of Practice (see Instruction Sheet) _____</p>	

5. RADIATION GENERATING EQUIPMENT (USE ADDITIONAL SHEETS IF NECESSARY)

List each machine on a separate line.

Type	# Tubes	Control Manufacturer	Model No.	Serial No.	Date Installed	Date Manufactured	Control Room #

6. CERTIFICATION
(This item must be completed by applicant.)

The applicant and any official executing this document on behalf of the applicant named in Item 1. a., certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services Regulation and Licensure, Title 180, Regulations for Control of Radiation and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge.

_____ *Applicant Name from Item 1. a.*

By: _____
Signature of certifying official authorized to act on behalf of applicant

Date: _____

_____ *Print Name and Title of certifying official*

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**NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATION AND LICENSURE
DIVISION OF PUBLIC HEALTH ASSURANCE
RADIOACTIVE MATERIALS PROGRAM**

APPLICATION FOR REGISTRATION OF SERVICES FOR RADIATION SOURCES

INSTRUCTIONS - (Use additional sheets where necessary.)

Type or Print except where indicated.

Retain one copy for your files and submit original application to: Department of Health and Human Services Regulation and Licensure, Division of Public Health Assurance, 301 Centennial Mall South, P.O. Box 95007, Lincoln, NE 68509-5007.

Upon approval of this application, the applicant will receive a Radioactive Material License, issued in accordance with the requirements contained in Title 180, Regulations for Control of Radiation and the Nebraska Radiation Control Act.

1. Name and Street Address of Applicant (Individual or Company) Applicant Name: _____ Address: _____ City, State Zip+4 _____ Telephone #: _____ FAX#: _____ E-mail Address: _____	
2. Person to Contact Regarding this Application _____ Telephone # _____	3. Individual User(s) Submit in duplicate on a separate sheet(s) the Name and Title of individual(s) qualified to perform each service listed below. Document training and experience in accordance with 180 NAC 15.
4. Services Provided (check as appropriate) <u>Radioactive Material Services Requiring Registration and an Agency, NRC or Agreement State Specific License:</u> <input type="checkbox"/> Analysis of Samples for Radioactivity <input type="checkbox"/> Bioassay <input type="checkbox"/> Calibration of Radiation monitoring Instruments <input type="checkbox"/> Decommissioning of Facilities <input type="checkbox"/> Decontamination of Facilities <input type="checkbox"/> Facility/Packaging Shielding Determination (Use of Radioactive Material) <input type="checkbox"/> Leak Test Service <input type="checkbox"/> Waste Disposal Services (Receipt of Waste)	

(continued)

4. Services Provided (check as appropriate) (Continued)

Radioactive Material Services Requiring Registration:

- Waste Disposal Consultation Services (No Receipt of Waste)

Radiation Generating Equipment Services Requiring Registration:

- Device Sales
- Device Services (Demonstration, Installation, Electronic Calibration, Repair, Survey)

General Radiation Services Requiring Registration:

- Facility/Packaging Shielding Review (Calculation Only) - Submit Procedures
- Radiation Protection or Health Physics Consultation
- Radiation Survey - Submit Instrumentation and Procedures
- Personnel Monitoring - Submit NVLAP Certification
- Other

5. CERTIFICATION

(This Item must be completed by applicant.)

The applicant and any official executing this document on behalf of the applicant named in Item 1., certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services Regulation and Licensure, Title 180, Regulations for Control of Radiation and that all information contained herein, including any Supplements attached hereto, is true and correct to the best of our knowledge and belief.

Applicant Name From Item 1.

By: _____ Date: _____
Signature

Print Name and Title of certifying official authorized to act on behalf of the applicant

Registration Does Not Imply Approval or Disapproval of Service

EFFECTIVE DATE
July 22, 2001

**NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE**

180 NAC 2

**ATTACHMENT NUMBER 2 – 1
21 CFR 1020.30(d)**

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compatible components without affecting the system's compliance, such as one of a set of interchangeable beam-limiting devices, or

(14) A component compatible with all x-ray systems with which it may be used and that does not require compatibility or installation instructions, such as a tabletop cassette holder.

(58) "Computed tomography (CT)" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

(59) "Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data may be collected simultaneously during a single scan for the production of one or more tomograms.

(60) "Scan time" means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

(61) "Tomogram" means the depiction of the x-ray attenuation properties of a section through a body.

(62) "Dose" means the absorbed dose as defined by the International Commission on Radiation Units and Measurements. The absorbed dose, D, is the quotient of de by dm where de is the mean energy imparted by ionizing radiation to matter of mass dm.

(c) *Certification of components.* Each component subject to this section and §§1020.31, 1020.32, and 1020.33, shall be certified by the manufacturer thereof as a product which meets all applicable standards in accordance with the provisions of §1010.2 of this chapter. Where a combination of two or more such components is manufactured, marketed, and delivered as a system or subsystem, its certification may be applicable to all components contained therein, if authorized in writing by the Director or Deputy Director of the Center for Devices and Radiological Health, or the Director, Office of Compliance of that Center upon application by the manufacturer. Certification that the product conforms to all applicable standards under this part shall be construed to mean that the component, system, or subsystem can meet the applicable provisions of this section and §§1020.31, 1020.32, and 1020.33, if in-

stalled in a diagnostic x-ray system in accordance with instructions.

(d) *Certification by assembler.* An assembler who installs one or more components certified as required by paragraph (c) of this section into an x-ray system shall install certified components that are of the type required by §1020.31, §1020.32 or §1020.33, and, except as provided for in paragraph (d)(2) of this section, shall assemble, install, adjust, and test the certified components in accordance with the instructions of their respective manufacturers. All assemblers who install certified components shall file a report of such assembly as specified in paragraphs (d) (1), (2), and (3) of this section. The report will be construed as the assembler's certification and identification under §§1010.2 and 1010.3 of this chapter. All assembler reports must be on a form prescribed by and available from the Director, Center for Devices and Radiological Health, 5800 Fishers Lane, Rockville, MD 20857. Completed reports must be submitted to the Director, the purchaser, and, where applicable, to the State agency responsible for radiation protection within 15 days following completion of the assembly.

(1) *Reporting compliance.* An assembler who installs one or more certified components into an x-ray system or subsystem, having properly followed the assembly instructions provided him by the component manufacturer, shall certify to this by filing a report containing the information prescribed on the form which shall include the following:

(i) The full name and address of the assembler and the date of assembly or installation.

(ii) The name and address of the purchaser and the location and specific identification of the x-ray system or subsystem.

(iii) An affirmation that all instruction manuals and other information as required by paragraph (h) of this section applicable to the newly installed x-ray equipment have been delivered to the purchaser.

(iv) A statement of the type and intended use of the x-ray system or subsystem into which the certified components were assembled or installed.

such as "radiographic—stationary general purpose."

(v) A list of all certified components which were assembled or installed by him into the x-ray system or subsystem in accordance with the instructions of the component manufacturers, identifying the components by type, manufacturer, model number, and serial number.

(vi) An affirmation that the certified components listed pursuant to paragraph (d)(2)(v) of this section were assembled according to the instructions provided by the manufacturer(s) of such components.

(vii) An affirmation that all certified components installed in the x-ray system or subsystem were of the type required by §1020.31, §1020.32, or §1020.33.

(viii) An affirmation that a copy of this report will be transmitted to the purchaser and, where applicable, to the State agency responsible for radiation protection, in accordance with the requirements of this paragraph.

(2) *Reporting noncompatibility.* An assembler who installs a certified component into an x-ray system shall file a report indicating noncompatibility if he is unable to follow the instructions of the manufacturer of such certified component, provided other component(s) of the system do not meet the manufacturer's specifications for compatibility as given by the certified component manufacturer pursuant to paragraph (g) of this section and provided there is no commercially available certified component of a similar type which is compatible with the x-ray system. In addition, the component(s) of the system not meeting the specification for compatibility must either be of a type listed in paragraph (a)(1) of this section which does not bear a certification label due to date of manufacture, or if it is a component not of the type listed in paragraph (a)(1) of this section, it must have been purchased as new prior to August 1, 1974. No assembler shall perform any modification of a certified component which will adversely affect the performance of the certified component with respect to the requirements of this section and §§1020.31, 1020.32 and 1020.33. The assembler

shall file a report indicating noncompatibility containing information prescribed on the form which shall include the following:

(i) The full name and address of the assembler and the date of assembly or installation.

(ii) The name and address of the purchaser and the location and specific identification of the x-ray system or subsystem.

(iii) An affirmation that all instruction manuals and other information as required by paragraph (h) of this section applicable to the newly installed x-ray equipment have been delivered to the purchaser.

(iv) A statement of the type or intended use of the x-ray system or subsystem into which the certified components were assembled or installed, such as "radiographic—stationary general purpose."

(v) A list of all certified component(s) which were assembled or installed by him into the x-ray system or subsystem and which could not be assembled, installed, adjusted, and tested in accordance with the manufacturer's instructions due to reasons specified in this paragraph (this paragraph (d)(2)), identifying the components by type, manufacturer, model number, and serial number.

(vi) An affirmation that the certified component(s) listed pursuant to paragraph (d)(2)(v) of this section could not be assembled, installed, adjusted, and tested in accordance with the installation instructions of their respective manufacturers due to reasons specified in this paragraph (this paragraph (d)(2)), and that no certified component was modified so as to adversely affect its performance with respect to the requirements of this section and §§1020.31, 1020.32 and 1020.33.

(vii) For each certified component listed pursuant to paragraph (d)(2)(v) of this section, a full and complete explanation of why the manufacturer's installation instructions could not be followed in performing the assembly including a listing by type, manufacturer, and model number of the incompatible component(s) already in the system, and either evidence of its date of purchase as new if it is not a type of

component listed in paragraph (a)(1) of this section, or if it is a type of component listed in paragraph (a)(1) of this section, a statement that it did not bear a certification label due to its date of manufacture.

(viii) An affirmation that all certified components installed in the x-ray system or subsystem were of the type required by § 1020.31, § 1020.32 or 1020.33.

(ix) An affirmation that a copy of this report will be transmitted to the purchaser and, where applicable, to the State agency responsible for radiation protection, in accordance with the requirements of this paragraph.

(3) *Accessory components.* The following requirements apply to the assembly of accessory certified components and x-ray systems that do not require assembly by the dealer or purchaser.

(i) The initial installation or assembly of interchangeable and removable accessory certified components within a diagnostic x-ray system following delivery at the user's facility shall be reported as required by paragraphs (d)(1) and (2) of this section. No report of assembly is required for subsequent use of such components.

(ii) *Assembler certification* as specified in paragraphs (d)(1) and (2) of this section is not required for certified components or systems that have been described by their manufacturer in the information furnished the user as not requiring assembler certification. Prior to stating that assembler certification is not required for a component or system, the manufacturer of the item must have reported to the Center for Devices and Radiological Health, in the report required by § 1002.10 of this chapter, that compliance with this section and §§ 1020.31, 1020.32 and 1020.33 is assured by the existence of the following conditions:

(a) Certification of compliance by the manufacturer is not contingent upon acts of assembly or installation by the dealer or purchaser.

(b) Preparation for use by either the dealer or user does not require adherence to the manufacturer's instructions to ensure compliance.

(c) Interconnection or use, or both, of the component or systems does not require compatibility specifications.

~~(e) Identification of x-ray components.~~ In addition to the identification requirements specified in § 1010.3 of this chapter, manufacturers of components subject to this section and §§ 1020.31, 1020.32 and 1020.33, except high voltage generators contained within tube housings and beam-limiting devices which are integral parts of tube housings, shall permanently inscribe or affix thereon the model number and serial number of the product, so as to be legible and accessible to view. Where the certification of a system or subsystem, consisting of two or more components, has been authorized pursuant to paragraph (c) of this section, a single inscription, tag, or label bearing such information may be used to identify the product.

(1) *Tube housing assemblies.* In a similar manner, manufacturers of tube housing assemblies shall also inscribe or affix thereon the name of the manufacturer, model number, and serial number of the x-ray tube which the tube housing assembly incorporates.

(2) *Replacement of tubes.* Except as specified in paragraph (e)(3) of this section, the replacement of an x-ray tube in a previously manufactured tube-housing assembly certified pursuant to paragraph (c) of this section constitutes manufacture of a new tube housing assembly, and the manufacturer is subject to the provisions of paragraph (e)(1) of this section. The manufacturer shall remove, cover, or deface any previously affixed inscriptions, tags, or labels that are no longer applicable.

(3) *Quick-change x-ray tubes.* The requirements of paragraph (e)(2) of this section shall not apply to tube-housing assemblies designed and designated by their original manufacturer to contain quick-change x-ray tubes. The manufacturer of such x-ray tubes shall include with each replacement tube a label with the tube manufacturer's name, the model, and serial number of the x-ray tube. The manufacturer of the tube shall instruct the assembler who installs the new tube to attach the label to the tube-housing assembly and to remove the cover or deface the

~~previously affixed inscriptions, tags, or labels that are described by the tube manufacturer as no longer applicable.~~

(1) *Limits of responsibility.* (1) *Manufacturer.* The manufacturer of a certified component installed or assembled into an x-ray system or subsystem by another person shall not be liable for the noncompliance of such component which is attributable solely to the improper installation or assembly of the component into the system, but shall be held responsible for noncompliance if improper assembly was a result of inadequate instructions provided by such component manufacturer.

(2) *Assembler.* The person who certified as to the assembly of an x-ray system or subsystem shall not be liable for noncompliance of a certified component if such assembly is in accordance with the instructions provided by the manufacturer of the component, but shall be held responsible for noncompliance of a component which is attributable solely to improper assembly or installation into the system or subsystem.

(g) *Information to be provided to assemblers.* Manufacturers of components listed in paragraph (a)(1) of this section shall provide to assemblers subject to paragraph (d) of this section and, upon request to others at a cost not to exceed the cost of publication and distribution, instructions for assembly, installation, adjustment, and testing of such components adequate to assure that the products will comply with applicable provisions of this section and §§ 1020.31, 1020.32, and 1020.33, when assembled, installed, adjusted, and tested as directed. Such instructions shall include specifications of other components compatible with that to be installed when compliance of the system or subsystem depends on their compatibility. Such specifications may describe pertinent physical characteristics of the components and/or may list by manufacturer model number the components which are compatible.

(h) *Information to be provided for users.* Manufacturers of x-ray equipment shall provide for purchasers and, upon request, to others at a cost not to exceed the cost of publication and dis-

seeds which shall include the following technical and safety information:

(1) *All x-ray equipment.* For x-ray equipment to which this section and §§ 1020.31, 1020.32, and 1020.33 are applicable, there shall be provided:

(i) Adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the equipment and

(ii) A schedule of the maintenance necessary to keep the equipment in compliance with this section and §§ 1020.31, 1020.32, and 1020.33.

(2) *Tube housing assemblies.* For each tube housing assembly, there shall be provided:

(i) Statements of the leakage technique factors for all combinations of tube housing assemblies and beam-limiting devices for which the tube housing assembly manufacturer states compatibility, the minimum filtration permanently in the useful beam expressed as millimeters of aluminum equivalent, and the peak tube potential at which the aluminum equivalent was obtained;

(ii) Cooling curves for the anode and tube housing; and

(iii) Tube rating charts.

If the tube is designed to operate from different types of x-ray high-voltage generators (such as single-phase self-rectified, single-phase half-wave rectified, single-phase full-wave rectified, three-phase six pulse, three-phase 12 pulse, constant potential, capacitor energy storage) or under modes of operation such as alternate focal spot sizes or speeds of anode rotation which affect its rating, specific identification of the difference in ratings shall be noted.

(3) *X-ray controls and generators.* For the x-ray control and associated x-ray high-voltage generator, there shall be provided:

(i) A statement of the rated line voltage and the range of line-voltage regulation for operation at maximum line current;

(ii) A statement of the maximum line current of the x-ray system based on the maximum input voltage and current characteristics of the tube.

lat. of CT number mean and standard deviation in addition to other information provided according to § 1020.30(h).

(The information collection requirements in paragraphs (c), (d), (e), and (j) were approved by the Office of Management and Budget under control number 0910-0026) 149 FR 34712, Aug. 31, 1984; 49 FR 37481, Sept. 24, 1984, as amended at 49 FR 47388, Dec. 4, 1984)

§ 1020.40 Cabinet x-ray systems.

(a) **Applicability.** The provisions of this section are applicable to cabinet x-ray systems manufactured or assembled on or after April 10, 1975, except that the provisions as applied to x-ray systems designed primarily for the inspection of carry-on baggage are applicable to such systems manufactured or assembled on or after April 25, 1974. The provisions of this section are not applicable to systems which are designed exclusively for microscopic examination of material, e.g., x-ray diffraction, spectroscopic, and electron microscope equipment or to systems for intentional exposure of humans to x-rays.

(b) **Definitions.** As used in this section the following definitions apply:

(1) "Access panel" means any barrier or panel which is designed to be removed or opened for maintenance or service purposes, requires tools to open, and permits access to the interior of the cabinet.

(2) "Aperture" means any opening in the outside surface of the cabinet, other than a port, which remains open during generation of x radiation.

(3) "Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure (hereinafter termed "cabinet") which, independently 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 airline, railroad, and bus terminals, and in similar facilities. An x-ray tube used within a

equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.

(4) "Door" means any barrier which is designed to be movable or opened for routine operation purposes, does not generally require tools to open, and permits access to the interior of the cabinet. For the purposes of paragraph (c)(4)(i) of this section, inflexible hardware rigidly affixed to the door shall be considered part of the door.

(5) "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.

(6) "External surface" means the outside surface of the cabinet x-ray system, including the high-voltage generator, doors, access panels, latches, control knobs, and other permanently mounted hardware and including the plane across any aperture or port.

(7) "Floor" means the underside external surface of the cabinet.

(8) "Ground fault" means an accidental electrical grounding of an electrical conductor.

(9) "Port" means any opening in the outside surface of the cabinet which is designed to remain open, during generation of x-rays, for the purpose of conveying material to be irradiated into and out of the cabinet, or for partial insertion for irradiation of an object whose dimensions do not permit complete insertion into the cabinet.

(10) "Primary beam" means the x radiation emitted directly from the from the target and passing through the window of the x-ray tube.

(11) "Safety interlock" means a device which is intended to prevent the generation of x radiation when access by any part of the human body to the interior of the cabinet x-ray system through a door or access panel is possible.

(12) "X-ray system" means an assemblage of components for the controlled generation of x-rays.

tron tube which is designed for the conversion of electrical energy into x-ray energy.

(c) **Requirements—(1) Emission limit.** (i) Radiation emitted from the cabinet x-ray system shall not exceed an exposure of 0.5 milliroentgen in one hour at any point five centimeters outside the external surface.

(ii) Compliance with the exposure limit in paragraph (c)(1)(i) of this section shall be determined by measurements averaged over a cross-sectional area of ten square centimeters with no linear dimension greater than 5 centimeters, with the cabinet x-ray system operated at those combinations of x-ray tube potential, current, beam orientation, and conditions of scatter radiation which produce the maximum x-ray exposure at the external surface, and with the door(s) and access panel(s) fully closed as well as fixed at any other position(s) which will allow the generation of x radiation.

(2) **Floors.** A cabinet x-ray system shall have a permanent floor. Any support surface to which a cabinet x-ray system is permanently affixed may be deemed the floor of the system.

(3) **Ports and apertures.** (i) The insertion of any part of the human body through any port into the primary beam shall not be possible.

(ii) The insertion of any part of the human body through any aperture shall not be possible.

(4) **Safety interlocks.** (i) Each door of a cabinet x-ray system shall have a minimum of two safety interlocks. One, but not both of the required interlocks shall be such that door opening results in physical disconnection of the energy supply circuit to the high-voltage generator, and such disconnection shall not be dependent upon any moving part other than the door.

(ii) Each access panel shall have at least one safety interlock.

(iii) Following interruption of x-ray generation by the functioning of any safety interlock, use of a control provided in accordance with paragraph (c)(6)(ii) of this section shall be necessary for resumption of x-ray generation.

of the cabinet x-ray system shall not cause failure of more than one required safety interlock.

(5) **Ground fault.** A ground fault shall not result in the generation of x-rays.

(6) **Controls and indicators for all cabinet x-ray systems.** For all systems to which this section is applicable there shall be provided:

(i) A key-actuated control to insure that x-ray generation is not possible with the key removed.

(ii) A control or controls to initiate and terminate the generation of x-rays other than by functioning of a safety interlock or the main power control.

(iii) Two independent means which indicate when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second, in which case the indicators shall be activated for one-half second, and which are discernible from any point at which initiation of x-ray generation is possible. Failure of a single component of the cabinet x-ray system shall not cause failure of both indicators to perform their intended function. One, but not both, of the indicators required by this subdivision may be a milliammeter labeled to indicate x-ray tube current. All other indicators shall be legibly labeled "X-RAY ON".

(iv) Additional means other than millimeters which indicate when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second in which case the indicators shall be activated for one-half second, as needed to insure that at least one indicator is visible from each door, access panel and port, and is legibly labeled "X RAY ON".

(7) **Additional controls and indicators for cabinet x-ray systems designed to admit humans.** For cabinet x-ray systems designed to admit human there shall also be provided:

(i) A control within the cabinet to prevent and terminating x-ray generation, which cannot be reset, overridden or bypassed from the outside of the cabinet.

tion can be initiated from within the cabinet.

(iii) Audible and visible warning signals within the cabinet which are actuated for at least 10 seconds immediately prior to the first initiation of x-ray generation after closing any door designed to admit humans. Failure of any single component of the cabinet x-ray system shall not cause failure of both the audible and visible warning signals.

(iv) A visible warning signal within the cabinet which remains actuated when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second in which case the indicators shall be actuated for one-half second.

(v) Signs indicating the meaning of the warning signals provided pursuant to paragraphs (c)(7) (iii) and (iv) of this section and containing instructions for the use of the control provided pursuant to paragraph (c)(7)(i) of this section. These signs shall be legible, accessible to view, and illuminated when the main power control is in the "on" position.

(8) **Warning labels.** (i) There shall be permanently affixed or inscribed on the cabinet x-ray system at the location of any controls which can be used to initiate x-ray generation, a clearly legible and visible label bearing the statement:

CAUTION: X-RAYS PRODUCED WHEN ENERGIZED

(ii) There shall be permanently affixed or inscribed on the cabinet x-ray system adjacent to each port a clearly legible and visible label bearing the statement:

CAUTION: DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ENERGIZED—X-RAY HAZARD

(9) **Instructions.** (i) Manufacturers of cabinet x-ray systems shall provide for purchasers, and to others upon request at a cost not to exceed the cost of preparation and distribution, manuals and instructions which shall include at least the following technical and safety information: Potential, current, and duty cycle ratings of the x-

ray generation equipment, adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the system; and a schedule of maintenance necessary to keep the system in compliance with this section.

(ii) Manufacturers of cabinet x-ray systems which are intended to be assembled or installed by the purchaser shall provide instructions for assembly, installation, adjustment and testing of the cabinet x-ray system adequate to assure that the system is in compliance with applicable provisions of this section when assembled, installed, adjusted and tested as directed.

(10) **Additional requirements for x-ray baggage inspection systems.** X-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and at similar facilities, shall be provided with means, pursuant to paragraphs (c)(10) (i) and (ii) of this section, to insure operator presence at the control area in a position which permits surveillance of the ports and doors during generation of x-radiation.

(i) During an exposure or preset succession of exposures of one-half second or greater duration, the means provided shall enable the operator to terminate the exposure or preset succession of exposures at any time.

(ii) During an exposure or preset succession of exposures of less than one-half second duration, the means provided may allow completion of the exposure in progress but shall enable the operator to prevent additional exposures.

(d) **Modification of a certified system.** The modification of a cabinet x-ray system, previously certified pursuant to §1010.2 by any person engaged in the business of manufacturing, assembling or modifying cabinet x-ray systems shall be construed as manufacturing under the act if the modification affects any aspect of the system's performance for which this section has an applicable requirement. The manufacturer who performs such modification shall recertify and re-identify the system in accordance with

the provisions of §§1010.2 and 1010.3 of this chapter.

[39 FR 12986, Apr. 10, 1974]

PART 1030—PERFORMANCE STANDARDS FOR MICROWAVE AND RADIO FREQUENCY EMITTING PRODUCTS

AUTHORITY: Secs. 501, 502, 510, 515-520, 701, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360, 360e-360j, 371, 381); secs. 354-360P of the Public Health Service Act (42 U.S.C. 263b-263h).

§ 1030.10 Microwave ovens.

(a) **Applicability.** The provisions of this standard are applicable to microwave ovens manufactured after October 6, 1971.

(b) **Definitions.** (1) "Microwave oven" means a device designed to heat, cook, or dry food through the application of electromagnetic energy at frequencies assigned by the Federal Communications Commission in the normal ISM heating bands ranging from 890 megahertz to 6,000 megahertz. As defined in this standard, "microwave ovens" are limited to those manufactured for use in homes, restaurants, food vending, or service establishments, on interstate carriers, and in similar facilities.

(2) "Cavity" means that portion of the microwave oven in which food may be heated, cooked, or dried.

(3) "Door" means the movable barrier which prevents access to the cavity during operation and whose function is to prevent emission of microwave energy from the passage or opening which provides access to the cavity.

(4) "Safety interlock" means a device or system of devices which is intended to prevent generation of microwave energy when access to the cavity is possible.

(5) "Service adjustments or service procedures" means those servicing methods prescribed by the manufacturer for a specific product model.

(6) "Stirrer" means that feature of a microwave oven which is intended to provide uniform heating of the load by constantly changing the standing wave pattern within the cavity or moving the load.

(7) "External surface" means outside surface of the cabinet or enclosure provided by the manufacturer part of the microwave oven, including doors, door handles, latches, and control knobs.

(8) "Equivalent plane-wave power density" means the square of the root-mean-square (rms) electric field strength divided by the impedance free space (377 ohms).

(c) **Requirements—(1) Power density limit.** The equivalent plane-wave power density existing in the proximity of the external oven surface shall not exceed 1 milliwatt per square centimeter at any point 5 centimeters more from the external surface of the oven, measured prior to acquisition by a purchaser, and, thereafter, milliwatts per square centimeter any such point.

(2) **Safety interlocks.** (i) Microwave ovens shall have a minimum of two operative safety interlocks. At least one operative safety interlock on a fully assembled microwave oven shall not be operable by any part of the human body, or any object with a straight insertable length of 10 centimeters. Such interlock must also be concealed unless its actuation is prevented when access to the interlock is possible. A visible actuator or device to prevent actuation of this safety interlock must not be removable without disassembly of the oven or its door. A magnetically operated interlock is considered to be concealed, or its actuation is considered to be prevented, only if a magnet held in place on the oven gravity or its own attraction can operate the safety interlock. The magnet shall be capable of lifting a weight of at least 450 grams, and at 1 centimeter air gap, at least 450 grams when the face of the magnet, which is toward the interlock, is pulling against one of the flat faces of a mild steel armature having dimensions of 80 millimeters by 50 millimeters by 8 millimeters.

(ii) Failure of any single mechanical or electrical component of the microwave oven shall not cause all safety interlocks to be inoperative.

(iii) Service adjustments or service procedures on the microwave oven

EFFECTIVE DATE
JULY 22, 2001

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- Attachment Number 3-1 10 CFR Chapter 1, Part 32, Section 32.21 & 32.26
- Attachment Number 3-2 10 CFR Chapter 1, Part 30, Section 30.33
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- Attachment Number 3-4 10 CFR Chapter 1, Part 70, Section 70.39
- Attachment Number 3-5 10 CFR Chapter 1, Part 31, Section 31.5
- Attachment Number 3-6 11 U.S.C. 101(2) & 101(14)

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JULY 22, 2001

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CHAPTER 3 LICENSING OF RADIOACTIVE MATERIAL

3-001 SCOPE AND AUTHORITY

3-001.01 180 NAC 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 180 NAC 3 or as otherwise provided in 180 NAC 3. The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Stat. Rev. sections 71-3501 to 3519.

3-001.02 In addition to the requirements of 180 NAC 3, all licensees are subject to the requirements of 180 NAC 1, 4, 13, 15, 46, 17, and 18. Licensees engaged in industrial radiographic operations are subject to the requirements of 180 NAC 5, licensees using sealed and unsealed sources in the healing arts are subject to the requirements of 180 NAC 7, licensees engaged in the management of radioactive waste are subject to the requirements of 180 NAC 12, licensees engaged in well logging and subsurface tracer studies are subject to the requirements of 180 NAC 14, and licensees using sealed sources containing radioactive materials in irradiators are subject to the requirements of 180 NAC 19.

3-002 DEFINITIONS: As used in 180 NAC 3.

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.

Principal activities means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no license material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

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

EXEMPTIONS

3-003 SOURCE MATERIAL

3-003.01 Any person is exempt from 180 NAC 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.

3-003.02 Any person is exempt from 180 NAC 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.

3-003.03 Any person is exempt from 180 NAC 3 to the extent that such person receives, possesses, uses, or transfers:

1. Any quantities of thorium contained in:
 - a. incandescent gas mantles,
 - b. vacuum tubes,
 - c. welding rods,
 - d. electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium,
 - e. germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than 2 grams of thorium,
 - f. rare earth metals and compounds, mixtures, and products containing not than 0.25 percent by weight thorium, uranium, or any combination of these, or
 - g. personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium;
2. Source material contained in the following products:
 - a. glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight source material,
 - b. glassware, containing not more than 10 percent by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile or other glass, or ceramic used in construction,
 - c. glass enamel or glass enamel frit containing not more than 10 percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983,¹ or
 - d. 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 the exemption contained in this subpart shall

¹On July 25, 1983, the exemption of glass enamel or glass enamel frit was suspended. The exemption was eliminated on September 11, 1984.

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:
 - a. 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;
 - b. each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM",²
 - c. each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED",³ and
 - d. the exemption contained in this division 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. Natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that:
 - a. The shipping container is conspicuously and legibly impressed with the legend "CAUTION - RADIOACTIVE SHIELDING - URANIUM", and
 - b. The uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of one-eighth inch (3.2mm).
7. Thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent by weight of thorium, and that the exemption shall not be deemed to authorize either:
 - a. 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
 - b. the receipt, possession, use, or transfer of thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments;

²The requirements specified in 180 NAC 3-003.03, items 5.b. and 5.c. need not be met by counter weights manufactured prior to December 31, 1969; provided, that such counter weights are impressed with the legend, "CAUTION, RADIOACTIVE MATERIAL - URANIUM", as previously required by Title 180.

³Ibid. p. 3

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8. Uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 185 Bq (0.005 microcurie) of uranium; or
9. Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:
 - a. the thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide), and
 - b. the thorium content in the nickel-thoria alloy does not exceed 4 percent by weight.

3-003.04 The exemptions in 180 NAC 3-003.03 do not authorize the manufacture of any of the products described.

3-004 RADIOACTIVE MATERIAL OTHER THAN SOURCE MATERIAL

3-004.01 Exempt Concentrations.

1. Except as provided in 3-003.01, item 2 any person is exempt from this 180 NAC 3 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 180 NAC 3, appendix 3-A.
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 180 NAC 3-004.01, item 1 or equivalent regulations of the U.S. Nuclear Regulatory Commission, or any Agreement State, except in accordance with a specific license issued pursuant to 180 NAC 3-014.01 or the general license provided in 180 NAC 3-028.

3-004.02 Exempt Quantities.

1. Except as provided in 180 NAC 3-004.02 , items 2 and 3., any person is exempt from Title 180 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 180 NAC 3, Appendix 3-B.
2. 180 NAC 3-004.02 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 180 NAC 3, Appendix 3-B knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under 180 NAC 3-004.02 or equivalent regulations of the U.S. Nuclear Regulatory Commission, or any Agreement 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 Agency

pursuant to 180 NAC 3-014.02 which license states that the radioactive material may be transferred by the licensee to persons exempt under 180 NAC 3-004.02 or the equivalent regulations of the U.S. Nuclear Regulatory Commission, or any Agreement State.

3-004.03 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 Title 180 to the extent that he receives, possesses, uses, transfers, owns, or acquires the following products:
 - a. Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified radiation dose rate:
 - (1) 925 MBq (25 millicuries) of tritium per timepiece.
 - (2) 185 MBq (5 millicuries) of tritium per hand.
 - (3) 555 MBq (15 millicuries) of tritium per dial (bezels when used shall be considered as part of the dial).
 - (4) 3.7 MBq (100 microcuries) of promethium-147 per watch or 7.4 MBq (200 microcuries) of promethium-147 per any other timepiece.
 - (5) 0.74 MBq (20 microcuries) of promethium-147 per watch hand or 1.48 MBq (40 microcuries) of promethium-147 per other timepiece hand.
 - (6) 2.22 MBq (60 microcuries) of promethium-147 per watch dial or 4.44 MBq (120 microcuries) of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial).
 - (7) 1.11 kBq (0.03 microcurie) of radium per hand.
 - (8) 3.33 kBq (0.09 microcurie) of radium per dial (when used bezels shall be considered as part of the dial).
 - (9) The radiation dose rate from hands and dials containing promethium-147 will not exceed the following, when measured through 50 milligrams per square centimeter of absorber:
 - (a) For wrist watches, 1 μ Gy (0.1 millirad) per hour at 10 centimeters from any surface.
 - (b) For pocket watches, 1 μ Gy (0.1 millirad) per hour at 1 centimeter from any surface.
 - (c) For any other timepiece, 2 μ Gy (0.2 millirad) per hour at 10 centimeters from any surface.
 - (10) 37 kBq (one microcurie) of radium-226 per timepiece in timepieces acquired prior to August 22, 1982.
 - b. Lock illuminators containing not more than 555 MBq (15 millicuries) of tritium or not more than 74 MBq (2 millicuries) of promethium-147 installed in automobile locks. The radiation dose rate from each lock illuminator

- containing promethium-147 will not exceed 10 μ Gy (1 millirad) per hour at 1 centimeter from any surface when measured through 50 milligrams per square centimeter of absorber.
- c. Precision balances containing not more than 37 MBq (1 millicurie) of tritium per balance or not more than 18.5 MBq (0.5 millicurie) of tritium per balance part.
 - d. Automobile shift quadrants containing not more than 925 MBq (25 millicuries) of tritium.
 - e. Marine compasses containing not more than 27.8 GBq (750 millicuries) of tritium gas and other marine navigational instruments containing not more than 9.25 GBq (250 millicuries) of tritium gas.
 - f. Thermostat dials and pointers containing not more than 925 MBq (25 millicuries) of tritium per thermostat.
 - g. Electron tubes; provided, that each tube does not contain more than one of the following specified quantities of radioactive material:
 - (1) 5.55 GBq (150 millicuries) of tritium per microwave receiver protector tube or 370 MBq (10 millicuries) of tritium per any other electron tube.
 - (2) 37 kBq (1 microcurie) of cobalt-60.
 - (3) 185 kBq (5 microcuries) of nickel-63.
 - (4) 1.11 MBq (30 microcuries) of krypton-85.
 - (5) 185 kBq (5 microcuries) of cesium-137.
 - (6) 1.11 MBq (30 microcuries) of promethium-147.

And provide further, that the levels of radiation from each electron tube containing radioactive material will not exceed 10 μ Gy (1 millirad) per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber.⁴

- h. Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material provided that:
 - (1) Each source contains no more than one exempt quantity set forth in 180 NAC 3, Appendix 3-B, and
 - (2) Each instrument contains no more than 10 exempt quantities. An instrument's source(s) may contain either one type or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in 180 NAC 3, Appendix 3-B provided that the sum of such fractions does not exceed unity.

⁴For purposes of this division, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

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- (3) For americium-241, 1.85 kBq (0.05 microcurie) is considered an exempt quantity under 180 NAC 3-004.03, item 1.h.
- i. Spark gap irradiators containing not more than 37 kBq (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.
- a. 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 Title 180 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 180 NAC 3-004.03, item 2 does not apply to tritium, krypton-85, or promethium-147 used in products for frivolous purposes or in toys or adornments.
- b. Radium-226. Any person is exempt from Title 180 to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 3.7 kBq (0.1 microcuries) of radium-226 which were acquired prior to August 22, 1982.
3. Gas and aerosol detectors containing radioactive material.
- a. Except for persons who manufacture, process, or produce gas and aerosol detectors containing radioactive material, any person is exempt from Title 180 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 pursuant to Section 32.26 of 10 CFR Part 32, or an Agreement State, pursuant to 180 NAC 3-014.03, which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.
- b. 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 180 NAC 3-004.03, item a., provided that the device is labeled in accordance with the specific license authorizing distribution of the generally licensed device, and provided further that they meet the requirements of 180 NAC 3-014.03.

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4. Resins Containing Scandium-46 and Designed for Sand Consolidation in Oil Wells. Any person is exempt from Title 180 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 Agency 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 U.S. Nuclear Regulatory Commission. This exemption does not authorize the manufacture of any resins containing scandium-46.

LICENSES

3-005 TYPES OF LICENSES: Licenses for radioactive materials are of two types: general and specific:

3-005.01 General licenses provided in this 180 NAC 3 are effective without the filing of applications with the Agency or the issuance of licensing documents to the particular persons, although the filing of a certificate with the Agency may be required by the particular general license. The general licensee is subject to all other applicable portions of Title 180 and any limitations based on the type and quantity of radioactive material of the general license.

3-005.02 Specific licenses require the submission of an application to the Agency and the issuance of a licensing document by the Agency. The licensee is subject to all applicable portions of Title 180 as well as any limitations based on quantities and types of radioactive materials, proposed use and upon the training and experience of the user(s) specified in the licensing document.

3-006 RADIOACTIVE DRUG: CAPSULES CONTAINING CARBON-14 UREA FOR "IN-VIVO" DIAGNOSTIC USE FOR HUMANS

3-006.01 Except as provided in 180 NAC 3-006.01 and 180 NAC 3-006.03, any person is exempt from the requirements for a license set forth in the Act and from the regulations in 180 NAC 3 and 7 provided that such person receives, possesses, uses, transfers, owns or acquires capsules containing 37 kBq (1 μ Ci) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each for "in vivo" diagnostic use for humans.

3-006.02 Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to 180 NAC 7.

3-006.03 Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license from the Nuclear Regulatory Commission pursuant to 10 CFR Chapter 1,

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Part 32, Section 32.21 attached hereto as Attachment Number 3-1 and incorporated herein by this reference.

3-006.04 Nothing in 180 NAC 3-006 relieves persons from complying with applicable FDA, other Federal, and State requirements governing receipt, administration, and use of drugs.

GENERAL LICENSES

3-007 GENERAL LICENSES - SOURCE MATERIAL

3-007.01 A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions and Federal, State and local government agencies to use and transfer not more than fifteen (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.

3-007.02 Persons who receive, possess, use, or transfer source material pursuant to the general license issued in 180 NAC 3-007.01 are exempt from the provisions of 180 NAC 4 and 10 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 this 180 NAC 3.

3-007.03 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.

3-007.04 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 180 NAC 3-007.04 items 2. through 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 180 NAC 3-007.04, item 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 180 NAC 3-014.13 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. Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by 180 NAC 3-007.04, item 1 shall:

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- a. File Agency Form NRH-11 "Certificate - Use of Depleted Uranium Under General License," with the Agency. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The registrant shall furnish on Agency Form NRH-11 the following information and such other information as may be required by that form:
 - (1) Name and address of the general licensee;
 - (2) A statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 180 NAC 3-007.04, item 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
 - (3) Name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in 180 NAC 3-007.04, item 3.a.(2).
 - b. Report in writing to the Agency any changes in information furnished by him in Agency Form NRH-11 "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 180 NAC 3-007.04, item 1:
- a. 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.
 - b. Shall not abandon such depleted uranium.
 - c. Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 180 NAC 3-025. In the case where the transferee receives the depleted uranium pursuant to the general license established by 180 NAC 3-007.04, item 1., the transferor shall furnish the transferee a copy of this regulation and a copy of Agency Form NRH-11. 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 regulation equivalent to 180 NAC 3-007.04, item 1., the transferor shall furnish the transferee a copy of Title 180 and a copy of Agency Form NRH-11 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 Title 180.

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- d. Within 30 days of any transfer, shall report in writing to the Agency the name and address of the person receiving the depleted uranium pursuant to such transfer.
5. Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by 180 NAC 3-007.04, item 1 is exempt from the requirements of 180 NAC 4 and 180 NAC 10 with respect to the depleted uranium covered by that general license.

3-007.05 Persons who receive, possess, use, or transfer source material pursuant to the general license in 180 NAC 3-007.01 are prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the agency in a specific license.

3-008 GENERAL LICENSES - RADIOACTIVE MATERIAL OTHER THAN SOURCE MATERIAL⁵

3-008.01 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 180 NAC 1-004 through 009, 180 NAC 3-004.01, item 2., 180 NAC 3-017, 3-025, and 3-026, 180 NAC 4,⁶ and 180 NAC 10, 13, 17 and 18.

1. Static Elimination Device. Devices designed for use as static eliminators which contain, as sealed source or sources, radioactive material consisting of a total of not more than 18.5 MBq (500 microcuries) of polonium-210 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 18.5 MBq (500 microcuries) of polonium-210 per device or a total of not more than 1.85 GBq (50 millicuries) of hydrogen-3 (tritium) per device.

3-008.02 Reserved

3-008.03 Reserved

3-008.04 Certain Measuring, Gauging and Controlling Devices

⁵Note: Different general licenses are issued in 180 NAC 3-008, each of which has its own specific conditions and requirements.

⁶Attention is directed particularly to the provisions of 180 NAC 4 which relate to the labeling of containers.

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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 180 NAC 3-008.04, items, 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 180 NAC 3-008.04, item 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 Agency pursuant to 180 NAC 3-014.04 or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission, or an Agreement State which authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission, or an Agreement State.
3. Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in 180 NAC 3-008.04, item 1:
 - a. 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;
 - b. Shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label, however,
 - (1) Devices containing only krypton need not be tested for leakage of radioactive material, and
 - (2) Devices containing only tritium or not more than 3.7 MBq (100 microcuries) of other beta and/or gamma emitting material or 0.37 MBq (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;
 - c. Shall assure that the tests required by 180 NAC 3-008.04, item 3.b. and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:
 - (1) In accordance with the instructions provided by the labels; or
 - (2) By a person holding an applicable specific license from the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform such activities;

- d. Shall maintain records showing compliance with the requirements of 180 NAC 3-008.04, items 3.b. and 3.c. The records shall show the results of the 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 180 NAC 3-008.04, item 3.b. shall be maintained until the sealed source is transferred or disposed of. Records of tests of the on/off mechanism and indicator required by 180 NAC 3-008.04, item 3.b. 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 180 NAC 3-008.04, item 3.c. shall be maintained for a period of two (2) years from the date of the recorded event or until the device is transferred or disposed of;
- e. 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 185 Bq (0.005 microcurie) or more of 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 Agency, the U.S. Nuclear Regulatory Commission, or any Agreement 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 Agency a report containing a brief description of the event and the remedial action taken;
- f. Shall not abandon the device containing radioactive material;
- g. Except as provided in 180 NAC 3-008.04, item 3.h., shall transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the Agency, the U.S. Nuclear Regulatory Commission, or any Agreement 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 Agency 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;
- h. Shall transfer the device to another general licensee only:
 - (1) Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this regulation and any safety documents identified in the label on the device and within 30 days of the transfer, report to the Agency 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

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- individual who may constitute a point of contact between the Agency and the transferee; or
- (2) 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
- i. Shall comply with the provisions of 180 NAC 4-055 and 4-056 for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of 180 NAC 4 and 10.
4. The general license in 180 NAC 3-008.04, item 1. does not authorize the manufacture of devices containing radioactive material.
5. The general license provided in 180 NAC 3-008.04, item 1. is subject to the provisions of 180 NAC 1-004 through 1-009, 180 NAC 3-017, 3-025, 3-027, and 180 NAC 13 .

3-008.05 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:
- a. Each device contains not more than 370 GBq (10 curies) of tritium or 11.1 GBq (300 millicuries) of promethium-147; and
- b. 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 Agency or any Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in 10 CFR Chapter I, Part 30, Section 30.33, attached hereto as Attachment Number 3-2 incorporated herein by this reference and Part 32, Section 32.53, attached hereto as part of Attachment Number 3-3 and incorporated herein by this reference.
2. Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in 180 NAC 3-008.05, item 1. are exempt from the requirements of 180 NAC 4 and 180 NAC 10 except that they shall comply with the provisions of 180 NAC 4-055 and 180 NAC 4-056.
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 ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.
5. This general license is subject to the provisions of 180 NAC 1-004 through 1-009, 180 NAC 3-017, 3-025, 3-027, and 13.

3-008.06 Ownership of Radioactive Material: A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of 180 NAC 3, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

3-008.07 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 180 NAC 3-008.07, items 4. and 5., americium-241 in the form of calibration or reference sources:
 - a. Any person who holds a specific license issued by the Agency which authorizes him to receive, possess, use, and transfer radioactive material; and
 - b. 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 180 NAC 3-008.07, items 4. and 5. to any person who holds a specific license issued by the Agency 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 180 NAC 3-008.07, items 4 and 5 to any person who holds a specific license issued by the Agency which authorizes him to receive, possess, use, and transfer radioactive material.
4. The general licenses in 180 NAC 3-008.07, items 1. through 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 10 CFR Chapter I, Part 30, Section 30.33, attached hereto as Attachment Number 3-2 and Part 32, Section 32.57, attached hereto as Attachment Number 3-3 and incorporated herein by this reference or 10 CFR Chapter I, Part 70, Section 70.39 except stricken text, attached hereto as part of Attachment Number 3-4 and incorporated herein by this reference, or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the Agency, or any Agreement State pursuant to licensing requirements equivalent to those contained in 10 CFR Chapter I, Part 30, Section 30.33, attached hereto as Attachment Number 3-2 and Part 32, Section 32.57, attached hereto as part of Attachment Number 3-3 or 10 CFR Chapter I, Part 70, Section 70.39 except stricken text, attached hereto as part of Attachment Number 3-4.

5. The general licenses provided in 180 NAC 3-008.07, items 1 through 3, are subject to the provisions of 180 NAC 1-004 through 1-009, 180 NAC 3-017, 3-025, 3-027, 180 NAC 4, 10, and 13. In addition, persons who own, receive, acquire, possess, use or transfer one or more calibration or reference sources pursuant to these general licenses:

- a. Shall not possess at any one time, at any one location of storage or use, more than 185 kBq (5 microcuries) of americium-241, 185 kBq (5 microcuries) of plutonium, and 185 kBq (5 microcuries) of radium-226 in such sources;
- b. Shall not receive, possess, use, or transfer such source unless the source, or the storage container, bears a label which includes the following statement or a substantially similar statement which contains the information called for in the following statement.

(1) 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 (RADIUM-226) (AMERICIUM-241). (PLUTONIUM)⁷ DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

Name of manufacturer or importer

- c. Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the Agency, the U.S. Nuclear Regulatory Commission, or any other Agreement State to receive the source;
- d. 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
- e. Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

⁷Showing only the name of the appropriate material.

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

3-008.08 Reserved

3-008.09 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 in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of 180 NAC 3-008.09, items 2. through 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:
 - a. Iodine-125, iodine-131, selenium-75, cobalt-57, and carbon-14 in units not exceeding 370 kBq (10 microcuries) each.
 - b. Hydrogen-3 (tritium), in units not exceeding 1.85 MBq (50 microcuries) each.
 - c. Iron-59, in units not exceeding 740 kBq (20 microcuries) each.
 - d. Mock Iodine-125 reference or calibration sources, in units not exceeding 1.85 kBq (0.05 microcurie) of iodine-129 and 1.85 Bq (0.005 microcurie) of americium-241 each.
2. No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by 180 NAC 3-008.09, item 1. until he has filed Agency Form NRH-17, "Certificate - In Vitro Testing with Radioactive Material Under General License", with the Agency and received from the Agency a validated copy of Agency Form NRH-17 with certification number assigned. The physician, veterinarian, clinical laboratory or hospital shall furnish on Agency Form NRH-17 the following information and such other information as may be required by that form:
 - a. Name and address of the physician, veterinarian, clinical laboratory or hospital;
 - b. The location of use; and
 - c. A statement that the physician, veterinarian in the practice of veterinary medicine, 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 180 NAC 3-008.09, item 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 180 NAC 3-008.09, item 1. shall comply with the following:

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- a. The general licensee shall not possess at any one time, pursuant to the general license in 180 NAC 3-008.09, item 1. at any one location of storage or use a total amount of iodine-125, iodine-131, iron-59, cobalt-57 and/or selenium-75 in excess of 7.4 MBq (200 microcuries).
 - b. The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.
 - c. The general licensee shall use the radioactive material only for the uses authorized by 180 NAC 3-008.09, item 1.
 - d. 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 Agency, the U.S. Nuclear Regulatory Commission, or any Agreement State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.
 - e. The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in 180 NAC 3-008.09, item 1.d. as required by 180 NAC 4-037 and 4-042.
4. The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to 180 NAC 3-008.09, item 1.:
- a. Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 180 NAC 3-014.08 or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, or any Agreement 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 180 NAC 3-008.09 or its' equivalent, and
 - b. Unless the following statement, or substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, 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

5. The physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital possessing or using radioactive material under the general license of 180 NAC 3-008.09, item 1. shall report in writing to the Agency, any changes in the information furnished by him in the "Certificate - In Vitro Testing with Radioactive Material Under General License", Agency Form NRH-17. 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 180 NAC 3-008.09, item 1. is exempt from the requirements of 180 NAC 4 and 180 NAC 10 with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in 180 NAC 3-008.09 item 1,d. shall comply with the provisions of 180 NAC 4-037, 4-055, and 4-056.

3-008.10 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 1.85 MBq (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 Agency or any Agreement State to the manufacturer of such device pursuant to licensing requirements equivalent to those in 10 CFR Chapter I, Part 30, Section 30.33, attached hereto as Attachment Number 3-2 and Part 32, Section 32.61, attached hereto as part of Attachment Number 3-3 and incorporated herein by this reference.
2. Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in 180 NAC 3-008.10,
 - a. 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 180 NAC 4-037;
 - b. 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
 - c. Are exempt from the requirements of 180 NAC 4 and 10 except that such persons shall comply with the provisions of 180 NAC 4-037, 4-055, and 4-056.

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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 180 NAC 1-004 through 180 NAC 1-009, 180 NAC 3-017, 180 NAC 3-025, 180 NAC 3-027, and 180 NAC 13.

3-009 RESERVED

SPECIFIC LICENSES

3-010 FILING APPLICATION FOR SPECIFIC LICENSES

3-010.01 Applications for specific licenses shall be filed on form NRH-5A (medical) for all medical licenses, form NRH-5B (teletherapy) for all teletherapy licenses, and form NRH-5 for all other licenses.

3-010.02 The Agency 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 Agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.

3-010.03 Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

3-010.04 An application for a license may include a request for a license authorizing one or more activities.

3-010.05 In his application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the Agency provided such references are clear and specific.

3-010.06 Applications and documents submitted to the Agency may be made available for public inspection except that the Agency may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

3-010.07 As provided by 180 NAC 3-018 certain applications for specific licenses filed under 180 NAC 3 and 5, and 7, must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning. In the case of renewal applications submitted before May 30, 1994, this submittal may follow the renewal application but must be submitted on or before May 30, 1994.

3-010.08 Emergency Plans

1. Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in 180 NAC 3, Appendix 3-E "Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release" must contain either:

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- a. An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 0.01 Sv (1 rem) effective dose equivalent or 0.05 Sv (5 rem) to the thyroid; or
 - b. An emergency plan for responding to a release of radioactive material.
2. One or more of the following factors may be used to support an evaluation submitted under 180 NAC 3-010.08, item 1.:
- a. The radioactive material is physically separated so that only a portion could be involved in an accident;
 - b. All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;
 - c. The release fraction in the respirable size range would be lower than the release fraction shown in 180 NAC 3, Appendix 3-E due to the chemical or physical form of the material;
 - d. The solubility of the radioactive material would reduce the dose received;
 - e. Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in 180 NAC 3, Appendix 3-E;
 - f. Operating restrictions or procedures would prevent a release fraction as large as that shown in 180 NAC 3, or
 - g. Other factors appropriate for the specific facility.
3. An emergency plan for responding to a release of radioactive material submitted under 180 NAC 3-010.08 must include the following information:
- a. Facility description: A brief description of the licensee's facility and area near the site.
 - b. Types of accidents: An identification of each type of radioactive materials accident for which protective actions may be needed.
 - c. Classification of accidents: A classification system for classifying accidents as alerts or site area emergencies.
 - d. Detection of accidents: Identification of the means of detecting each type of accident in a timely manner.
 - e. Mitigation of consequences: A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.
 - f. Assessment of releases: A brief description of the methods and equipment to assess releases of radioactive materials.
 - g. Responsibilities: A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the Agency; also responsibilities for developing, maintaining, and updating the plan.
 - h. Notification and coordination: A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so

that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the Agency immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.⁸

- i. Information to be communicated: A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the Agency.
 - j. Training: A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.
 - k. Safe shutdown: A brief description of the means of restoring the facility to a safe condition after an accident.
 - l. Exercises: Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.
 - m. Hazardous chemicals: A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.
4. The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the Agency. The licensee shall provide any comments received within the 60 days to the Agency with the emergency plan.

⁸These reporting requirements do not supersede or release licensees of complying with the requirements under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499 or other state or federal reporting requirements.

3-011 GENERAL REQUIREMENTS FOR THE ISSUANCE OF SPECIFIC LICENSES: A license application will be approved 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 Title 180 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 the 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 180 NAC 3-012, 180 NAC 3-013, 180 NAC 3-014, or 180 NAC 3-015, 180 NAC 5, 180 NAC 7, 180 NAC 12, 180 NAC 14 or 180 NAC 19.

3-011.01 Environmental Report, Commencement of Construction: In the case of an application for a license to receive and possess radioactive material for commercial waste management, source material milling, or for the conduct of any other activity which the Agency determines will significantly affect the quality of the environment, the Agency, before commencement of construction of the plant or facility in which the activity will be conducted, has concluded, 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 conclusion 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 roads for site exploration, 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 the environmental values.

3-011.02 Financial Surety Arrangements for Site Reclamation

1. Pursuant to Radiation Control Act 71-3508.04, Reissued Revised Statutes of Nebraska 1943, as amended 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 180 NAC 3-011.02 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 the Act.
 - a. The amount of funds to be ensured by such surety arrangements shall be based on Agency approved cost estimates equal to meet the requirements of 180 NAC 3-011.02, item 1.

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- b. 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 180 NAC 3-011.02, item 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, except as provided in 3-011.02, item 3.
3. If application is made to amend an existing license to fall within the purview of 180 NAC 3-011.06 then the financial surety arrangements for site reclamation must be established prior to the issuance of the amendment.
4. The following specific licensees are required to make financial surety arrangements:
 - a. Major processors;
 - b. Waste management licensees, except the commercial disposal of low-level radioactive waste in a disposal facility, designated by the Central Interstate Low-Level Radioactive Waste Compact Commission;
 - c. Former U.S. Atomic Energy Commission or U.S. Nuclear Regulatory Commission licensed facilities;
 - d. Source material milling operations; and
 - e. All others except persons exempt pursuant to 180 NAC 3-011.02, item 5.
5. The following persons are exempt from the requirements of 180 NAC 3-011.02, item 1. because they are exempt from licensure:
 - a. All State, local, or other government agencies unless they are subject to 180 NAC 3-011.02, item 4.b. or 4.d.,
 - b. Persons authorized to possess no more than 1,000 times the quantity specified in 180 NAC 3, Appendix 3-B or combination of radioactive material listed therein as given in 180 NAC 3, Appendix 3-B, Note 1.;
 - c. Persons authorized to possess hydrogen-3 contained as hydrogen gas in a sealed source; or
 - d. Persons authorized to possess radioactive noble gases in sealed sources with no radioactive daughter product with half-life greater than 30 days.
6. Long-term Care Requirements: Pursuant to Radiation Control Act 71-3508.04, Reissued Revised Statutes of Nebraska, 1943, as amended 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:
 - a. Waste management licensees.
 - b. Source material milling and mill tailings licensees.

3-012 RESERVED

3-013 SPECIAL REQUIREMENTS FOR SPECIFIC LICENSES OF BROAD SCOPE: 180 NAC 3-013 prescribes requirements for the issuance of specific licenses of broad scope for radioactive material ("broad licenses") and certain regulations governing holders of such licenses:

3-013.01 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, and the limits are based on types of radioactive materials, proposed use and upon the training and experience of the user(s).
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 180 NAC 3, Appendix 3-C for any authorized purpose. The possession limit for a Type B broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Column I of 180 NAC 3, Appendix 3-C, 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 180 NAC 3, Appendix 3-C, 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 180 NAC 3, Appendix 3-C for any authorized purpose. The possession limit for a Type C broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in 180 NAC 3, Appendix 3-C, 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 180 NAC 3, Appendix 3-C, Column II for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

3-013.02 An application for a Type A specific license of broad scope will be approved if:

1. The applicant satisfies the general requirements specified in 180 NAC 3-011;
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:

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- a. 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;
- b. The appointment of a radiation safety officer who is qualified in training and experience in radiation protection consistent with the requirements of training specified in 180 NAC 15-015.01, item 1, and who is available for advice and assistance on radiation safety matters; and
- c. Authorized users designated by the Radiation Safety Committee shall have formal training and experience in the safe handling of radioactive material consistent with the requirements of training specified in 180 NAC 15-015.01, item 2.; and
- d. The establishment of appropriate administrative procedures to assure:
 - (1) Control of procurement and use of radioactive material;
 - (2) Completion of safety evaluations of proposed uses of radioactive material which takes into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and
 - (3) Review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with 180 NAC 3-013.02, item 3.d.(2). prior to use of the radioactive material.

3-013.03 An application for a Type B specific license of broad scope will be approved if:

1. The applicant satisfies the general requirements specified in 180 NAC 3-011; 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:
 - a. The appointment of a radiation safety officer who is qualified by training and experience in radiation protection consistent with the requirements of training specified in 180 NAC 15-015.01, item 1. and who is available for advice and assistance on radiation safety matters,
 - b. Authorized users shall have formal training and experience in the safe handling of radioactive material consistent with the requirements of training specified in 180 NAC 15-015.01, item 2.; and
 - c. The establishment of appropriate administrative procedures to assure:
 - (1) Control of procurement and use of radioactive material,
 - (2) 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
 - (3) Review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with 180 NAC 3-013.03, item 2.c. prior to use of the radioactive material.

3-013.04 An application for a Type C specific license of broad scope will be approved if:

1. The applicant satisfies the general requirements specified in 180 NAC 3-011;
2. The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:
 - a. A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering, and
 - b. At least 40 hours of formal training and 160 hours 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.

3-013.05 Specific licenses of broad scope are subject, based on quantities and types of radioactive materials, proposed use and upon the training and experience of the user(s), to the following conditions:

1. Unless specifically authorized, persons licensed pursuant to 180 NAC 3-013 shall not:
 - a. Conduct tracer studies in the environment involving direct release of radioactive material;
 - b. Receive, acquire, own, possess, use or transfer devices containing 3.7 PBq (100,000 curies) or more of radioactive material in sealed sources used for irradiation of materials;
 - c. Conduct activities for which a specific license issued by the Agency under 180 NAC 3-012, 3-014, 3-015 or 180 NAC 7, and 12 is required; or
 - d. 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 this 180 NAC 3-013.05 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 180 NAC 3-013.05 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 this 180 NAC 3-013.05, item 4 shall be subject to the condition that radioactive material

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possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of 180 NAC 3-013.04.

3-014 SPECIAL REQUIREMENTS FOR A SPECIFIC LICENSE TO MANUFACTURE, ASSEMBLE, REPAIR, OR DISTRIBUTE COMMODITIES, PRODUCTS, OR DEVICES WHICH CONTAIN RADIOACTIVE MATERIAL

3-014.01 Licensing the Introduction of Radioactive Material Into Products In Exempt Concentrations

1. In addition to the requirements set forth in 180 NAC 3-011, 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 180 NAC 3-004.01, item 1. will be issued if:
 - a. 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
 - b. The applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in 180 NAC 3, Appendix 3-A, that reconcentration of the radioactive material in concentrations exceeding those in Appendix 3-A of 180 NAC 3 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 180 NAC 3-014.01 shall file an annual report with the Agency 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 180 NAC 3-014.01 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.
3. The Radiation Safety Officer and/or authorized user shall have training and experience requirements consistent with training specified in 180 NAC 15-018.01.

3-014.02 Licensing the Distribution of Radioactive Material in Exempt Quantities

1. An application for a specific license to distribute NARM, to persons exempted from Title 180 pursuant to 180 NAC 3-004.02 will be approved if:
 - a. 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;
 - b. 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;
 - c. The applicant submits copies of prototype labels and brochures and the Agency approves such labels and brochures; and
 - d. Out-of-State manufacturers of the product have a license issued by a State with requirements comparable to those under this rule for manufacturer of similar products.

2. The license issued under 180 NAC 3-014.02, item 1. is subject to the following conditions:
 - a. 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.
 - b. 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 180 NAC 3-004.02. The outer package shall be such that the dose rate at the external surface of the package does not exceed 5 μ Sv (0.5 millirem) per hour.
 - c. 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."
 - d. In addition to the labeling information required by 180 NAC 3-014.02, item 2.c., the label affixed to the immediate container, or an accompanying brochure, shall (a) state that the contents are exempt from U.S. Nuclear Regulatory Commission or Agreement 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 180 NAC 3-014.02 shall maintain records of transfer of material for a period of two years after such transfer, identifying, by name and address, each person to whom radioactive material is transferred for use under 180 NAC 3-004.02 or the equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement 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 Agency. Each report shall cover the year ending June 30, and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to 180 NAC 3-014.02 during the reporting period, the report shall so indicate.
4. The Radiation Safety Officer and/or authorized user shall have training and experience requirements consistent with training specified in 180 NAC 15-018.01.

3-014.03 Licensing the Incorporation of Naturally Occurring 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 180 NAC 3-004.03, item 3. will be approved if the application satisfies the requirements of Section 32.26 of 10 CFR Part 32 attached hereto as part of Attachment Number 3-1 and incorporated herein by this reference. The maximum quantity of radium-226 in each device shall not exceed 3.7 kBq (0.1 microcurie).

3-014.04 Licensing the Manufacture and Distribution of Devices to Persons Generally Licensed Under 180 NAC 3-008.04

1. An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under 180 NAC 3-008.04 or equivalent regulations of the U.S. Nuclear Regulatory Commission, or an Agreement State will be approved if:
 - a. The applicant satisfies the general requirements of 180 NAC 3-011;
 - b. 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:
 - (1) The device can be safely operated by persons not having training in radiological protection;
 - (2) 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 one year a dose in excess of 10 percent of the annual limits specified in 180 NAC 4-005.01; and
 - (3) 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:

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Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	150 mSv (15 rems)
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	2 Sv (200 rems)
Other organs	500 mSv (50 rems)

- c. Each device bears a durable, legible, clearly visible label or labels approved by the Agency, which contain in a clearly identified and separate statement:
- (1) 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;
 - (2) 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
 - (3) The information called for in the following statement, as appropriate in the same or substantially similar form:

The receipt, possession, use, and transfer of this device Model _____⁹, Serial No. _____¹⁰, 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 Distributor¹¹

⁹The 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.

¹⁰Ibid. p. 3-31

¹¹Ibid. p. 3-31

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 Agency will consider information which includes, but is not limited to:
 - a. Primary containment or source capsule;
 - b. Protection of primary containment;
 - c. Method of sealing containment;
 - d. Containment construction materials;
 - e. Form of contained radioactive material;
 - f. Maximum temperature withstood during prototype tests;
 - g. Maximum pressure withstood during prototype tests;
 - h. Maximum quantity of contained radioactive material;
 - i. Radiotoxicity of contained radioactive material; and
 - j. Operating experience with identical devices or similarly designed and constructed devices.
3. In the event the applicant desires that the general licensee under 180 NAC 3-008.04, or under equivalent regulations of U.S. Nuclear Regulatory Commission, or an Agreement State be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the applicant shall include in his application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases 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 dose in excess of 10 percent of the annual limits specified in 180 NAC 4-005.01.
4. Each person licensed under 180 NAC 3-014.04 to distribute devices to generally licensed persons shall:
 - a. Furnish a copy of the general license contained in 180 NAC 3-008.04 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 180 NAC 3-008.04.
 - b. Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's, or Agreement State's regulation equivalent to 180 NAC 3-008.04 or alternatively, furnish a copy of the general license contained in 180 NAC 3-008.04 to each person to whom he directly or

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through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission, or an Agreement State. If a copy of the general license in 180 NAC 3-008.04 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, or an Agreement State under requirements substantially the same as those in 180 NAC 3-008.04.

- c. Report to the Agency all transfers of such devices to persons for use under the general license in 180 NAC 3-008.04. 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 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 180 NAC 3-008.04 during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter.
- d. Furnish reports to other agencies.
 - (1) 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 10 CFR Chapter I, Part 31, Section 31.5 except stricken text attached hereto as part of Attachment Number 3-5 and incorporated herein by this reference.
 - (2) Report to the responsible State agency all transfers of devices manufactured and distributed pursuant to 180 NAC 3-014.04 for use under a general license in that state's regulations equivalent to 180 NAC 3-008.04.
 - (3) 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 agency 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.

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- (4) 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.
 - (5) 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 the Agency.
- e. 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 180 NAC 3-008.04, or equivalent regulations to the U.S. Nuclear Regulatory Commission, or an Agreement 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 180 NAC 3-014.04, item e. The records required by this paragraph shall be maintained for a period of five years from the date of the recorded event.
5. The Radiation Safety Officer and/or authorized user shall have training and experience requirements consistent with training specified in 180 NAC 15-018.01.

3-014.05 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 180 NAC 008.05 will be approved subject to the following conditions:

1. The applicant satisfies the general requirements specified in 180 NAC 3-011, and
2. The applicant satisfies the requirements of 10 CFR Chapter I, Part 30, Section 30.33, attached hereto as Attachment Number 3-2 and Part 32, Sections 32.53-32.56 and 32.101 except stricken text attached hereto as part of Attachment Number 3-3 and incorporated herein by this reference or their equivalent, and
3. The Radiation Safety Officer and/or authorized user shall have training and experience requirements consistent with training specified in 180 NAC 15-018.01.

3-014.06 Special Requirements for License to Manufacture Calibration Sources Containing Americium-241, Plutonium or Radium-226 for Distribution to Persons Generally Licensed Under 180 NAC 3-008.07. An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under 180 NAC 3-008.07 will be approved subject to the following conditions:

1. The applicant satisfies the general requirement of 180 NAC 3-011, and
2. The applicant satisfies the requirements of 10 CFR Chapter I, Part 30, Section 30.33 attached hereto as Attachment Number 3-2 and Part 32, Sections 32.57-32.59 and 32.102 attached hereto as part of Attachment Number 3-3 and 10 CFR

Chapter I, Part 70, Section 70.39 as part of Attachment Number 3-4 herein and incorporated herein by this reference or their equivalent, and

3. The Radiation Safety Officer and/or authorized user shall have training and experience requirements consistent with training specified in 180 NAC 15-018.01.

3-014.07 Reserved

3-014.08 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 180 NAC 3-008.09 will be approved if:

1. The applicant satisfies the general requirements specified in 180 NAC 3-011.
2. The radioactive material is to be prepared for distribution in prepackaged units of:
 - a. Iodine-125 in units not exceeding 370 kBq (10 microcuries) each.
 - b. Iodine-131 in units not exceeding 370 kBq (10 microcuries) each.
 - c. Carbon-14 in units not exceeding 370 kBq (10 microcuries) each.
 - d. Hydrogen-3 (tritium) in units not exceeding 1.85 MBq (50 microcuries) each.
 - e. Iron-59 in units not exceeding 740 kBq (20 microcuries) each.
 - f. Cobalt-57 in units not exceeding 370 kBq (10 microcuries) each.
 - g. Selenium-75 in units not exceeding 370 kBq (10 microcuries) each.
 - h. Mock Iodine-125 in units not exceeding 1.85 kBq (0.05 microcurie) of iodine-129 and 185 Bq (0.005 microcurie) of americium-241 each.
3. Each prepackaged unit bears a durable, clearly visible label:
 - a. Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 370 kBq (10 microcuries) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 1.85 MBq (50 microcuries) of hydrogen-3 (tritium); 740 kBq (20 microcuries) of iron-59; or Mock Iodine-125 in units not exceeding 1.85 kBq (0.05 microcurie) of iodine-129 and 185 Bq (0.005 microcurie) of americium-241 each; and
 - b. Displaying the radiation caution symbol described in 180 NAC 4-031.01 and the words, "CAUTION, RADIOACTIVE MATERIAL" and "Not for Internal or External Use in Humans or Animals."
4. The following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, 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

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 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 180 NAC 4-037.
6. The Radiation Safety Officer and/or authorized user shall have training and experience requirements consistent with training specified in 180 NAC 15-019.01.

3-014.09 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 180 NAC 3-008.10 will be approved subject to the following conditions: (1) the applicant satisfies the general requirements of 180 NAC 3-011 and 180 NAC 3-012 the criteria of 10 CFR Chapter I, Part 30, Section 30.33, attached hereto as Attachment Number 3-2 and Part 32, Sections 32.61, 32.62, 32.103 as attached hereto as part of Attachment Number 3-3 and incorporated herein by this reference are met. The Radiation Safety Officer and/or authorized user shall have training and experience requirements consistent with training specified in 180 NAC 15-018.01.

3-014.10 Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs Containing Radioactive Material for Medical Use Under 180 NAC 7.

1. An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons authorized pursuant to 180 NAC 7, will be approved if:
 - a. The applicant satisfies the general requirements specified in 180 NAC 3-011;
 - b. The applicant submits evidence that the applicant is at least one of the following:
 - (1) Registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer;
 - (2) Registered or licensed with a state agency as a drug manufacturer;
 - (3) Licensed as a pharmacy by a State Board of Pharmacy; or
 - (4) Operating as a nuclear pharmacy within a Federal medical institution.
 - c. The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the

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packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

- d. The applicant satisfies the following labeling requirements:
- (1) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half life greater than 100 days, the time may be omitted.
 - (2) A label is affixed to each syringe, vial or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.
2. A licensee described by 180 NAC 3-014.10, item b.(3) or b.(4).
- a. May prepare radioactive drugs for medical use, as defined in 180 NAC 7-002, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in 180 NAC 3-014.10, item 1.b. and c, or an individual under the supervision of an authorized nuclear pharmacist as specified in 180 NAC 7-013.
 - b. May allow a pharmacist to work as an authorized nuclear pharmacist if:
 - (1) This individual qualifies as an authorized nuclear pharmacist as defined in 180 NAC 7-002;
 - (2) This individual meets the requirements specified in 180 NAC 7-066.15 and 7-066.12 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or
 - (3) This individual is designated as an authorized nuclear pharmacist in accordance with 180 NAC 3-014.10, item 2.c.
 - c. The actions authorized in 180 NAC 3-014.10, items 2.a. and b. are permitted in spite of more restrictive language in license conditions.
 - d. May designate a pharmacist (as defined in 180 NAC 7-002) as an authorized nuclear pharmacist if the individual is identified as of the effective date of Title 180 , as an "authorized user" on a nuclear pharmacy license issued by the Agency under 180 NAC 3.

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- e. Shall provide to the Agency a copy of each individual's certification by the Board of Pharmaceutical Specialties, the Agency, U.S. Nuclear Regulatory Commission, or any Agreement State license, or the permit issued by a licensee of broad scope, and a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to 180 NAC 3-014.10, item 2.b.(1) and (3), the individual to work as an authorized nuclear pharmacist.
3. A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:
 - a. Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and
 - b. Check each instrument for constancy and proper operation at the beginning of each day of use.
 4. Nothing in 180 NAC 3-014.10 relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

3-014.11 Reserved

3-014.12. 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 180 NAC 7 for use as a calibration or reference source or for the uses listed in 180 NAC 7-044 and 7-046 will be approved if:

1. The applicant satisfies the general requirements in 180 NAC 3-011.
2. The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:
 - a. The radioactive material contained, its chemical and physical form, and amount,
 - b. Details of design and construction of the source or device,
 - c. 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,
 - d. For devices containing radioactive material, the radiation profile of a prototype device,
 - e. Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,
 - f. Procedures and standards for calibrating sources and devices,

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- g. Legend and methods for labeling sources and devices as to their radioactive content, and
 - h. Instructions 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.
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 Agency for distribution to persons licensed pursuant to 180 NAC 7 and 180 NAC 7-044 and 7-046 or under equivalent licenses of the U.S. Nuclear Regulatory Commission, or an Agreement 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.
5. In determining the acceptable interval for test of leakage of radioactive material, the Agency will consider information that includes, but is not limited to:
- a. Primary containment or source capsule;
 - b. Protection of primary containment;
 - c. Method of sealing containment;
 - d. Containment construction materials;
 - e. Form of contained radioactive material;
 - f. Maximum temperature withstood during prototype tests;
 - g. Maximum pressure withstood during prototype tests;
 - h. Maximum quantity of contained radioactive material;
 - i. Radiotoxicity of contained radioactive material; and
 - j. Operating experience with identical sources or devices or similarly designed and constructed sources or devices.
6. The Radiation Safety Officer and/or authorized user shall have training and experience requirements consistent with training specified in 180 NAC 15-018.01.

3-014.13 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 180 NAC 3-007.04 or

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equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:

- a. The applicant satisfies the general requirements specified in 180 NAC 3-011;
 - b. 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 year a radiation dose in excess of 10 percent of the annual limits specified in 180 NAC 4-005.01; and
 - c. 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 Agency will approve an application for a specific license under 180 NAC 3-014.13 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 Agency may deny any application for a specific license under 180 NAC 3-014.13 if the end use or uses of the industrial product or device cannot be reasonably foreseen.
 4. Each person licensed pursuant to 180 NAC 3-014.13 item 1. shall:
 - a. 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;
 - b. 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 of an Agreement State;
 - c. 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";

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- d. Furnish:
- (1) A copy of the general license contained in 180 NAC 3-007.04 and a copy of Agency Form NRH-11 to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license contained in 180 NAC 3-007.04; or
 - (2) A copy of the general license contained in the U.S. Nuclear Regulatory Commission or Agreement State's regulation equivalent to 180 NAC 3-007.04 and a copy of the U.S. Nuclear Regulatory Commission or Agreement State's certificate; or alternatively, furnish a copy of the general license contained in 180 NAC 3-007.04 and a copy of Agency Form NRH-11 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 180 NAC 3-007.04;
- e. Report to the Agency all transfers of industrial products or devices to persons for use under the general license in 180 NAC 3-007.04. 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 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 180 NAC 3-007.04 during the reporting period, the report shall so indicate;
- f. File a report which identifies 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. The licensee shall report:
- (1) 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;
 - (2) To the responsible State agency all transfers of devices manufactured and distributed pursuant to 180 NAC 3-014.13 for use under a general license in that State's regulations equivalent to 180 NAC 3-007.04;

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- (3) To U.S. Nuclear Regulatory Commission if no transfers have been made by the licensees during the reporting period;
 - (4) To the responsible Agreement State Agency, upon the request of the Agency, if no transfers have been made to general licensees within a particular Agreement State during the reporting period; and
5. 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 180 NAC 3-008.04 or equivalent regulations of the U.S. Nuclear Regulatory Commission or of an Agreement State. The records shall be maintained for a period of two 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.
 6. The Radiation Safety Officer and/or authorized user shall have training and experience consistent with the requirements of training specified in 180 NAC 15-018.01.

3-015 SPECIAL REQUIREMENTS FOR ISSUANCE OF SPECIFIC LICENSES FOR SOURCE MATERIAL MILLING: In addition to the requirements set forth in 180 NAC 3-011, a specific license for source material milling will be issued if the applicant submits to the agency a satisfactory application as described herein and meets the other conditions specified below:

3-015.01 An Application for a License to Receive Title to, Receive, Possess, and Use Source Material for Milling or Byproduct Material as Defined in 180 NAC 1-002 shall address the following:

1. Description of the proposed project or action;
2. Area/site characteristics including geology, topography, hydrology, and
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 meteorology;
6. Site and project alternatives.

3-015.02 Pursuant to 180 NAC 3-011.05, the applicant shall not commence construction of the project until the Agency has weighed the environmental, economic, technical, and other benefits against the environmental costs and has concluded that the issuance of the license is appropriate.

3-015.03 At least 1 full year prior to any major site construction, a pre-operational 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.

3-015.04 Prior to issuance of the license, the applicant shall establish financial surety arrangements consistent with the requirements of 180 NAC 3-011.06.

1. The amount of funds to be ensured by financial surety arrangements shall be based on Agency-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 Agency 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 Agency 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.

3-015.05 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 180 NAC 4 and are as low as is reasonably achievable.
2. The mill operator shall conduct daily inspections 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 Agency.
3. The mill operator shall immediately notify the Agency of the following:
 - a. Any failure in a tailings or waste retention system which results in a release of tailings or waste into unrestricted areas, and
 - b. 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.

3-015.06 Continued Surveillance Requirements for Source Material Millings 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 Agency within 60 days following each inspection. The Agency 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. 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, 180 NAC 3-015.06, item 1. additional funding requirements may be specified by the Agency. The charge will be reviewed annually to recognize or adjust for inflation.

3-016 ISSUANCE OF SPECIFIC LICENSES

3-016.01 Upon a determination that an application meets the requirements of the Act and the regulations of the Agency, the Agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary, based on quantities and types of radioactive materials, proposed use and upon the training and experience of the user(s).

3-016.02 The Agency 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 including the requirement of reports, keeping of records and to provide for inspections as it deems appropriate or necessary in order to:

1. Minimize danger to public health and safety or property; and
2. Prevent loss or theft of material subject to 180 NAC 3-016.02.

3-017 SPECIFIC TERMS AND CONDITIONS OF LICENSE

3-017.01 Each license issued pursuant to 180 NAC 3, 5, 7, 12, 14 and 19 shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations, and orders of the Agency.

3-017.02 No license issued or granted under 180 NAC 3, 5, 7, 12, 14, and 19 and no right to possess or utilize radioactive material granted by any license issued pursuant to 180 NAC 3, 5, 7, 12, 14, and 19 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 Agency shall, after securing full information find that the transfer is in accordance with the provisions of the Act, and shall give its consent in writing.

3-017.03 Each person licensed by the Agency pursuant to, 180 NAC 3, 5, 7, 12, 14 and 19 shall confine his use and possession of the material licensed to the locations and purposes authorized in the license.

3-017.04 Each licensee shall notify the Agency in writing when the licensee decides to permanently discontinue all activities involving materials under the license. This notification requirement applies to all specific licenses issued under, 180 NAC 3, 180 NAC 5, 180 NAC 7, 180 NAC 12, 180 NAC 14, and 180 NAC 19.

3-017.05 Each licensee shall notify the Agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

1. The licensee;
2. An entity (as that term is defined in 11 U.S.C. 101(14)) attached hereto as Attachment Number 3-6 and incorporated herein by this reference controlling the licensee or listing the license or licensee as property of the estate; or
3. An affiliate (as that term is defined in 11 U.S.C. 101(2)) attached hereto as Attachment Number 3-6 and incorporated herein by this reference of the licensee.
4. This notification must indicate:
 - a. The bankruptcy court in which the petition for bankruptcy was filed; and
 - b. The date of the filing of the petition.

3-018 FINANCIAL ASSURANCE AND RECORDKEEPING FOR DECOMMISSIONING

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3-018.01 Each applicant for a specific license authorizing the possession and use of unsealed byproduct material of half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in 180 NAC 4, Appendix 4-F shall submit a decommissioning funding plan as described in 180 NAC 3-018.05. The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 10^5 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix 4-F of 180 NAC 4.

3-018.02 Each applicant for a specific license authorizing possession and use of byproduct material of half-life greater than 120 days and in quantities specified in 180 NAC 3-018.04 shall either-

1. Submit a decommissioning funding plan as described in 180 NAC 3-018.05 or
2. Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by 180 NAC 3-018.04 using one of the methods described in 180 NAC 3-018.06. For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but prior to the receipt of radioactive material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy 180 NAC 3-018.06 must be submitted to the Agency before receipt of radioactive material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to the Agency as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of 180 NAC 3-018.06.

3-018.03 Each holder of a specific license:

1. Issued on or after May 30, 1994 and of a type described in 180 NAC 3-018.01 or 3-018.02, shall provide financial assurance for decommissioning in accordance with the criteria set for 180 NAC 3-018.03.
2. Issued before May 30, 1994, and of a type described in 180 NAC 3-018.01 shall submit, on or before May 30, 1994, a decommissioning funding plan or a certification of financial assurance for decommissioning in an amount at least equal to \$750,000 in accordance with the criteria set forth in 180 NAC 3-018.03, item 2. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan, the licensee shall include a decommissioning funding plan in any application for license renewal.
3. Issued before May 30, 1994, and of a type described in 180 NAC 3-018.02 shall submit, on or before May 30, 1994, a certification of financial assurance for decommissioning in accordance with the criteria set forth in 180 NAC 3-018.03.

3-018.04 Table of required amounts of financial assurance for decommissioning by quantity of material.

Greater than 10^4 but less than or equal to 10^5 times the applicable quantities of 180 NAC 4, Appendix 004-F in unsealed form. (For a combination of isotopes, if R , as defined in 180 NAC 3-018.01, divided by 10^4 is greater

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than 1 but R divided by 10^5 is less than or equal to 1.) \$750,000

Greater than 10^3 but less than or equal to 10^4 times the applicable quantities of 180 NAC 4, Appendix 4-F in unsealed form. (For a combination of isotopes, if R, as defined in 180 NAC 3-018.01; divided by 10^3 is greater than 1 but R divided by 10^4 is less than or equal to 1.)

\$150,000

Greater than 10^{10} times the applicable quantities of 180 NAC 4, Appendix 4-F in sealed sources or plated foils. (For a combination of isotopes, if R, as defined in 180 NAC 3-018.01, divided by 10^{10} is greater than 1.)

\$75,000

3-018.05 Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from 180 NAC 3-018.06, including means of adjusting cost estimates and associated funding levels periodically over the life of the facility. The decommissioning funding plan must also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning and a signed original of the financial statement obtained to satisfy the requirements of 180 NAC 3-018.06.

3-018.06 Financial assurance for decommissioning must be provided by one or more of the following methods:

1. Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.
2. A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in 180 NAC 3, Appendix 3-A. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of 180 NAC 3-018.06, item 2. A guarantee of funds by the applicant or licensee for decommissioning based on a financial test may be used if the guarantee and test are as contained in 180 NAC 3, Appendix 3-D. A guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of 180 NAC 3-018.06, item 2. or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any

surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

- a. The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the Agency, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Agency within 30 days after receipt of notification of cancellation.
 - b. The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the Agency. An acceptable trustee includes an appropriate State or Federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.
 - c. The surety method or insurance must remain in effect until the Agency has terminated the license.
3. An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions must be as stated in 180 NAC 3-018.06, item 2.
 4. In the case of Federal, State, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the Table in 180 NAC 3-018.04, and indicating that funds for decommissioning will be obtained when necessary.

3-018.07 Each person licensed under 180 NAC 3, 5, 7, 14 and 19 shall keep records of information important to the decommissioning of the facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with 180 NAC 3-017.02, licensees shall transfer all records described in 180 NAC 3-018.07 to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used. Information the Agency considers important to decommissioning consists of:

1. Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.
2. As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.
3. Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or byproduct materials having only half-lives of less than 65 days, a list contained in a single document and updated every 2 years, of the following:
 - a. All areas designated and formerly designated as restricted areas as defined under 180 NAC 1-002 ;
 - b. All areas outside of restricted areas that require documentation under 180 NAC 3-018.07, item 1.;
 - c. All areas outside of restricted areas where current and previous wastes have been buried as documented under 180 NAC 4-052; and
 - d. All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or apply for approval for disposal under 180 NAC 4-038.
4. Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

3-019 EXPIRATION AND TERMINATION OF LICENSES AND DECOMMISSIONING OF SITES AND SEPARATE BUILDINGS OR OUTDOOR AREAS

3-019.01 Each specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under 180 NAC 3-020 not less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days prior to the expiration date stated in the existing license, the existing license expires at the end of the day on which the Agency makes a final determination to deny the renewal application or if the determination states an expiration date, the expiration date stated in the determination.

3-019.02 Each specific license revoked by the Agency expires at the end of the day on the date of the Agency's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Agency Order.

3-019.03 Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material until the Agency notifies the licensee in writing that the license is terminated. During this time, the licensee shall-

1. Limit actions involving radioactive material to those related to decommissioning; and
2. Continue to control entry to restricted area until they are suitable for release in accordance with Agency requirements.

3-019.04 Within 60 days of the occurrence of any of the following, consistent with the administrative directions in 180 NAC 1-012, each licensee shall provide notification to the Agency in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with Agency requirements, or submit within 12 months of notification a decommissioning plan, if required by 180 NAC 3-019.07 and begin decommissioning upon approval of that plan if -

1. The license has expired pursuant to 180 NAC 3-019.01 and 3-019.02; or
2. The licensee has decided to permanently cease principal activities, as defined in 180 NAC 3-002, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Agency requirements; or
3. No principal activities under the license have been conducted for a period of 24 months; or
4. No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Agency requirements.

3-019.05 Coincident with the notification required by 180 NAC 3-019.04, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to 180 NAC 3-018 in conjunction with a license issuance or renewal or as required by 180 NAC 3-019.05. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to 180 NAC 3-019.07, item 4.e.

1. Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so effective September 17, 1997.
2. Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Agency.

3-019.06 The Agency may grant a request to extend the time periods established in 180 NAC 3-019.04 if the Agency determines that this relief is not detrimental to the public health

and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to 180 NAC 3-019.04. The schedule for decommissioning set forth in 180 NAC 3-019.04 may not commence until the Agency has made a determination on the request.

3-019.07 Decommissioning Plans

1. A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Agency and these procedures could increase potential health and safety impacts to workers or to the public; such as in the following cases;
 - a. Procedures would involve techniques not applied routinely during cleanup or maintenance operations;
 - b. Workers could be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;
 - c. Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or
 - d. Procedures could result in significantly greater releases of radioactive materials to the environment than those associated with operation.
2. The Agency may approve an alternate schedule for submittal of a decommissioning plan required pursuant to 180 NAC 019.04 if the Agency determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.
3. Procedures such as those listed in 180 NAC 3-019.07, item 1. with potential health and safety impacts may not be carried out prior to the approval of the decommissioning plan.
4. The proposed decommissioning plan for the site or separate building or outdoor area shall include:
 - a. A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;
 - b. A description of planned decommissioning activities;
 - c. A description of methods used to ensure the protection of workers and the environment against radiation hazards during decommissioning;
 - d. A description of the planned final radiation survey; and
 - e. An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.
 - f. For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in 180 NAC 3-019.09.

5. The proposed decommissioning plan will be approved by the Agency if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

3-019.08 Decommissioning

1. Except as provided in 180 NAC 3-019.09, licensees shall complete decommissioning of the site or separate building or outdoor area as soon as is practicable but no later than 24 months following the initiation of decommissioning.
2. Except as provided in 180 NAC 3-019.09, when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

3-019.09 The Agency may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Agency determines that the alternative is warranted by consideration of the following:

1. Whether it is technically feasible to complete decommissioning within the allotted 24 month period;
2. Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24 month period;
3. Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;
4. Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and
5. Other site-specific factors which the Agency may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration; actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

3-019.10 As the final step in decommissioning, the licensee shall -

1. Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed Agency Form NRH-60 or equivalent information; and
2. Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates that the premises are suitable for release in some other manner. The licensee shall, as appropriate -
 - a. Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or

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microcuries) per 100 square centimeters - removable and fixed - for surfaces, megabecquerels (microcuries) per milliliter for water, becquerels (picocuries) per gram for solids such as soil or concrete; and

- b. Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

3-019.11 Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Agency determines:

1. Radioactive material has been properly disposed;
2. Reasonable effort has been made to eliminate residual radioactive contamination, if present; and
3. Demonstration of suitability for release.
 - a. A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with Agency requirements; or
 - b. Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with Agency requirements.
4. Records required by 180 NAC 3-030.06 and 3-030.08 have been received.

3-020 RENEWAL OF LICENSES

3-020.01 Applications for renewal of specific licenses shall be filed in accordance with 180 NAC 003.10.

3-020.02 In any case in which a licensee, not less than thirty (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 the application has been finally determined by the Agency.

3-021 AMENDMENT OF LICENSES AT REQUEST OF LICENSEE: Applications for amendment of a license shall be filed in accordance with 3-010 and shall specify the respects in which the licensee desires his license to be amended and the grounds for such amendment.

3-022 AGENCY ACTION ON APPLICATIONS TO RENEW AND AMEND: In considering an application by a licensee to renew or amend his license, the Agency will apply the criteria set forth in 180 NAC 3-011 and 3-012, 3-013 or 3-014, and 3-015 and in 180 NAC 5, 7, 12, 14 or 19 as applicable.

3-023 RESERVED

3-024 RESERVED

3-025 TRANSFER OF MATERIAL

3-025.01 No licensee shall transfer radioactive material except as authorized pursuant to 180 NAC 3-025.

3-025.02 Except as otherwise provided in his license and subject to the provisions of 180 NAC 3-025.03 and 3-025.04, any licensee may transfer radioactive material:

1. To the Agency;¹²
2. To the U.S. Department of Energy;
3. To any person exempt from the regulations 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 Agency, the U.S. Nuclear Regulatory Commission, or any Agreement State, or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Agency, or any Agreement State, or
5. As otherwise authorized by the Agency in writing.
6. To the agency in any Agreement State which regulates radioactive material pursuant to an agreement under Section 274 of the Atomic Energy Act of 1954.¹³

3-025.03 Before transferring radioactive material to a specific licensee of the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State, or to a general licensee who is required to register with the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

3-025.04 The following methods for the verification required by 180 NAC 3-025.03 are acceptable:

1. The transferor may have in his possession, and read, a current copy of the transferee's specific license or registration certificate;
2. The transferor may have in his possession a written certification by the transferee that he 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 he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the

¹²A licensee may transfer material to the Agency only after receiving prior approval from the Agency.

¹³Ibid. p. 3-52

- license or registration certificate number, issuing agency, and expiration date; provided, that the oral certification is confirmed in writing within ten (10) days;
4. The transferor may obtain other sources of information compiled by a reporting service from official records of the Agency, the U.S. Nuclear Regulatory Commission, the licensing agency of an Agreement State as to 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 180 NAC 3-025.04, items 1. through 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 Agency, the U.S. Nuclear Regulatory Commission, or the licensing agency of an Agreement State that the transferee is licensed to receive the radioactive material.

3-025.05 Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of 180 NAC 13.

3-026 REPORTING REQUIREMENTS

3-026.01 Immediate Report: Each licensee shall notify the Agency as soon as possible but not later than four hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of radioactive material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

3-026.02 Twenty-Four Hour Report: Each licensee shall notify the Agency within 24 hours after the discovery of any of the following events involving radioactive material:

1. An unplanned contamination event that:
 - a. Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;
 - b. Involves a quantity of material greater than five times the lowest annual limit on intake specified in 180 NAC 4, Appendix 4-B for the material; and
 - c. Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.
2. An event in which equipment is disabled or fails to function as designed when:
 - a. The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;
 - b. The equipment is required to be available and operable when it is disabled or fails to function; and
 - c. No redundant equipment is available and operable to perform the required safety function.

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3. An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.
4. An unplanned fire or explosion damaging any radioactive material or any device, container, or equipment containing radioactive material when:
 - a. The quantity of radioactive material involved is greater than five times the lowest annual limit on intake specified in 180 NAC 4, Appendix 4-B for the material; and
 - b. The damage affects the integrity of the radioactive material or its container.

3-026.03 Preparation and submission of reports: Reports made by licensees in response to the requirements of 180 NAC 3-026.03 must be made as follows:

1. Licensees shall make reports required by 180 NAC 3-026.01 and 3-026.02 by telephone to the Agency.¹⁴ To the extent that the information is available at the time of notification, the information provided in these reports must include:
 - a. The caller's name and call back telephone number;
 - b. A description of the event, including date and time;
 - c. The exact location of the event;
 - d. The isotopes, quantities, and chemical and physical form of the radioactive material involved; and
 - e. Any personnel radiation exposure data available.
2. Written report. Each licensee who makes a report required by 180 NAC 3-026.01 or 180 NAC 3-026.02 shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be sent to:

Department of Health and Human Services Regulation and Licensure
Public Health Assurance Division
301 Centennial Mall South
P.O. Box 95007
Lincoln, NE 68509-5007

The reports must include the following:

- a. A description of the event, including the probable cause and the manufacturer and model number, if applicable, of any equipment that failed or malfunctioned;
- b. The exact location of the event;
- c. The isotopes, quantities, and chemical and physical form of the radioactive material involved;

¹⁴The telephone number for the Agency is (402) 471-2168.

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- d. Date and time of the event;
- e. Corrective actions taken or planned and the results of any evaluations or assessments; and
- f. The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

3-027 MODIFICATION AND REVOCATION OF LICENSES: The terms and conditions of all licenses shall be subject to amendment, revision, modification, limitation, suspension or revocation upon:

3-027.01 Amendments to the Radiation Control Act or the rules and regulations adopted pursuant thereto;

3-027.02 Voluntary application for license amendment, revision, modification, limitation, suspension or surrender made by the licensee;

3-027.03 Disciplinary action pursuant to 180 NAC 17 ;or

3-027.04 Pursuant to emergency order as provided by Section 71-3513(6) of the Act.

RECIPROCITY

3-028 RECIPROCAL RECOGNITION OF LICENSES

3-028.01 Licenses of Radioactive Material Except Special Nuclear Material in Quantities Sufficient to Form a Critical Mass

1. Subject to Title 180, 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:
 - a. The licensing document does not limit the activity authorized by such document to specified installations or locations;
 - b. The out-of-state licensee notifies the Agency in writing at least three (3) days prior to engaging in such activity. Such notification shall include:
 - (1) Name of company for whom services will be performed, an individual to be contacted representing the company and telephone number.
 - (2) The exact location, start date, duration, and type of activity to be conducted.
 - (3) The name(s), documentation of training, and in-state address(es) of the individual(s) performing the activity,
 - (4) The identification of the sources of radiation to be used,
 - (5) A copy of the pertinent license,
 - (6) A copy of the licensee's operating and emergency procedures, and

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- (7) An annual fee as specified in 180 NAC 18 .
- (8) The out-of-state licensee notifies the Agency of changes in work locations, radioactive material, or work activities different from the information contained on the initial notification.

If, for a specific case, the three (3) day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Agency, obtain permission to proceed sooner. The Agency 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 180 NAC 3-028.01.

- c. The out-of-state licensee complies with all applicable regulations of the Agency and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable regulations of the Agency;
 - d. The out-of-state licensee maintains a current copy of the appropriate license, and all amendments thereto, issued by the Agency;
 - e. The out-of-state licensee supplies such other information as the Agency may request;
 - f. The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in 180 NAC 3-028.01, item 1. except by transfer to a person:
 - (1) Specifically licensed by the Agency or by the U.S. Nuclear Regulatory Commission to receive such material, or
 - (2) Exempt from the requirements for a license for such material under 180 NAC 3-004.01.
2. Notwithstanding the provisions of 180 NAC 3-028.01, item 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 180 NAC 3-008.04, item 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 this State provided that:
- a. Such person shall file a report with the Agency within thirty (30) days after the end of each calendar quarter in which any device is transferred to or installed in this State. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type and model of device transferred, and the quantity and type of radioactive material contained in the device;
 - b. 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;
 - c. 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

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- d. 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 180 NAC 3-008.04.
3. The Agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by another agency, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to achieve compliance with Title 180 or to prevent undue hazard to public health and safety or property.
4. Before radioactive materials can be used at a temporary job site within the State at any Federal facility, the jurisdictional status of the job site must be determined. If the jurisdictional status is unknown, the Federal agency should be contacted to determine if the job site is under exclusive Federal jurisdiction.
 - a. In areas of exclusive Federal jurisdiction, the general license is subject to all the applicable rules, regulations, orders and fees of the U.S. Nuclear Regulatory Commission, and
 - b. Authorizations for use of radioactive materials at job sites under exclusive Federal jurisdiction shall be obtained from the U.S. Nuclear Regulatory Commission by either (1) filing a NRC Form-241 in accordance with 10 CFR 150.20(b); or (2) by applying for a specific U.S. Nuclear Regulatory Commission license.
5. Before radioactive material can be used at a temporary job site in another State, authorization shall be obtained for the State if it is an Agreement State, or from the U.S. Nuclear Regulatory Commission for any non-Agreement State, either by filing for reciprocity or applying for a specific license.

3-029 RESERVED

3-030 RECORDS

3-030.01 Each person who receives radioactive material pursuant to a license issued pursuant to 180 NAC 3, 5, 7, 12, 14, and 19 shall keep records showing the receipt, use, transfer, and disposal of such radioactive material.

3-030.02 Records which are required pursuant to 180 NAC 3-030.01 shall be maintained for the period specified by the appropriate regulation. If a retention period is not otherwise specified by regulation such records shall be maintained for a period of one year after the records of the licensee have been inspected by the Agency unless any litigation, claim, negotiation, audit, licensure action, or other action involving the records has been initiated before the expiration of the one-year period, in which case the records must be retained until the completion of the action and resolution of all issues, or until the end of the regular one-year period, whichever is later.

3-030.03 Records of receipt of radioactive material which must be maintained pursuant to 180 NAC 3-030.01 will be maintained as long as the licensee retains possession of the

radioactive material and for five years following transfer, or disposition of the radioactive material and;

1. Records of transfer of radioactive material shall be maintained by the licensee who transferred the material until the Agency authorizes their disposition and;
2. Records of disposal of radioactive material shall be maintained in accordance with 180 NAC 4-052.
3. If radioactive material is combined or mixed with other licensed material and subsequently treated in a manner which makes direct correlation of a receipt record with a transfer, export, or disposition record impossible, evaluative techniques such as first-in-first-out may be used for purposes of the records retention requirements of 180 NAC 3-030.

3-030.04 Records which must be maintained pursuant to 180 NAC 3-030.01 may be the original or reproduced copy of 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 Agency regulations. The record may also be stored in electronic media with the capability for producing legible, accurate and complete record during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

3-030.05 If there is a conflict between the Agency's regulations in this Chapter, license condition, or other written Agency approval or authorization pertaining to the retention period for the same type of record, the retention period specified in 180 NAC 3-030 for such records shall apply unless the Agency pursuant to 180 NAC 1-003.01 has granted a specific exemption from the record retention requirements specified in 180 NAC 3-030.05.

3-030.06 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 180 NAC 4-038, 180 NAC 4-039, 180 NAC 4-040 and 180 NAC 4-041; and
2. Records required by 180 NAC 4-046.02, item 4.

3-030.07 If licensed activities are transferred or assigned in accordance with 180 NAC 3-017.02, 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, 180 NAC 3-038, 3-039, 3-040, 3-041 and
2. Records required by 180 NAC 4-046.02, item 4.

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3-030.08 Prior to license termination, each licensee shall forward the records required by 180 NAC 3-018.07 to the Agency.

EXEMPT CONCENTRATIONS:

Element (atomic number)	Isotope	Column I Gas Concentration $\mu\text{Ci/ml}^*$	Column II Liquid and Solid Concentration $\mu\text{Ci/ml}^{**}$
Antimony (51)	Sb-122		3E-4
	Sb-124		2E-4
	Sb-125		1E-3
Argon (18)	Ar-37	1E-3	
	Ar-41	4E-7	
Arsenic (33)	As-73		5E-3
	As-74		5E-4
	As-76		2E-4
	As-77		8E-4
Barium (56)	Ba-131		2E-3
	Ba-140		3E-4
Beryllium (4)	Be-7		2E-2
Bismuth (83)	Bi-206		4E-4
Bromine (35)	Br-82	4E-7	3E-3
Cadmium (48)	Cd-109		2E-3
	Cd-115m		3E-4
	Cd-115		3E-4
Calcium (20)	Ca-45		9E-5
	Ca-47		5E-4
Carbon (6)	C-14	1E-6	8E-3
Cerium (58)	Ce-141		9E-4
	Ce-143		4E-4
	Ce-144		1E-4
Cesium (55)	Cs-131		2E-2
	Cs-134m		6E-2
	Cs-134		9E-5
Chlorine (17)	Cl-38	9E-7	4E-3
Chromium (24)	Cr-51		2E-2
Cobalt (27)	Co-57		5E-3
	Co-58		1E-3

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Element (atomic number)	Isotope	Column I Gas Concentration $\mu\text{Ci/ml}^*$	Column II Liquid and Solid Concentration $\mu\text{Ci/ml}^{**}$
Copper (29)	Co-60		5E-4
	Cu-64		3E-3
Dysprosium (66)	Dy-165		4E-3
	Dy-166		4E-4
Erbium (68)	Er-169		9E-4
	Er-171		1E-3
Europium (63)	Eu-152 (T/2=9.2hrs)		6E-4
	Eu-155		2E-3
Fluorine (9)	F-18	2E-6	8E-3
Gadolinium (64)	Gd-153		2E-3
	Gd-159		8E-4
Gallium (31)	Ga-72		4E-4
Germanium (32)	Ge-71		2E-2
Gold (79)	Au-196		2E-3
	Au-198		5E-4
	Au-199		2E-3
Hafnium (72)	Hf-181		7E-4
Hydrogen (1)	H-3	5E-6	3E-2
Indium (49)	In-113m		1E-2
	In-114m		2E-4
Iodine (53)	I-126	3E-9	2E-5
	I-131	3E-9	2E-5
	I-132	8E-8	6E-4
	I-133	1E-8	7E-5
	I-134	2E-7	1E-3
Iridium (77)	Ir-190		2E-3
	Ir-192		4E-4
	Ir-194		3E-4
Iron (26)	Fe-55		8E-3
	Fe-59		6E-4
Krypton (36)	Kr-85m	1E-6	
	Kr-85	3E-6	
Lanthanum (57)	La-140		2E-4

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Element (atomic number)	Isotope	Column I Gas Concentration $\mu\text{Ci/ml}^*$	Column II Liquid and Solid Concentration $\mu\text{Ci/ml}^{**}$
Lead (82)	Pb-203		4E-3
Lutetium (71)	Lu-177		1E-3
Manganese (25)	Mn-52		3E-4
	Mn-54		1E-3
	Mn-56		1E-3
Mercury (80)	Hg-197m		2E-3
	Hg-197		3E-3
	Hg-203		2E-4
Molybdenum (42)	Mo-99		2E-3
Neodymium (60)	Nd-147		6E-4
	Nd-149		3E-3
Nickel (28)	Ni-65		1E-3
Niobium (Columbium)(41)	Nb-95		1E-3
	Nb-97		9E-3
Osmium (76)	Os-185		7E-4
	Os-191m		3E-2
	Os-191		2E-3
	Os-193		6E-4
Palladium (46)	Pd-103		3E-3
	Pd-109		9E-4
Phosphorus (15)	P-32		2E-4
Platinum (78)	Pt-191		1E-3
	Pt-193m		1E-2
	Pt-197m		1E-2
	Pt-197		1E-3
Potassium (19)	K-42		3E-3
Praseodymium (59)	Pr-142		3E-4
	Pr-143		5E-4
Promethium (61)	Pm-147		2E-3
	Pm-149		4E-4
Rhenium (75)	Re-183		6E-3
	Re-186		9E-4
	Re-188		6E-4

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Element (atomic number)	Isotope	Column I Gas Concentration $\mu\text{Ci/ml}^*$	Column II Liquid and Solid Concentration $\mu\text{Ci/ml}^{**}$
Rhodium (45)	Rh-103m		1E-1
	Rh-105		1E-3
Rubidium (37)	Rb-86		7E-4
Ruthenium (44)	Ru-97		4E-3
	Ru-103		8E-4
	Ru-105		1E-3
	Ru-106		1E-4
Samarium (62)	Sm-153		8E-4
Scandium (21)	Sc-46		4E-4
	Sc-47		9E-4
	Sc-48		3E-4
Selenium (34)	Se-75		3E-3
Silicon (14)	Si-31		9E-3
Silver (47)	Ag-105		1E-3
	Ag-110m		3E-4
	Ag-111		4E-4
Sodium (11)	Na-24		2E-3
Strontium (38)	Sr-85		1E-3
	Sr-89		1E-4
	Sr-91		7E-4
	Sr-92		7E-4
Sulfur (16)	S-35	9E-8	6E-4
Tantalum (73)	Ta-182		4E-4
Technetium (43)	Tc-96m		1E-1
	Tc-96		1E-3
Tellurium (52)	Te-125m		2E-3
	Te-127m		6E-4
	Te-127		3E-3
	Te-129m		3E-4
	Te-131m		6E-4
	Te-132		3E-4
Terbium (65)	Tb-160		4E-4
Thallium (81)	Tl-200		4E-3

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Element (atomic number)	Isotope	Column I Gas Concentration $\mu\text{Ci/ml}^*$	Column II Liquid and Solid Concentration $\mu\text{Ci/ml}^{**}$
	Tl-201		3E-3
	Tl-202		1E-3
	Tl-204		1E-3
Thulium (69)	Tm-170		5E-4
	Tm-171		5E-3
Tin (50)	Sn-113		9E-4
	Sn-125		2E-4
Tungsten (Wolfram)(74)	W-181		4E-3
	W-187		7E-4
Vanadium (23)	V-48		3E-4
Xenon (54)	Xe-131m	4E-6	
	Xe-133	3E-6	
	Xe-135	1E-6	
Ytterbium (70)	Yb-175		1E-3
Yttrium (39)	Y-90		2E-4
	Y-91m		3E-2
	Y-91		3E-4
	Y-92		6E-4
	Y-93		3E-4
Zinc (30)	Zn-65		1E-3
	Zn-69m		7E-4
	Zn-69		2E-2
Zirconium (40)	Zr-95		6E-4
	Zr-97		2E-4
Beta and/or gamma emitting radioactive material not listed above with half-life less than 3 years		1E-10	1E-6

*Values are given in Column I only for those materials normally used as gases.

** $\mu\text{Ci/gm}$ for solids.

NOTE 1: Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in 180 NAC 3, Appendix 003-A the activity stated is that of the parent isotope and takes into account the daughters.

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NOTE 2: For purposes of 180 NAC 3-004 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 concentration present in the product and the exempt concentration established in Appendix 003-A for the specific isotope when not in combination. The sum of such ratios may not exceed "1" (i.e., unity).

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 $\mu\text{Ci/ml}$ to SI units of megabecquerels per liter multiply the above value by 37.

EXAMPLE: Zirconium (40) Zr-97 $2\text{E-}4 \mu\text{Ci/ml}$ multiplied by 37 is equivalent to $74\text{E+}4 \text{ MBq /l}$

APPENDIX 3-B

Radioactive Material

Microcuries

EXEMPT QUANTITIES

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

APPENDIX 3-B

Radioactive Material	Microcuries
Europium-152 (Eu 152) 9.2h	100
Europium-152 (Eu 152) 13 yr	1
Europium-154 (Eu 154)	1
Europium-155 (Eu 155)	10
Fluorine-18 (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-71 (Ge 71)	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)	0.1
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

APPENDIX 3-B

<u>Radioactive Material</u>	<u>Microcuries</u>
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 143)	100
Promethium-147 (Pm 147).....	10
Promethium-149 (Pm 149).....	10
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

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Radioactive Material	Microcuries
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

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<u>Radioactive Material</u>	<u>Microcuries</u>
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: To convert microcuries (μCi) to SI units of kilobecquerels (kBq), multiply the above values by 37.

EXAMPLE: Zirconium-97 (10 μCi multiplied by 37 is equivalent to 370 kBq).

APPENDIX 3-C

LIMITS FOR BROAD LICENSES 180 NAC 3-013:

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.....	1.0
Cerium-141.....	10.....	0.1
Cerium-143.....	10.....	0.1
Cerium-144.....	0.1.....	0.001
Cesium-131.....	100.....	1.0
Cesium-134m.....	100.....	1.0
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.....	1.0
Chromium-51.....	100.....	1.0
Cobalt-57.....	10.....	0.1
Cobalt-58m.....	100.....	1.0
Cobalt-58.....	1.....	0.01
Cobalt-60.....	0.1.....	0.001
Copper-64.....	10.....	0.1
Dysprosium-165.....	100.....	1.0
Dysprosium-166.....	10.....	0.1
Erbium-169.....	10.....	0.1
Erbium-171.....	10.....	0.1
Europium-152 (9.2h).....	10.....	0.1
Europium-152 (13 y).....	0.1.....	0.001
Europium-154.....	0.1.....	0.001
Europium-155.....	1.....	0.01

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Radioactive Material	Col. I curies	Col. II curies
Fluorine-18.....	100.....	1.0
Gadolinium-153.....	1.....	0.01
Gadolinium-159.....	10.....	0.1
Gallium-72.....	10.....	0.1
Germanium-71.....	100.....	1.0
Gold-198.....	10.....	0.1
Gold-199.....	10.....	0.1
Hafnium-181.....	1.....	0.01
Holmium-166.....	10.....	0.1
Hydrogen-3.....	100.....	1.0
Indium-113m.....	100.....	1.0
Indium-114m.....	1.....	0.01
Indium-115m.....	100.....	1.0
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.....	1.0
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.....	1.0
Osmium-185.....	1.....	0.01

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Radioactive Material	Col. I curies	Col. II curies
Osmium-191m	100	1.0
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	1.0
Platinum-193	10	0.1
Platinum-197m	100	1.0
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	10.0
Rhodium-105	10	0.1
Rubidium-86	1	0.01
Rubidium-87	1	0.01
Ruthenium-97	100	1.0
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	10.0
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

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Radioactive Material	Col. I curies	Col. II curies
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	1.0
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	1.0
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	10.0
Xenon-133	100	1.0
Xenon-135	100	1.0
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	1.0
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: 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)

APPENDIX 3-D

Criteria Relating to Use of Financial Tests and Self-Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

1. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section 2 of this Appendix. The terms of this self-guarantee are in Section 3 of this Appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for obtaining a self-guarantee.

2. Financial Test

A. To pass the financial test, a company must meet all of the following criteria:

- (1) Tangible net worth of at least 10 times the total current decommissioning cost estimate (or the current amount if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and a parent-guarantor.
- (2) Assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the total current decommissioning cost estimate (or the current amount if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and a parent-guarantor.
- (3) A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poor's (S&P) or Aaa, Aa, or A as issued by Moody's.

B. To pass the financial test, a company must meet all of the following additional requirements:

- (1) The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.
- (2) The company's independent certified public accountant must have compared the data used by the company in the financial test, which is derived from the independently audited, year end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the Agency within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.
- (3) After the initial financial test, the company must repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

C. If the company no longer meets the requirements of Section 2.A. of this Appendix, the licensee must send immediate notice to the Agency of its intent to establish alternate financial assurance as specified in the Agency's regulations within 120 days of such notice.

3. Company Self-Guarantee

APPENDIX 3-D

The terms of a self-guarantee which an applicant or licensee furnishes shall provide that:

- A. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the Agency. Cancellation may not occur, however during the 120 days beginning on the date of receipt of the notice of cancellation by the Agency, as evidenced by the return receipt.
- B. The licensee shall provide alternative financial assurance as specified in the Agency's regulations within 90 days following receipt by the Agency of a notice of cancellation of the guarantee.
- C. The guarantee and financial test provisions must remain in effect until the Agency has terminated the license or until another financial assurance method acceptable to the Agency has been put in effect by the licensee.
- D. The licensee will promptly forward to the Agency and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of Section 13 of the Securities and Exchange Act of 1934.
- E. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moody's, the licensee will provide notice in writing of such fact to the Agency within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by both Standard and Poors or Moody's, the licensee no longer meets the requirements of Section 2.A. of this Appendix.
- F. The applicant or licensee must provide to the Agency a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Agency, the licensee will set up and fund a trust in the amount of the current cost estimate for decommissioning.

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APPENDIX 3-E

Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release.

Radioactive material ¹	Release fraction	Quantity (curies)
Actinium-228.....	0.001.....	4,000
Americium-241.....	0.001.....	2
Americium-242.....	0.001.....	2
Americium-243.....	0.001.....	2
Antimony-124.....	0.01.....	4,000
Antimony-126.....	0.01.....	6,000
Barium-133.....	0.01.....	10,000
Barium-140.....	0.01.....	30,000
Bismuth-207.....	0.01.....	5,000
Bismuth-210.....	0.01.....	600
Cadmium-109.....	0.01.....	1,000
Cadmium-113.....	0.01.....	80
Calcium-45.....	0.01.....	20,000
Californium-252.....	0.00.....	19 (20 mg)
Carbon-14 (Non CO).....	0.01.....	50,000
Cerium-141.....	0.01.....	10,000
Cerium-144.....	0.01.....	300
Cesium-134.....	0.01.....	2,000
Cesium-137.....	0.01.....	3,000
Chlorine-36.....	0.5.....	100
Chromium-51.....	0.01.....	300,000
Cobalt-60.....	0.001.....	5,000
Copper-64.....	0.01.....	200,000
Curium-242.....	0.001.....	60
Curium-243.....	0.001.....	3
Curium-244.....	0.001.....	4
Curium-245.....	0.001.....	2
Europium-152.....	0.01.....	500
Europium-154.....	0.01.....	400
Europium-155.....	0.01.....	3,000
Germanium-68.....	0.01.....	2,000
Gadolinium-153.....	0.01.....	5,000
Gold-198.....	0.01.....	30,000
Hafnium-172.....	0.01.....	400
Hafnium-181.....	0.01.....	7,000
Holmium-166m.....	0.01.....	100
Hydrogen-3.....	0.5.....	20,000
Iodine-125.....	0.5.....	10
Iodine-131.....	0.5.....	10

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Radioactive material ¹	Release fraction	Quantity (curies)
Indium-114m.....	0.01	1,000
Iridium-192.....	0.001	40,000
Iron-55	0.01	40,000
Iron-59	0.01	7,000
Krypton-85	1.0	6,000,000
Lead-210.....	0.01	8
Manganese-56.....	0.01	60,000
Mercury-203.....	0.01	10,000
Molybdenum-99.....	0.01	30,000
Neptunium-237	0.001	2
Nickel-63.....	0.01	20,000
Niobium-94	0.01	300
Phosphorus-32	0.5	100
Phosphorus-33	0.5	1,000
Polonium-210.....	0.01	10
Potassium-42.....	0.01	9,000
Promethium-145	0.01	4,000
Promethium-147	0.01	4,000
Ruthenium-106	0.01	200
Samarium-151	0.01	4,000
Scandium-46	0.01	3,000
Selenium-75.....	0.01	10,000
Silver-110m.....	0.01	1,000
Sodium-22	0.01	9,000
Sodium-24	0.01	10,000
Strontium-89	0.01	3,000
Strontium-90	0.01	90
Sulfur-35	0.5	900
Technetium-99.....	0.01	10,000
Technetium-99m.....	0.01	400,000
Tellurium-127m.....	0.01	5,000
Tellurium-129m.....	0.01	5,000
Terbium-160	0.01	4,000
Thulium-170.....	0.01	4,000
Tin-113.....	0.01	10,000
Tin-123.....	0.01	3,000
Tin-126.....	0.01	1,000
Titanium-44.....	0.01	100
Vanadium-48	0.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	0.01	2,000
Zinc-65.....	0.01	5,000
Zirconium-93.....	0.01	400
Zirconium-95.....	0.01	5,000
Any other beta-gamma emitter.....	0.01	10,000

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Radioactive material ¹	Release fraction	Quantity (curies)
Mixed fission products	0.01	1,000
Mixed Corrosion products	0.01	10,000
Contaminated equipment beta-gamma	0.001	10,000
Irradiated material, any form other than solid noncombustible	0.01	1,000
Irradiated material, solid noncombustible	0.001	10,000
Mixed radioactive waste, beta-gamma	0.01	1,000
Packaged mixed waste, beta-gamma ²	0.001	10,000
Any other alpha emitter	0.001	2
Contaminated equipment, alpha	0.0001	20
Packaged waste, alpha ²	0.0001	20
Combinations of radio- active materials listed above ¹	-----	-----

¹For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in 180 NAC 3, Appendix 003-E exceeds one.

²Waste packaged in Type B containers does not require an emergency plan.

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NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATION AND LICENSURE
DIVISION OF PUBLIC HEALTH ASSURANCE - RADIOACTIVE MATERIALS PROGRAM

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE

INSTRUCTIONS - (Use additional sheets where necessary.)

New or Renewal Application - Complete Items 1. through 15.

Amendment to License - Complete Items 1.a, 3., and 15. And indicate other changes as appropriate.

Retain one copy for your files and submit original application to: Department of Health and Human Services Regulation and Licensure, Division of Public Health Assurance, 301 Centennial Mall South, P.O. Box 95007, Lincoln, NE 68509-5007.

Upon approval of this application, the applicant will receive a Radioactive Material License, issued in accordance with the requirements contained in Title 180, Regulations for the Control of Radiation and the Nebraska Radiation Control Act.

<p>1.a Legal Name and Street address of Applicant (Institution, Firm, Person, etc.)</p> <p>Applicant Name: _____</p> <p>Address: _____</p> <p>_____</p> <p>City, State Zip +4: _____</p> <p>Telephone #: _____</p> <p>FAX #: _____</p> <p>E-Mail Address: _____</p>											
<p>1.b Street address(es) at which Radioactive Material will be used. (If different than 1.a)</p> <p>(1) Permanent Address: _____</p> <p>_____</p> <p>City, State Zip+4: _____</p> <p>(2) Temporary Job Sites Throughout Nebraska? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>											
<p>2. Department to Use Radioactive Material</p> <p>_____</p> <p>Person to Contact: _____</p> <p>Telephone #: _____</p>	<p>3. This is an application for:</p> <p><input type="checkbox"/> New License</p> <p><input type="checkbox"/> Amendment to License No. _____</p> <p><input type="checkbox"/> Renewal of License No. _____</p>										
<p>4. Individual User(s)</p> <p><input type="checkbox"/> Individual users approved by the Licensee's radiation safety committee.</p> <p><input type="checkbox"/> Individual users approved by the Licensee's radiation safety officer.</p> <p><input type="checkbox"/> Individual users satisfy the requirements of 180 NAC 3-013</p> <p>OR</p> <p><input type="checkbox"/> Name and Title of individual(s) who will use or directly supervise use of Radioactive Materials. Give training and experience in Items 7. And 8.</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left; border-bottom: 1px solid black;">First Name + Middle Initial</th> <th style="text-align: left; border-bottom: 1px solid black;">Last Name</th> <th style="text-align: left; border-bottom: 1px solid black;">Title</th> </tr> </thead> <tbody> <tr> <td style="height: 20px;"> </td> <td> </td> <td> </td> </tr> <tr> <td style="height: 20px;"> </td> <td> </td> <td> </td> </tr> </tbody> </table>	First Name + Middle Initial	Last Name	Title							<p>5. Radiation Safety Officer (RSO) (Name and Title of Individual designated as Radiation Safety Officer.)</p> <p>_____</p> <p>Telephone #: _____</p> <p>Attach documentation of his/her training and experience as in Items 7. and 8.</p> <div style="border: 1px solid black; padding: 5px; text-align: center; margin-top: 10px;"> <p>*Agency Use Only*</p> </div> <div style="border: 1px solid black; padding: 5px; text-align: center; margin-top: 10px;"> <p>Date Received Stamp</p> </div>	
First Name + Middle Initial	Last Name	Title									

6. Radioactive Material Data

Type B Broad Scope, 180 NAC 3-013.01, item 2

Type C Broad Scope, 180 NAC 3-013.01, item 3

Specific License, Radioactive Material Listed below:

6.a. Element and Mass Number	6.b. Chemical or Physical Form (Make and Model if sealed source)	6.c. Maximum Activity Requested (Expressed as Curies, Millicuries or Microcuries)	6.d. Use of Each Form (If sealed source, also give Make and Model Number of the storage and/or device in which sealed source will be stored and/or used)

7. Training of Individuals in Items 4. and 5.

Name of Individual:

	Formal Course Title	Location and Date(s) of Training	Clock Hours in Lecture or Laboratory
7.a. Radiation Physics and Instrumentation			
7.b. Radiation Protection			
7.c. Mathematics Pertaining to the Use and Measurement of Radioactivity			
7.d. Biological Effects of Radiation			

8. Experience with Radiation of Individuals in Items 4. and 5.

(Actual use of Radioisotopes or Equivalent Experience)

Name of Individual:

Isotope	Maximum Activity	Where Experience Was Gained	Months/Years	Type of Use

9. Radiation Detection Instruments					
Type of Instrument	Manufacturer=s Name	Model Number	Number Available	Radiation Detected	Sensitivity Range
10. Calibration of Instruments Listed in Item 9.					
<input type="checkbox"/> a. Calibrated by Service Company Name and Address of Service Company and Frequency of Calibration			<input type="checkbox"/> b. Calibrated by Applicant		
11. Personnel Monitoring Devices (Check and/or complete as appropriate)					
Type	Supplier (Service Company)	Exchange Frequency			
<input type="checkbox"/> Film Badge <input type="checkbox"/> TLD <input type="checkbox"/> DOSL <input type="checkbox"/> Other (Specify): _____		<input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Other (Specify): _____			

Information to be Submitted on Additional Sheets

12. Facilities and Equipment

Describe laboratory facilities and remote handling equipment, storage containers, shielding, fume hoods, etc. Attach an explanatory sketch of the facility.

13. Radiation Protection Program

Describe the radiation protection program as appropriate for the material to be used, including: the duties and responsibilities of the Radiation Safety Officer (RSO); control measures; bioassay procedures (if needed); day-to-day general safety instructions to be followed; etc. If the application is for sealed sources also submit leak testing procedures, or if leak testing will be performed using a leak test kit, specify manufacturer and model number of the leak test kit.

14. Waste Disposal

If a commercial waste disposal service is employed, specify the name and address of the company. Otherwise, submit a detailed description of methods which will be used for disposing of radioactive wastes and estimates of the type and amount of activity involved. If the application is for sealed sources and devices and they will be returned to the manufacturer, so state.

15. CERTIFICATION

(This item must be completed by applicant.)

The applicant and any official executing this document on behalf of the applicant named in Item 1.a., certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services Regulation and Licensure, Title 180, Regulations for Control of Radiation - Ionizing and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

Applicant Name From Item 1.a.

By: _____ Date: _____
Signature

Print Name and Title of certifying official authorized to act on behalf of the applicant

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATION AND LICENSURE
DIVISION OF PUBLIC HEALTH ASSURANCE
RADIOACTIVE MATERIALS PROGRAM

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE - Medical or Teletherapy

INSTRUCTIONS - (Use additional sheets where necessary.)

Medical Application - Complete Items 1. through 26.

Teletherapy Application - Complete Items 1. through 26, as applicable and Supplement C.

Retain one copy for your files and submit original application to: Department of Health and Human Services Regulation and Licensure, Division of Public Health Assurance, 301 Centennial Mall South, P.O. Box 95007, Lincoln, NE 68509-5007.

Upon approval of this application, the applicant will receive a Radioactive Material License, issued in accordance with the requirements contained in Title 180, Regulations for Control of Radiation and the Nebraska Radiation Control Act.

1.a Legal Name and Street address of Applicant (Institution, Firm, Hospital, Person, etc.)																							
Applicant Name:																							
Address:																							
City, State Zip +4:																							
Telephone #:																							
FAX #:																							
eMail Address:																							
1.b Street address(es) at which Radioactive Material will be used. (If different than 1.a)																							
(1) Permanent	Address:																						
	City, State Zip+4:																						
(2) Temporary Job Sites Throughout Nebraska?	<input type="checkbox"/> Yes <input type="checkbox"/> No																						
2. Person to Contact Regarding this Application	3. This is an application for:																						
_____	<input type="checkbox"/> New License																						
Telephone #: _____	<input type="checkbox"/> Amendment to License No. _____																						
	<input type="checkbox"/> Renewal of License No. _____																						
4. Individual User(s) (Name and Title of individual(s) who will use or directly supervise use of, Radioactive Materials. Complete NRH-5A, Supplement A and B for each individual listed.)	5. Radiation Safety Officer (RSO) (Name and Title of Individual designated as Radiation Safety Officer.)																						
<table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 35%; border-bottom: 1px solid black;">First Name + Middle Initial</th> <th style="width: 35%; border-bottom: 1px solid black;">Last Name</th> <th style="width: 30%; border-bottom: 1px solid black;">Title</th> </tr> </thead> <tbody> <tr><td style="border-bottom: 1px solid black;"> </td><td style="border-bottom: 1px solid black;"> </td><td style="border-bottom: 1px solid black;"> </td></tr> <tr><td style="border-bottom: 1px solid black;"> </td><td style="border-bottom: 1px solid black;"> </td><td style="border-bottom: 1px solid black;"> </td></tr> <tr><td style="border-bottom: 1px solid black;"> </td><td style="border-bottom: 1px solid black;"> </td><td style="border-bottom: 1px solid black;"> </td></tr> <tr><td style="border-bottom: 1px solid black;"> </td><td style="border-bottom: 1px solid black;"> </td><td style="border-bottom: 1px solid black;"> </td></tr> <tr><td style="border-bottom: 1px solid black;"> </td><td style="border-bottom: 1px solid black;"> </td><td style="border-bottom: 1px solid black;"> </td></tr> <tr><td style="border-bottom: 1px solid black;"> </td><td style="border-bottom: 1px solid black;"> </td><td style="border-bottom: 1px solid black;"> </td></tr> </tbody> </table>	First Name + Middle Initial	Last Name	Title																			_____ Telephone #: _____ Attach documentation of his/her training and experience as in NRH-5A, Supplement A.)	
First Name + Middle Initial	Last Name	Title																					
	Agency Use Only																						
	Date Received Stamp																						

1.a Legal Name and Street address of Applicant (Institution, Firm, Hospital, Person, etc.)

6. Radioactive Material Data

6. Radioactive Material for Medical Use

Radioactive Material Listed In:	Items Desired (X)	Maximum Possession Limits (In millicuries)
Title 180 NAC 3-008.09 for Invitro Studies		
Title 180 NAC 7-034.01		
Title 180 NAC 7-036		
Title 180 NAC 7-040		
Title 180 NAC 7-044		
Title 180 NAC 7-046		
Additional Items		
Xenon-133 as gas or gas in saline for blood flow studies and pulmonary function studies		
Technetium-99m aerosolized DTPA for pulmonary function studies		
High dose rate remote afterloading brachytherapy device		

6.b. Radioactive Material for Uses not Listed in Item 6.a.

6.b.(1) <u>Element and Mass Number</u>	6.b.(2) <u>Chemical or Physical Form</u> <u>(Make and Model if sealed source)</u>	6.b.(3) <u>Maximum Activity Requested</u> <u>(Expressed as Curies, Millicuries, or Microcuries)</u>	6.b.(4) <u>Use of Each Form</u> <u>(If sealed source, also give Make and Model Number of the storage and/or device in which sealed source will be stored and/or used)</u>

Instructions for Items 7. Through 23.

For Items 7. through 23., check the appropriate box(es) and submit a detailed description of all the requested information. Begin each Item on a separate sheet, identifying the Item number and the date of the application in the lower right hand corner of each page. If you indicate that you will follow an Appendix to the *Guide for Preparation of Applications for Medical Programs 7.0*, do not submit the pages, but specify the revision number and date of the *Guide*.

The Most current *Guide* is: Revision: _____ Date: _____

- 7. Radiation Safety Committee**
 Names and Specialities attached; **AND**
 Duties as in Appendix B; **OR**
Equivalent Duties attached
- 8. Training and Experience**
 Supplements A and B attached for each individual user; **AND**
 Supplement A attached for RSO
- 9. Instrumentation**
 Appendix C Form attached; **OR**
 List by Name and Model Number
- 10. Calibration of Instruments**
a. Survey Instruments
 Appendix D Procedures followed; **OR**
 Equivalent Procedures attached
- AND**
- b. Dose Calibrator**
 Appendix D Procedures followed; **OR**
 Equivalent Procedures attached
- 11. Facilities and Equipment**
 Description or diagram attached; **OR**
 See Supplements C - Teletherapy Requirements
- 12. Personnel Training Program**
 Description of training attached
- 13. Procedures for Ordering and Receiving Radioactive Materials**
 Detailed Information Attached
- 14. Procedures for Safely Opening Packages Containing Radioactive Materials**
 Appendix F Procedures followed; **OR**
 Equivalent Procedures attached
- 15. General Rules for the safe use of Radioactive Material**
 Appendix G Procedures followed; **OR**
 Equivalent Procedures attached
- 16. Emergency Procedures**
 Appendix H Procedures followed; **OR**
 Equivalent Procedures attached
- 17. Area Survey Procedures**
 Appendix I Procedures followed; **OR**
 Equivalent Procedures attached
- 18. Waste Disposal**
 Appendix J Form attached; **OR**
 Equivalent Information attached
- 19. Therapeutic Use of Radiopharmaceuticals**
 Appendix K Procedures followed; **OR**
 Equivalent Procedures attached
- 20. Therapeutic Use of Sealed Sources**
 Detailed Information attached; **AND**
 Appendix L Procedures followed; **OR**
 Equivalent Procedures attached
- 21. Procedures and Precautions for use of Radioactive Gases (e.g., Xenon-133)**
 Detailed Information attached
- 22. Procedures and Precautions for Use of Radioactive Material in Animals**
 Detailed Information attached
- 23. Procedures and Precautions for Use of Radioactive Material Specified in Item 6.b.**
 Detailed Information attached

24. Personnel Monitoring Devices (Check and/or complete as appropriate)		
Type	Supplier/Service Company	Exchange Frequency
24.a. Whole Body <input type="checkbox"/> Film Badge <input type="checkbox"/> TLD <input type="checkbox"/> DOSL <input type="checkbox"/> Other: (Specify)		<input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Other: (Specify)
24.b. Finger <input type="checkbox"/> Film Badge <input type="checkbox"/> TLD <input type="checkbox"/> Other: (Specify)		<input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Other: (Specify)
24.c. Wrist <input type="checkbox"/> Film Badge <input type="checkbox"/> TLD <input type="checkbox"/> Other: (Specify)		<input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Other: (Specify)
24d. Other (Specify)		
25. Private Practice Applicants Only		
25.a. Hospital Agreeing to accept patients containing Radioactive Material: Name: _____ Mailing Address: _____ _____ City, State Zip+4: _____		
25.b. Attach a copy of the agreement letter signed by the hospital administrator.		
25.c. When requesting Therapy Procedures, attach a copy of Radiation Safety Precautions to be taken and list available radiation detection instruments.		

26. CERTIFICATION

(This Item must be completed by applicant.)

The applicant and any official executing this document on behalf of the applicant named in Item 1.a., certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services Regulation and Licensure, Title 180, Regulations for Control of Radiation and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

Applicant Name From Item 1.a.

By: _____

Signature

Date: _____

Print Name and Title of certifying official authorized to act on behalf of the applicant

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APPLICATION FOR RADIOACTIVE MATERIAL LICENSE
Medical or Teletherapy

SUPPLEMENT A

Training and Experience
Authorized User or Radiation Safety Officer (RSO)

1. Name of Individual <hr style="border: none; border-top: 1px solid black; margin: 5px 0;"/> <input type="checkbox"/> Authorized User <input type="checkbox"/> Radiation Safety Officer	2. Physician who is licensed to dispense drugs in the practice of medicine in Nebraska? <input type="checkbox"/> YES <input type="checkbox"/> NO			
3. Certification				
3.a. Specialty Board	3.b. Category	3.c. Month and Year Certified		
4. Training Received in Basic Radioisotope Handling Techniques				
	<u>Location and Dates of Training</u>	<u>Clock Hours in Lecture or Laboratory</u>	<u>Clock Hours of Supervised Laboratory Experience</u>	
4.a. Radiation Physics and Instrumentation				
4.b. Radiation Protection				
4.c. Mathematics Pertaining to the Use and Measurement of				
4.d. Biological Effects of Radiation				
4.e. Radiopharmaceutical Chemistry				
5. Experience with Radiation (Actual Use of Radioisotopes or Equivalent Experience)				
<u>Isotope</u>	<u>Maximum Activity</u>	<u>Where Experience Was Gained</u>	<u>Months/Years</u>	<u>Type of Use</u>

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APPLICATION FOR RADIOACTIVE MATERIAL LICENSE
Medical or Teletherapy

SUPPLEMENT B
Preceptor Statement

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. Full Name and Street Address of Applicant Physician	
Full Name:	
Address:	
City, State Zip+4	

2. Clinical Training and Experience with Radiation (Actual Use of Radioisotopes)			
<u>Isotope</u>	<u>Conditions Diagnosed or Treated</u>	<u>Number of Cases Involving Personal Participation¹</u>	<u>Comments²</u>
I-125 or I-131	Diagnosis of Thyroid Function		
	Determination of Blood and Blood Plasma Volume		
	Liver Function Studies		
	Fat Absorption Studies		
	Kidney Function Studies		
	In vitro Studies		
Other			
I-125	Detection of Thrombosis		
I-131	Thyroid Imaging		
P-32	Eye Tumor Localization		
Se-75	Pancreas Imaging		
Yb-169	Cisternography		
Xe-133	Blood Flow Studies and Pulmonary Function Studies		
Other			
Tc-99m	Brain Imaging		
	Cardiac Imaging		
	Thyroid Imaging		
	Salivary Gland Imaging		
	Blood Pool Imaging		
	Placenta Localization		
	Liver and Spleen Imaging		
	Lung Imaging		
Bone Imaging			

2. Clinical Training and Experience with Radiation (Actual Use of Radioisotopes)			
Other			
P-32 (Soluble)	Treatment of Polycythemia Vera, Leukemia, and Bone Metastases		
P-32 (Colloidal)	Intracavitary Treatment		
I-131	Diagnosis of Thyroid Function		
	Treatment of Hyperthyroidism		
Au-198	Intracavitary Treatment		
Co-60 or Cs-137	Interstitial Treatment		
	Intracavitary Treatment		
I-125 or Ir-192	Interstitial Treatment		
Ra-226	Intracavitary Treatment		
	Interstitial Treatment		
	Superficial Treatment		
Co-60 or Cs-137	Teletherapy Treatment		
Sr-90	Treatment of Eye Disease		
	Radiopharmaceutical Preparation		
Mo-99/Tc-99m	Generator		
Sn-113/In-113m	Generator		
Tc-99m	Reagent Kits		
X-Ray and Accelerator Therapy	Courses of Therapy Treatment		
Other			

¹ Key to column

Personal Participation should consist of:

1. Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.
2. Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements, and plotting of data.
3. Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

² Additional information or comments may be submitted in duplicate on separate sheets.

3. Dates and Total Number of Hours Received in Clinical Radioisotope Training

(Submit in duplicate on separate sheets)

4. Training and Experience Obtained Under the Supervision of:

Supervisor's
Name:

Institution
Name:

Address

City, State
Zip+4

Radioactive material License Number(s):

5. Preceptor's Verification

Preceptor's
Name: _____
(Type or Print)

Preceptor's
Name: _____
(Type or Print)

(Date)

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APPLICATION FOR RADIOACTIVE MATERIAL LICENSE
Medical or Teletherapy

SUPPLEMENT C

Requirements Specific to Teletherapy

1. Facilities and Equipment

- Description and drawing of facilities attached; **AND**
- Description of patient viewing and communicating systems attached; **AND**
- Description of area safeguards attached

2. Beam Stops

- Description of stops used to restrict beam orientation attached

3. Shielding Evaluation

- Evaluation of proposed shielding attached

4. Operating and Emergency Procedures

- Description of operating procedures attached; **AND**
- Copy of emergency procedures attached

5. Instruction of Personnel

- Training program and schedule in Appendix A followed; **OR**
- Description of instruction program for employees attached

6. Leak Tests of Sealed Sources

- Description of leak test procedures attached

7. Teletherapy Physicist (Use only if individual fails to meet 180 NAC 7-066.10 requirements)

- Statement of qualifications of the physicist who will perform teletherapy calibrations attached.

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NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATION AND
LICENSURE
PUBLIC HEALTH ASSURANCE DIVISION

CERTIFICATE - USE OF DEPLETED URANIUM
UNDER GENERAL LICENSE

180 NAC 3-007.04 establishes a general license authorizing a person to receive, acquire, possess, use, or transfer in accordance with the provisions of 180 NAC 3-007.04, items 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.

Possession of depleted uranium is not authorized under 180 NAC 3-007.04 until a licensee has filed Form NRH-11 and received from the Agency a validated copy of NRH-11 with a certification number.

CONDITIONS AND LIMITATIONS OF GENERAL LICENSE 3-007.04

3-007.04 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 180 NAC 3-007.04 items 2. through 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 180 NAC 3-007.04, item 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 180 NAC 3-014.13 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. Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by 180 NAC 3-007.04, item 1 shall:
 - a. File Agency Form NRH-11 "Certificate - Use of Depleted Uranium Under General License," with the Agency. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The registrant shall furnish on Agency Form NRH-11 the following information and such other information as may be required by that form:
 - (1) Name and address of the general licensee;
 - (2) A statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 180 NAC 3-007.04, item 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
 - (3) Name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in 180 NAC 3-007.04, item 3.a.(2).

- b. Report in writing to the Agency any changes in information furnished by him in Agency Form NRH-11 "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 180 NAC 3-007.04, item 1:
 - a. 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.
 - b. Shall not abandon such depleted uranium.
 - c. Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 180 NAC 3-025. In the case where the transferee receives the depleted uranium pursuant to the general license established by 180 NAC 3-007.04, item 1., the transferor shall furnish the transferee a copy of this regulation and a copy of Agency Form NRH-11. 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 regulation equivalent to 180 NAC 3-007.04, item 1., the transferor shall furnish the transferee a copy of Title 180 and a copy of Agency Form NRH-11 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 Title 180.
 - d. Within 30 days of any transfer, shall report in writing to the Agency the name and address of the person receiving the depleted uranium pursuant to such transfer.
5. Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by 180 NAC 3-007.04, item 1 is exempt from the requirements of 180 NAC 4 and 180 NAC 10 with respect to the depleted uranium covered by that general license.

INSTRUCTIONS

Submit this form in duplicate to the Department of Health and Human Services Regulation and Licensure, Public Health Assurance Division, 301 Centennial Mall South, P.O. Box 95007, Lincoln, Nebraska 68509-5007.

A certification number will be assigned and a validated copy of NRH-11 will be returned.

(Print or Type)

1. Licensee Information

Legal Name: _____

Address: _____

City, State and Zip+4 _____

Person Authorized to sign binding documents for the Licensee _____

2. I hereby apply for a Certificate number pursuant to 180 NAC 3-007.04 on behalf of the above Licensee.

3. Certification:

I certify that:

- a. All information in this certificate is true and complete.
- b. I understand the Agency's regulations require that any change in the information furnished on this certificate be reported to the Department within 30 days from the date of such change.
- c. I have read and understand the provisions of 180 NAC 3-007.04 of 180 NAC 3 of the Agency's regulations, and I understand that I am required to comply with those provisions as to the depleted uranium which I receive, possess, use, or transfer under the general license.

(Signature of Person listed in Item 1.)

(Date)

4. To be completed by the Agency:

Certification Number _____ ***Date*** _____

Radioactive Materials Program Manager _____

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NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATION AND LICENSURE
PUBLIC HEALTH ASSURANCE DIVISION

**CERTIFICATE - IN VITRO TESTING
WITH RADIOACTIVE MATERIAL UNDER GENERAL LICENSE**

180 NAC 3-008.09 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 180 NAC 3-008.09 is not authorized until the physician, veterinarian, clinical laboratory, or hospital has filed Form NRH-17 and received from the Agency a validated copy of Form NRH-17 with a certification number.

CONDITIONS AND LIMITATIONS OF GENERAL LICENSE 180 NAC 3-008.09

3-008.09 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 in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of 180 NAC 3-008.09, items 2. through 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:
 - a. Iodine-125, iodine-131, selenium-75, cobalt-57, and carbon-14 in units not exceeding 370 kBq (10 microcuries) each.
 - b. Hydrogen-3 (tritium), in units not exceeding 1.85 MBq (50 microcuries) each.
 - c. Iron-59, in units not exceeding 740 kBq (20 microcuries) each.
 - d. Mock Iodine-125 reference or calibration sources, in units not exceeding 1.85 kBq (0.05 microcurie) of iodine-129 and 1.85 Bq (0.005 microcurie) of americium-241 each.

2. No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by 180 NAC 3-008.09, item 1. until he has filed Agency Form NRH-17, "Certificate - In Vitro Testing with Radioactive Material Under General License", with the Agency and received from the Agency a validated copy of Agency Form NRH-17 with certification number assigned. The physician, veterinarian, clinical laboratory or hospital shall furnish on Agency Form NRH-17 the following information and such other information as may be required by that form:
 - a. Name and address of the physician, veterinarian, clinical laboratory or hospital;
 - b. The location of use; and
 - c. A statement that the physician, veterinarian in the practice of veterinary medicine, 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 180 NAC 3-008.09, item 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 180 NAC 3-008.09, item 1. shall comply with the following:
 - a. The general licensee shall not possess at any one time, pursuant to the general license in 180 NAC 3-008.09, item 1. at any one location of storage or use a total amount of iodine-125, iodine-131, iron-59, cobalt-57 and/or selenium-75 in excess of 7.4 MBq (200 microcuries).
 - b. The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.
 - c. The general licensee shall use the radioactive material only for the uses authorized by 180 NAC 3-008.09, item 1.
 - d. 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 Agency, the U.S. Nuclear Regulatory Commission, or any Agreement State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.
 - e. The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in 180 NAC 3-008.09, item 1.d. as required by 180 NAC 4-037 and 4-042.

4. The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to 180 NAC 3-008.09, item 1.:
 - a. Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 180 NAC 3-014.08 or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, or any Agreement 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 180 NAC 3-008.09 or its' equivalent, and
 - b. Unless the following statement, or substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, 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

5. The physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital possessing or using radioactive material under the general license of 180 NAC 3-008.09, item 1. shall report in writing to the Agency, any changes in the information furnished by him in the "Certificate - In Vitro Testing with Radioactive Material Under General License", Agency Form NRH-17. 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 180 NAC 3-008.09, item 1. is exempt from the requirements of 180 NAC 4 and 180 NAC 10 with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in 180 NAC 3-008.09 item 1.d. shall comply with the provisions of 180 NAC 4-037, 4-055, and 4-056.

INSTRUCTIONS

Submit this form in duplicate to the Department of Health and Human Services Regulation and Licensure, Public Health Assurance Division, 301 Centennial Mall South, P.O. Box 95007, Lincoln, Nebraska 68509-5007.

A certification number will be assigned and a validated copy of NRH-17 will be returned.

(Print or Type)

1. Licensee Information

Legal Name:
(Physician, Veterinarian,
Clinical Laboratory or
Hospital)

Address:

City, State and Zip+4

Person Authorized to sign
binding documents for the
Licensee

2. I hereby apply for a Certificate Number pursuant to 180 NAC 3-008.09 for use of radioactive materials for:

- a. Myself, a duly licensed physician authorized to dispense drugs in the practice of medicine, or a veterinarian licensed to practice veterinary medicine.
- b. The above named clinical laboratory.
- c. The above named hospital.

3. If place of use is different from address in Item 1, please give complete address:

4. Certification:

I certify that:

- a. All information in this certificate 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 180 NAC 3-008.09. The tests will be performed only by personnel competent in the use of the instruments and in the handling of the radioactive materials.
- c. I understand that Agency regulations require that any change in the information furnished on this certificate be reported to the Agency within 30 days from the date of such change.

- d. I have read and understand the provisions of 180 NAC 3-008.09 of the Agency regulations; 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 certification number is filed with the Agency.

(Signature of Person listed in Item 1.)

(Date)

4. To be completed by the Agency:

Certification Number _____ **Date** _____

Radioactive Materials Program Manager _____

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NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATION AND LICENSURE
DIVISION OF PUBLIC HEALTH ASSURANCE
RADIOACTIVE MATERIALS PROGRAM

CERTIFICATION OF DISPOSITION OF MATERIALS

INSTRUCTIONS - (Use additional sheets where necessary.)

Type or Print except where indicated.

Retain one copy for your files and submit original application to: Department of Health and Human Services Regulation and Licensure, Division of Public Health Assurance, 301 Centennial Mall South, P.O. Box 95007, Lincoln, NE 68509-5007.

Upon approval of this application, the applicant will receive a Radioactive Material License, issued in accordance with the requirements contained in Title 180, Regulations for Control of Radiation and the Nebraska Radiation Control Act.

1. Licensee Information Licensee Number: _____ License Expiration Date: _____ Licensee Name and Street Address: Applicant Name: _____ Address: _____ City, State Zip+4 _____ Telephone #: _____ FAX#: _____ E-mail Address: _____	2. Person to Contact Regarding this Application _____ Telephone #: _____
3. Materials Data <input type="checkbox"/> No Materials have ever been procured or possessed by the Licensee under this License. <input type="checkbox"/> All Materials procured and/or possessed by the Licensee under the License Number cited above have been disposed of in the following manner: <input type="checkbox"/> Transfer Specify the date of the transfer, the name of the licensed recipient and the recipient's Agency, NRC or Agreement State license number. Describe specific materials transfer actions and if there were radioactive wastes generated in terminating this license, the disposal actions, including the disposition of low-level radioactive waste, mixed waste, Greater-than-Class-C waste, and sealed sources, if applicable. <input type="checkbox"/> Disposed of directly by Licensee Describe specific disposal procedures (e.g. decay in storage).	
4. Other Data <input type="checkbox"/> Our License has not yet expired, please terminate it. A Radiation Survey was conducted to confirm the absence of licensed radioactive materials and to determine whether any contamination remains on the premises covered by the license: <input type="checkbox"/> NO (Attach Explanation) <input type="checkbox"/> YES, the results: <input type="checkbox"/> Are attached <input type="checkbox"/> Were forwarded to the Agency on (Date) _____	

4. Other Data (Continued)

Address all future correspondence regarding this license to:

Name: _____

Address: _____

City, State Zip+4: _____

Telephone #: _____

FAX#: _____

E-mail Address: _____

5. CERTIFICATION

(This item must be completed by applicant.)

The applicant and any official executing this document on behalf of the applicant named in Item 1., certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services Regulation and Licensure, Title 180, Regulations for Control of Radiation and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

Applicant Name From Item 1.

By: _____

Signature

Date: _____

Print Name and Title of certifying official authorized to act on behalf of the applicant

ATTACHMENT 3-1

10 CFR Chapter 1, Part 32, Section 32.21 and 32.26

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§32.21 Radioactive drug: Manufacture, preparation, or transfer for commercial distribution of capsules containing carbon-14 urea each for "in vivo" diagnostic use for humans to persons exempt from licensing; Requirements for a license.

(a) An application for a specific license to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution capsules containing 37 kBq (1 μ Ci) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each for "in vivo" diagnostic use, to persons exempt from licensing under §30.21 of this chapter or the equivalent regulations of an Agreement State will be approved if:

(1) The applicant satisfies the general requirements specified in §30.33 of this chapter, provided that the requirements of §30.33(a)(2) and (3) of this chapter do not apply to an application for a license to transfer byproduct material manufactured, prepared, processed, produced, packaged, or repackaged pursuant to a license issued by an Agreement State;

(2) The applicant meets the requirements under §32.72(a)(2) of this part;

(3) The applicant provides evidence that each capsule contains 37 kBq (1 μ Ci) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process);

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

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

(6) The applicant submits copies of prototype labels and brochures and the NRC approves these labels and brochures.

(b) Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing drugs.

[62 FR 63640, Dec. 2, 1997]

Effective Date Note: At 62 FR 63640, Dec. 2, 1997, §32.21 was added, effective Jan. 2, 1998.

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Attachment Number 3 - 1

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§32.26 Gas and aerosol detectors containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer.

An application for a specific license to manufacture, process, or produce gas and aerosol detectors containing byproduct material and designed to protect life or property from fires and airborne hazards, or to initially transfer such products for use pursuant to §30.20 of this chapter or equivalent regulations of an Agreement State, will be approved if:

(a) The applicant satisfies the general requirements specified in §30.33 of this chapter: *Provided, however,* That the requirements of §30.33(a) (2) and (3) do not apply to an application for a license to transfer byproduct material in gas and aerosol detectors manufactured, processed or produced pursuant to a license issued by an Agreement State.

(b) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the gas and aerosol detector to demonstrate that the product will meet the safety criteria set forth in §32.27. The information should include:

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

(2) The type and quantity of byproduct material in each unit;

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

(4) Solubility in water and body fluids of the forms of the byproduct material identified in paragraphs (b) (3) and (12) of this section;

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

(6) Maximum external radiation levels at 5 and 25 centimeters from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement;

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

(8) Total quantity of byproduct material expected to be distributed in the product annually;

(9) The expected useful life of the product;

(10) The proposed methods of labeling or marking the detector and its point-of-sale package to satisfy the requirements of §32.29(b);

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

(12) Results of the prototype testing of the product, including any change in the form of the byproduct material contained in the product, the extent to which the byproduct material may be released to the

environment, any increase in external radiation levels, and any other changes in safety features;

(13) The estimated external radiation doses and dose commitments relevant to the safety criteria in §32.27 and the basis for such estimates;

(14) A determination that the probabilities with respect to the doses referred to in §32.27(c) meet the criteria of that paragraph;

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

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

[34 FR 6653, Apr. 18, 1969, as amended at 43 FR 6923, Feb. 17, 1978; 45 FR 38342, June 9, 1980]

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ATTACHMENT 3-2

10 CFR Chapter 1, Part 30, Section 30.33

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§ 30.33 General requirements for issuance of specific licenses.

(a) An application for a specific license will be approved if:

(1) The application is for a purpose authorized by the Act;

(2) The applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property;

(3) The applicant is qualified by training and experience to use the material for the purpose requested in such manner as to protect health and minimize danger to life or property;

(4) The applicant satisfies any special requirements contained in Parts 2 through 35 and 39; and

(5) In the case of an application for a license to receive and possess byproduct material for the conduct of any activity which the Commission determines will significantly affect the quality of the environment, the Director of Nuclear Material Safety and Safeguards or his designee, before commencement of construction of the plant or facility in which the activity will be conducted, on the basis of information filed and evaluations made pursuant to Subpart A of Part 51 of this chapter, has concluded, 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 conclusion shall be grounds for denial of a license to receive and possess byproduct 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 roads for site exploration, 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.

(b) Upon a determination that an application meets the requirements of the Act, and the regulations of the Commission, the Commission will issue a specific license authorizing the possession and use of byproduct material (Form NRC 374, "Byproduct Material License").

§ 30.34 Terms and conditions of licenses.

(a) Each license issued pursuant to the regulations in this part and the regulations in Parts 31 through 35 and

39 of this chapter shall be subject to all the provisions of the Act, now or hereafter in effect, and to all valid rules, regulations and orders of the Commission.

(b) No license issued or granted pursuant to the regulations in this part and Parts 31 through 35, and 39 nor any right under a license 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 Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing.

(c) Each person licensed by the Commission pursuant to the regulations in this part and Parts 31 through 35 and 39 shall confine his possession and use of the byproduct material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to the regulations in this part and Parts 31 through 35 and 39 of this chapter shall carry with it the right to receive, acquire, own, and possess byproduct material. Preparation for shipment and transport of byproduct material shall be in accordance with the provisions of Part 71 of this chapter.

(d) Each license issued pursuant to the regulations in this part and Parts 31 through 35 and 39 shall be deemed to contain the provisions set forth in section 183b-d, inclusive, of the Act, whether or not these provisions are expressly set forth in the license.

(e) The Commission may incorporate, in any license issued pursuant to the regulations in this part and Parts 31 through 35 and 39, 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 byproduct material as it deems appropriate or necessary in order to:

- (1) Promote the common defense and security;
- (2) Protect health or to minimize danger to life or property;
- (3) Protect restricted data;
- (4) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be necessary or appropriate to effectuate the purposes of the Act and regulations thereunder.

(f) Licensees required to submit emergency plans by § 30.32(i) shall follow the emergency plan approved by the Commission. The licensee may change the approved without Commission approval only if the changes do not decrease the effectiveness of the plan. The licensee shall furnish the change to the

appropriate NRC Regional Office specified in § 30.6 and to affected offsite response organizations within six months after the change is made. Proposed changes that decrease, or potentially decrease, the effectiveness of the approved emergency plan may not be implemented without prior application to and prior approval by the Commission.

(g) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators shall test the generator eluates for molybdenum-99 breakthrough in accordance with § 35.204 of this chapter. The licensee shall record the results of each test and retain each record for three years after the record is made.

(h)(1) Each licensee shall notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

- (I) The licensee;
 - (II) An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the licensee or licensee as property of the estate; or
 - (III) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.
- (2) This notification must indicate:
- (i) The bankruptcy court in which the petition for bankruptcy was filed; and
 - (ii) The date of the filing of the petition.

§ 30.35 Financial assurance and recordkeeping for decommissioning.

(a) Each applicant for a specific license authorizing the possession and use of unsealed byproduct material of half-life greater than 120 days and in quantities exceeding 10^4 times the applicable quantities set forth in Appendix C to 10 CFR Part 20 shall submit a decommissioning funding plan as described in paragraph (a) of this section. The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 10^4 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each

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ATTACHMENT 3-3

10 CFR Chapter 1, Part 32, Sections 32.53-32.62, 32.72, 32.101-32.103

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to the intended user. If no transfers have been made to persons generally licensed under § 31.5 of this chapter during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter. The first report to be filed pursuant to this paragraph as revised and effective on January 15, 1975, shall cover the first calendar quarter in 1975. The report, if any, required for the fourth calendar quarter in 1974 shall be filed pursuant to the requirements of this paragraph in effect on January 4, 1975.

(b) Report to the responsible Agreement State agency all transfers of such devices to persons for use under a general license in an Agreement State's regulation equivalent to § 31.5 of this chapter. 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 device transferred, and the quantity and type of byproduct 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. If no transfers have been made to a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency upon request of the agency. The first report, if any, to be filed pursuant to this paragraph as revised and effective on January 15, 1975, shall cover the first calendar quarter in 1975.

(c) Keep records showing the name, address, and a point of contact for each general licensee to whom he directly or through an intermediate person transfers byproduct material in devices for use pursuant to the general license provided in § 31.5 of this chapter or equivalent regulations of an Agreement State. The records shall show the date of each transfer, the isotope and quantity of radioactivity in each device transferred, the identity of any intermediate person, and com-

pliance with the report requirements of this section.

The records required by this paragraph shall be maintained for a period of five years from the date of the recorded event.

§ 32.53 Luminous safety devices for use in aircraft: requirements for license to manufacture, assemble, repair or initially transfer.

An application for a specific license to manufacture, assemble, repair or initially transfer luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under § 31.7 of this chapter, will be approved if:

- (a) The applicant satisfies the general requirements specified in § 30.33 of this chapter;
- (b) The applicant submits sufficient information regarding each device pertinent to evaluation of the potential radiation exposure, including:
 - (1) Chemical and physical form and maximum quantity of tritium or promethium-147 in each device;
 - (2) Details of construction and design;
 - (3) Details of the method of binding or containing the tritium or promethium-147;
 - (4) Procedures for and results of prototype testing to demonstrate that the tritium or promethium-147 will not be released to the environment under the most severe conditions likely to be encountered in normal use;
 - (5) Any quality control procedures proposed as alternatives to those prescribed by § 32.55;
 - (6) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the device.

(c) Each device will contain no more than 10 curies of tritium or 300 millicuries of promethium-147. The levels of radiation from each device containing promethium-147 will not exceed 0.5 millirad per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber.

(d) The Commission determines that:

- (1) The method of incorporation and binding of the tritium or promethium-147 in the device is such that the tritium or promethium-147 will not be released under the most severe conditions which are likely to be encountered in normal use and handling of the device;
- (2) The tritium or promethium-147 is incorporated or enclosed so as to preclude direct physical contact by any person with it;
- (3) The device is so designed that it cannot easily be disassembled; and
- (4) The device has been subjected to and has satisfactorily passed the prototype tests prescribed by § 32.101, Schedule B.

§ 32.54 Same: labeling of devices.

(a) A person licensed under § 32.53 to manufacture, assemble, or initially transfer devices containing tritium or promethium-147 for distribution to persons generally licensed under § 31.7 of this chapter shall, except as provided in paragraph (b) of this section, affix to each device a label containing the radiation symbol prescribed by § 20.203(a) of this chapter, such other information as may be required by the Commission including disposal instructions when appropriate, and the following or a substantially similar statement which contains the information called for in the following statement:

The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____, containing _____ (identity and quantity of radioactive material) are subject to a general license or the equivalent and the regulations of the U.S. NRC or of a State with which the NRC has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION--RADIOACTIVE MATERIAL

(Name of manufacturer, assembler, or initial transferor)

¹ Devices licensed under section 32.53 prior to January 19, 1975, may bear labels authorized by the regulations in effect on January 1, 1975.

*The model, serial number, and name of manufacturer, assembler, or initial transferor may be omitted from this label provided they are elsewhere specified in labeling affixed to the device.

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(b) If the Commission determines that it is not feasible to affix a label to the device containing all the information called for in paragraph (a) of this section, it may waive the requirements of that paragraph and require in lieu thereof that:

(1) A label be affixed to the device identifying:

- (i) The manufacturer, assembler, or initial transferor; and
(ii) The type of radioactive material; and

(2) A leaflet bearing the following information be enclosed in or accompany the container in which the device is shipped:

- (i) The name of the manufacturer, assembler, or initial transferor.
(ii) The type and quantity of radioactive material,
(iii) The model number,
(iv) A statement that the receipt, possession, use, and transfer of the device are subject to a general license or the equivalent and the regulations of the U.S. NRC or of an Agreement State, and
(v) Such other information as may be required by the Commission, including disposal instructions when appropriate.

§ 32.55 Same: quality assurance; prohibition of transfer.

(a) Each person licensed under § 32.53 shall visually inspect each device and shall reject any which has an observable physical defect that could affect containment of the tritium or promethium-147.

(b) Each person licensed under § 32.53 shall take a random sample of the size required by the table in § 32.110 for Lot Tolerance Percent Defective of 5.0 percent from each inspection lot, and shall subject each unit in the sample to the following tests:

(1) Each device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of water entry. Absolute pressure of the air above the water shall then be reduced to 1 inch of mercury. Lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be

increased to normal atmospheric pressure. Any device which leaks as evidenced by bubbles emanating from within the device, or water entering the device, shall be considered as a defective unit.

(2) The immersion test water from the preceding test in paragraph (b) (1) of this section shall be measured for tritium or promethium-147 content by an apparatus that has been calibrated to measure tritium or promethium-147, as appropriate. If more than 0.1 percent of the original amount of tritium or promethium-147 in any device is found to have leaked into the immersion test water, the leaking device shall be considered as a defective unit.

(3) The levels of radiation from each device containing promethium-147 shall be measured. Any device which has a radiation level in excess of 0.5 millirad per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber, shall be considered as a defective unit.

(c) An application for a license or for amendment of a license may include a description of procedures proposed as alternatives to those prescribed by paragraph (b) of this section, and proposed criteria for acceptance under those procedures. The Commission will approve the proposed alternative procedures if the applicant demonstrates that:

- (1) They will consider defective any sampled device which has a leakage rate exceeding 0.1 percent of the original quantity of tritium or promethium-147 in any 24-hour period; and
(2) The operating characteristic curve or confidence interval estimate for the alternative procedures provides a Lot Tolerance Percent Defective of 5.0 percent at the consumer's risk of 0.10.

(d) No person licensed under § 32.53 shall transfer to persons generally licensed under § 31.7 of this chapter:

- (1) Any luminous safety device which has been tested and found defective under the criteria and procedures specified in this section, unless the defective units have been repaired or reworked and have then met the tests set out in paragraph (b) of this section; or
(2) Any inspection lot which has been rejected as a result of the procedure

in § 32.110 or alternative procedures in paragraph (c) of this section, unless the defective units have been sorted and removed or have been repaired or reworked and have then met the tests set out in paragraph (b) of this section.

§ 32.56 Same: material transfer reports.

Each person licensed under § 32.53 shall file an annual report with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with a copy to the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter, which shall state the total quantity of tritium or promethium-147 transferred to persons generally licensed under § 31.7 of this chapter. The report shall identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. Each report shall cover the year ending June 30 and shall be filed within thirty (30) days thereafter.

§ 32.57 Calibration or reference sources containing americium-241: requirements for license to manufacture or initially transfer.

An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241, for distribution to persons generally licensed under § 31.8 of this chapter, will be approved if:

- (a) The applicant satisfies the general requirements of § 30.33 of this chapter.
(b) The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:
(1) Chemical and physical form and maximum quantity of americium-241 in the source;
(2) Details of construction and design;
(3) Details of the method of incorporation and binding of the americium-241 in the source;
(4) Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie of americium-241, to demonstrate that the americium-241 contained in each source will not be released or be removed from the source under normal conditions of use.

43 FR 8115
33 FR 16330
FR 8185
FR 22120

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(5) Details of quality control procedures to be followed in manufacture of the source;

(6) Description of labeling to be affixed to the source or the storage container for the source;

(7) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the source.

(c) Each source will contain no more than 5 microcuries of americium-241.

(d) The Commission determines, with respect to any type of source containing more than 0.005 microcurie of americium-241, that:

(1) The method of incorporation and binding of the americium-241 in the source is such that the americium-241 will not be released or be removed from the source under normal conditions of use and handling of the source; and

(2) The source has been subjected to and has satisfactorily passed the prototype tests prescribed by § 32.102, Schedule C.

§ 32.58 Same: labeling of devices.

Each person licensed under § 32.57 shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:*

The receipt, possession, use and transfer of this source, Model _____ Serial No. _____ are subject to a general license and the regulations of the United States 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. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

(Name of manufacturer or initial transferor)

*Sources licensed under section 32.57 prior to January 19, 1975, may bear labels authorized by the regulations in effect on January 1, 1975.

§ 32.59 Same: leak testing of each source.

Each person licensed under § 32.57 shall perform a dry wipe test upon each source containing more than 0.1 microcurie of americium-241 prior to transferring the source to a general licensee under § 31.8 of this chapter. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the paper shall be measured by using radiation detection instrumentation capable of detecting 0.005 microcurie of americium-241. If any such test discloses more than 0.005 microcurie of radioactive material, the source shall be deemed to be leaking or losing americium-241 and shall not be transferred to a general licensee under § 31.8 of this chapter.

§ 32.60 [Revoked 42 FR 43965.]

§ 32.61 Ice detection devices containing strontium-90: requirements for license to manufacture or initially transfer.

An application for a specific license to manufacture or initially transfer ice detection devices containing strontium-90 for distribution to persons generally licensed under § 31.10 of this chapter will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

(b) The applicant submits sufficient information regarding each type of device pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of strontium-90 in the device;

(2) Details of construction and design of the source of radiation and its shielding;

(3) Radiation profile of a prototype device;

(4) Procedures for and results of prototype testing of devices to demonstrate that the strontium-90 contained in each device will not be released or be removed from the device under the most severe conditions likely to be encountered in normal handling and use;

(5) Details of quality control procedures to be followed in manufacture of the device;

(6) Description of labeling to be affixed to the device.

(7) Instructions for handling and installation of the device.

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

(c) Each device will contain no more than 50 microcuries of strontium-90 in an insoluble form.

(d) Each device will bear durable, legible labeling which includes the radiation caution symbol prescribed by § 20.203(a) of this chapter, a statement that the device contains strontium-90 and the quantity thereof, instructions for disposal and statements that the device may be possessed pursuant to a general license, that the manufacturer or civil authorities should be notified if the device is found, that removal of the labeling is prohibited and that disassembly and repair of the device may be performed only by a person holding a specific license to manufacture or service such devices.

(e) The Commission determines that:

(1) The method of incorporation and binding of the strontium-90 in the device is such that the strontium-90 will not be released from the device under the most severe conditions which are likely to be encountered in normal use and handling of the device;

(2) The strontium-90 is incorporated or enclosed so as to preclude direct physical contact by any individual with it and is shielded so that no individual will receive a radiation exposure to a major portion of his body in excess of 0.5 rem in a year under ordinary circumstances of use;

(3) The device is so designed that it cannot be easily disassembled;

(4) The device has been subjected to and has satisfactorily passed the prototype tests prescribed by § 32.103; and

(5) Quality control procedures have been established to satisfy the requirements of § 32.62.

§ 32.62 Same: quality assurance; prohibition of transfer.

[Introductory sentence deleted 43 FR 6915.]

(a) Each person licensed under § 32.61 shall visually inspect each device and shall reject any which has an observable physical defect that could affect containment of the strontium-90.

(b) Each person licensed under § 32.61 shall test each device for possible

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loss of strontium-90 or for contamination by wiping with filter paper an area of at least 100 square centimeters on the outside surface of the device, or by wiping the entire surface area if it is less than 100 square centimeters. The detection on the filter paper of more than 2,200 disintegrations per minute of radioactive material per 100 square centimeters of surface wiped shall be cause for rejection of the tested device.

(c) Each person licensed under § 32.61 shall take a random sample of the size required by the table in § 32.110 for Lot Tolerance Percent Defective of 5.0 percent from each inspection lot, and shall subject each unit in the sample to the following tests:

(1) Each device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of physical contact between the water and the strontium-90. Absolute pressure of the air above the water shall then be reduced to 1 inch of mercury. Lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any device which leaks, as evidenced by physical contact between the water and the strontium-90, shall be considered as a defective unit.

(2) The immersion test water from the preceding test in paragraph (c)(1) of this section shall be measured for radioactive material. If the amount of radioactive material in the immersion test water is greater than 0.1 percent of the original amount of strontium-90 in any device, the device shall be considered as a defective unit.

(d) An application for a license or for amendment of a license may include a description of procedures proposed as alternatives to those prescribed by paragraph (c) of this section, and proposed criteria for acceptance under those procedures. The Commission will approve the proposed alternative procedures if the applicant demonstrates that:

(1) They will consider defective any sampled device which has a leakage rate exceeding 0.1 percent of the original quantity of strontium-90 in any 24-hour period; and

(2) The operating characteristic curve or confidence interval estimate for the alternative procedures provides a Lot Tolerance Percent Defective of 5.0 percent at the consumer's risk of 0.10.

(e) No person licensed under § 32.61 shall transfer to persons generally licensed under § 31.10 of this chapter:

(1) Any device which has been tested and found defective under the criteria and procedures specified in this § 32.62 unless the defective units have been repaired or reworked and then met the tests set out in paragraph (c) of this section; or

(2) Any inspection lot which has been rejected as a result of the procedures in § 32.110 or alternative procedures in paragraph (d) of this section, unless the defective units have been sorted and removed or have been repaired or reworked and have then met the tests set out in paragraph (c) of this section.

§ 32.63 [Revoked 42 FR 43965.]

§ 32.70 [Removed] 51 FR 36932

~~§ 32.71 Manufacture and distribution of byproduct material for certain in vitro clinical or laboratory testing under general license.~~

~~An application for a specific license to manufacture or distribute byproduct material for use under the general license of § 31.11 of this chapter will be approved if:~~

~~(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter.~~

~~(b) The byproduct material is to be prepared for distribution in prepackaged units of:~~

~~(1) Iodine-125 in units not exceeding 10 microcuries each.~~

~~(2) Iodine-131 in units not exceeding 10 microcuries each.~~

~~(3) Carbon-14 in units not exceeding 10 microcuries each.~~

~~(4) Hydrogen-3 (tritium) in units not exceeding 50 microcuries each.~~

~~(5) Iron-59 in units not exceeding 20 microcuries each.~~

~~(6) Selenium-75 in units not exceeding 10 microcuries each.~~

~~(7) Mock Iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each.~~

~~(c) Each prepackaged unit bears a durable, clearly visible label.~~

~~(1) Identifying the radioactive contents as to chemical form and radio-nuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries of iodine-131, iodine-125, selenium-75, 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~~

~~(2) Displaying the radiation caution symbol described in § 20.203(a)(1) of this chapter and the words, "Caution, Radioactive Material", and "Not For Internal or External Use in Humans or Animals."~~

~~(d) The following statement, or a substantially similar statement which con-~~

32.71(d)

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contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, 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)

(e) 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 byproduct 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 § 20.301 of Part 20 of this chapter.

license issued by FDA, or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) accepted by FDA; or (ii) The manufacture and distribution of the radiopharmaceutical containing byproduct 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 byproduct material that 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 or the leaflet or brochure that accompanies each package, contains a statement that the U.S. Nuclear Regulatory Commission has approved distribution of the radiopharmaceutical to persons licensed to use byproduct material listed in §§ 35.100, 35.200 or 35.300, as appropriate, and to persons who hold an equivalent license issued by an Agreement State. However, labels worded in accordance with requirements that were in place on March 30, 1967 may be used until March 30, 1969.

(ii) The labels, leaflets or brochures required by this paragraph 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.

(b) If an application is filed pursuant to paragraph (a) of this section on or before October 15, 1974, for a license to manufacture and distribute a radiopharmaceutical that was distributed commercially on or before August 16, 1974, the applicant may continue the distribution of such radiopharmaceutical to group licensees until the Commission issues the license or notifies the applicant otherwise.

§ 32.73 Manufacture and distribution of generators or reagent kits for preparation of radiopharmaceuticals containing byproduct material.

(a) An application for a specific license to manufacture and distribute generators or reagent kits containing byproduct material for preparation of radiopharmaceuticals by persons licensed

pursuant to § 35.14 of this chapter for the uses listed in Group III of Schedule A. § 35.100 of this chapter will be approved if (See Note 1):

(1) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

(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 (NDA) approved by the Food and Drug Administration (FDA), a biologic product license issued by FDA, or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) accepted by 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 byproduct 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 distribution to persons licensed by the U.S. Nuclear Regulatory Commission to use byproduct material identified in § 35.200 or under an equivalent license of an Agreement State. However, labels worded in accordance with requirements that were in place on March 30, 1967 may be used until March 30, 1969.

The labels, leaflets or brochures required by this paragraph are in addition to the labeling required by FDA and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

§ 32.72 Manufacture and distribution of radiopharmaceuticals containing byproduct material for medical use under Part 35.

(a) An application for a specific license to manufacture and distribute radiopharmaceuticals containing byproduct material for use by persons authorized pursuant to Part 35 of this chapter will be approved if:

(1) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

(2) The applicant submits evidence that:

(i) The radiopharmaceutical containing byproduct 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), a biologic product

*Labels authorized by the regulations in effect on September 26, 1979, may be used until one year from September 27, 1979.

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(b) If an application is filed pursuant to paragraph (a) of this section on or before October 15, 1974, for a license to manufacture and distribute a generator or reagent kit that was distributed commercially on or before August 16, 1974, the applicant may continue the distribution of such generator or reagent kit until the Commission issues the license or notifies the applicant otherwise.

NOTE 1. Although the Commission does not regulate the manufacture and distribution of reagent kits that do not contain byproduct material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing byproduct material as part of its licensing and regulation of the users of byproduct material. Any manufacturer of reagent kits that do not contain byproduct material who desires to have his reagent kits approved by the Commission for use by persons licensed pursuant to § 35.14 and Group III of Schedule A, § 35.100 of this chapter may submit the pertinent information specified in this § 32.73.

§ 32.74 Manufacture and distribution of sources or devices containing byproduct material for medical use.

(a) An application for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed pursuant to Part 35 of this chapter for use as a calibration or reference source or for the uses listed in §§ 35.400 and 35.500 of this chapter will be approved if:

- (1) The applicant satisfies the general requirements in § 30.33 of this chapter;
- (2) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:
 - (i) The byproduct 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 byproduct 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;

(viii) Instructions 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;

(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 U.S. Nuclear Regulatory Commission has approved distribution of the (name of source or device) to persons licensed to use byproduct material identified in §§ 35.58, 35.400, or 35.500, as appropriate, and to persons who hold an equivalent license issued by an Agreement State. However, labels worded in accordance with requirements that were in place on March 30, 1967 may be used until March 30, 1969.

(b) (1) 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.

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

- (i) Primary containment (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;

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

(c) If an application is filed pursuant to paragraph (a) of this section on or before October 15, 1974, for a license to manufacture and distribute a source or device that was distributed commercially on or before August 16, 1974, the applicant may continue the distribution of such source or device to group licensees until the Commission issues the license or notifies the applicant otherwise.

§ 32.101 Schedule B—Prototype tests for luminous safety devices for use in aircraft.

An applicant for a license pursuant to § 32.53 shall conduct prototype tests on each of five prototype luminous safety devices for use in aircraft as follows:

(a) *Temperature-altitude test.* The device shall be placed in a test chamber as it would be used in service. A temperature-altitude condition schedule shall be followed as outlined in the following steps:

- Step 1. The internal temperature of the test chamber shall be reduced to -62° C. (-80° F.) and the device shall be maintained for at least 1 hour at this temperature at atmospheric pressure.
- Step 2. The internal temperature of the test chamber shall be raised to -54° C. (-65° F.) and maintained until the temperature of the device has stabilized at -54° C. at atmospheric pressure.
- Step 3. The atmospheric pressure of the chamber shall be reduced to 83 millimeters of mercury absolute pressure while the chamber temperature is maintained at -54° C.
- Step 4. The internal temperature of the chamber shall be raised to -10° C. (+14° F.) and maintained until the temperature of the device has stabilized at -10° C., and the internal pressure of the chamber shall then be adjusted to atmospheric pressure. The test chamber door shall then be opened in order that frost will form on the device, and shall remain open until the frost has melted but not long enough to allow the moisture to evaporate. The door shall then be closed.

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Step 5. The internal temperature of the chamber shall be raised to +85° C. (185° F.) at atmospheric pressure. The temperature of the device shall be stabilized at +85° C. and maintained for 2 hours. The device shall then be visually inspected to determine the extent of any deterioration.

Step 6. The chamber temperature shall be reduced to +71° C. (160° F.) at atmospheric pressure. The temperature of the device shall be stabilized at +71° C. for a period of 30 minutes.

Step 7. The chamber temperature shall be reduced to +55° C. (130° F.) at atmospheric pressure. The temperature of the device shall be stabilized at this temperature for a period of 4 hours.

Step 8. The internal temperature of the chamber shall be reduced to +30° C. (86° F.) and the pressure to 138 millimeters of mercury absolute pressure and stabilized. The device shall be maintained under these conditions for a period of 4 hours.

Step 9. The temperature of the test chamber shall be raised to +35° C. (95° F.) and the pressure reduced to 83 millimeters of mercury absolute pressure and stabilized. The device shall be maintained under these conditions for a period of 30 minutes.

Step 10. The internal pressure of the chamber shall be maintained at 83 millimeters of mercury absolute pressure and the temperature reduced to +20° C. (68° F.) and stabilized. The device shall be maintained under these conditions for a period of 4 hours.

(b) *Vibration tests.* This procedure applies to items of equipment (including vibration isolating assemblies) intended to be mounted directly on the structure of aircraft powered by reciprocating, turbo-jet, or turbo-propeller engines or to be mounted directly on gas-turbine engines. The device shall be mounted on an apparatus dynamically similar to the most severe conditions likely to be encountered in normal use. At the end of the test period, the device shall be inspected thoroughly for possible damage. Vibration tests shall be conducted under both resonant and cycling conditions according to the following Vibration Test Schedule (Table I):

VIBRATION TEST SCHEDULE

TABLE I

[Times shown refer to one axis of vibration]

Type	Vibration at room temperature	Vibration at 160° F. (71° C.)	Vibration at -65° F. (-54° C.)
Resonance ---	Minutes 60	Minutes 15	Minutes 15
Cycling -----	Minutes 60	Minutes 15	Minutes 15

(1) *Determination of resonance frequency.* Individual resonance frequency surveys shall be conducted by applying vibration to each device along each of any set of three mutually perpendicular axes and varying the frequency of applied vibration slowly through a range of frequencies from 5 cycles per second to 500 cycles per second with the double amplitude of the vibration not exceeding that shown in Figure 1 for the related frequency.

(2) *Resonance tests.* The device shall be vibrated at the determined resonance frequency for each axis of vibration for the periods and temperature conditions shown in Table I and with the applied double amplitude specified in Figure 1 for that resonance frequency. When more than one resonant frequency is encountered with vibration applied along any one axis, the test period may be accomplished at the most severe resonance or the period may be divided

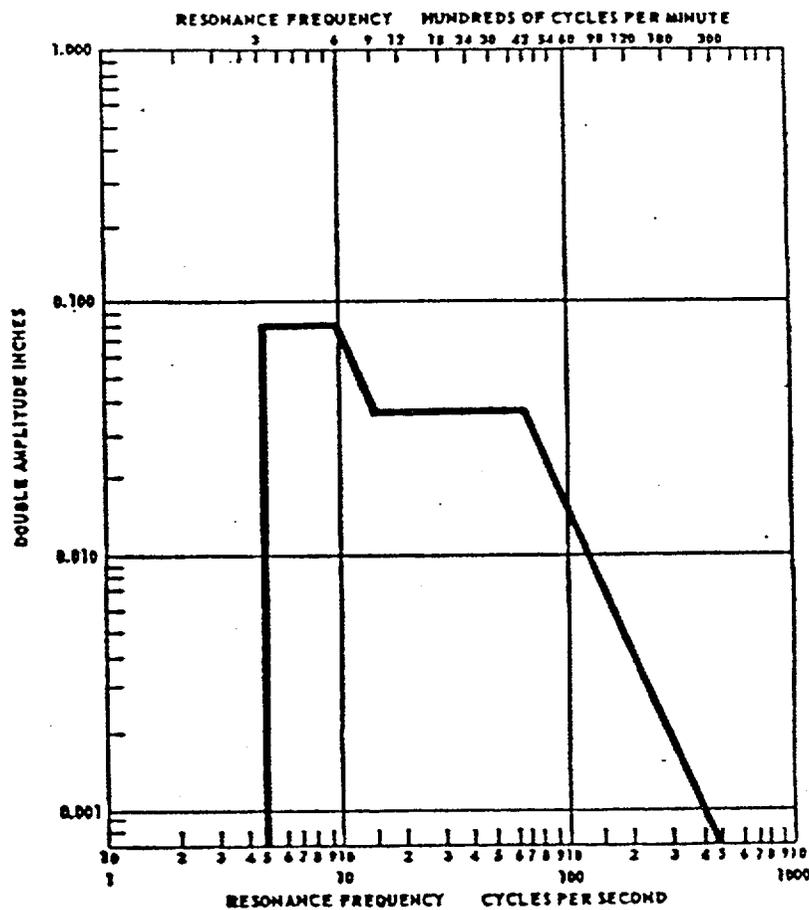


FIGURE 1—Amplitude of vibration at resonance frequency.

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among the resonant frequencies, whichever is considered most likely to produce failure. When resonant frequencies are not apparent within the specified frequency range, the specimen shall be vibrated for periods twice as long as those shown for resonance in Table I at a frequency of 55 cycles per second and an applied double amplitude of 0.060 inch.

(3) *Cycling.* Devices to be mounted only on vibration isolators shall be tested by applying vibration along each of three mutually perpendicular axes of the device with an applied double amplitude of 0.060 inch and the frequency cycling between 10 and 55 cycles per second in 1-minute cycles for the periods and temperature conditions shown in Table I. Devices to be installed in aircraft without vibration isolators shall be tested by applying vibration along each of three mutually perpendicular axes of the device with an applied double amplitude of 0.036 inch or an applied acceleration of 10G, whichever is the limiting value, and the frequency cycling between 10 and 500 cycles per second in 15-minute cycles for the periods and temperature conditions shown in Table I.

(c) *Accelerated weathering tests.* The device shall be subjected to 100 hours of accelerated weathering in a suitable weathering machine. Panels of Correx D glass shall surround the arc to cut off the ultraviolet radiation below a wavelength of 2,700 angstroms. The light of the carbon arcs shall fall directly on the face of the device. The temperature at the sample shall be maintained at 50° C. plus or minus 3° C. Temperature measurements shall be made with a black panel thermometer.

(d) *Shock test.* The device shall be dropped upon a concrete or iron surface in a 3-foot free gravitational fall, or shall be subjected to equivalent treatment in a test device simulating such a free fall. The drop test shall be repeated 100 times from random orientations.

(e) *Hermetic seal and waterproof test.* On completion of all other tests prescribed by this section, the device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of water entry. Absolute pressure of the air above the water shall then be reduced to 1 inch of mercury. Lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any evidence of bubbles

emanating from within the device, or water entering the device, shall be considered leakage.

(f) *Observations.* After each of the tests prescribed by this section, each device shall be examined for evidence of physical damage and for loss of tritium or promethium-147. Any evidence of damage to or failure of any device which could affect containment of the tritium or promethium-147 shall be cause for rejection of the design if the damage or failure is attributable to a design defect. Loss of tritium or promethium-147 from each tested device shall be measured by wiping with filter paper an area of at least 100 square centimeters on the outside surface on the device, or by wiping the entire surface area if it is less than 100 square centimeters. The amount of tritium or promethium-147 in the water used in the hermetic seal and waterproof test prescribed by test paragraph (e) of this section shall also be measured. Measurements shall be made in an apparatus calibrated to measure tritium or promethium-147, as appropriate. The detection on the filter paper of more than 2,200 disintegrations per minute of tritium or promethium-147 per 100 square centimeters of surface wiped or in the water of more than 0.1 percent of the original amount of tritium or promethium-147 in any device shall be cause for rejection of the tested device.

§ 32.102 Schedule C—Prototype tests for calibration or reference sources containing americium-241.

An applicant for a license pursuant to § 32.57 shall, for any type of source which is designed to contain more than 0.005 microcurie of americium-241, conduct prototype tests, in the order listed, on each of five prototypes of such source, which contains more than 0.005 microcurie of americium-241, as follows:

(a) *Initial measurement.* The quantity of radioactive material deposited on the source shall be measured by direct counting of the source.

(b) *Dry wipe test.* The entire radioactive surface of the source shall be wiped with filter paper with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper or by direct measurement of the radioactivity on the source following the dry wipe.

(c) *Wet wipe test.* The entire radioactive surface of the source shall be wiped

with filter paper, moistened with water, with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper after it has dried or by direct measurement of the radioactivity on the source following the wet wipe.

(d) *Water soak test.* The source shall be immersed in water at room temperature for a period of 24 consecutive hours. The source shall then be removed from the water. Removal of radioactive material from the source shall be determined by direct measurement of the radioactivity on the source after it has dried or by measuring the radioactivity in the residue obtained by evaporation of the water in which the source was immersed.

(e) *Dry wipe test.* On completion of the preceding tests in this section, the dry wipe test described in paragraph (b) of this section shall be repeated.

(f) *Observations.* Removal of more than 0.005 microcurie of radioactivity in any test prescribed by this section shall be cause for rejection of the source design. Results of prototype tests submitted to the Commission shall be given in terms of radioactivity in microcuries and percent of removal from the total amount of radioactive material deposited on the source.

§ 32.103 Schedule D—Prototype tests for ice detection devices containing strontium-90.

An applicant for a license pursuant to § 32.61 shall conduct prototype tests on each of five prototype ice detection devices as follows:

(a) *Temperature-altitude test.* The device shall be placed in a test chamber as it would be used in service. A temperature-altitude condition schedule shall be followed as outlined in Step 1 through Step 10 of § 32.101(a).

(b) *Vibration tests.* The device shall be subjected to vibration tests as set forth in § 32.101(b).

(c) *Shock test.* The device shall be subjected to shock test as set forth in § 32.101(d).

(d) *Hermetic seal and waterproof test.* On completion of all other tests prescribed by this section, the device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of physical contact between the water and the strontium-90. Absolute pressure of the air above the water shall then be

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reduced to 1 inch of mercury. Lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any visible evidence of physical contact between the water and the strontium-90 shall be considered leakage.

(e) Observations. After each of the tests prescribed by this section, each device shall be examined for evidence of physical damage and for loss of strontium-90. Any evidence of leakage or damage to or failure of any device which could affect containment of the strontium-90 shall be cause for rejection of the design if the damage or failure is attributable to a design defect. Loss of strontium-90 from each tested device shall be measured by wiping with filter paper an area of at least 100 square centimeters on the outside surface of the device, or by wiping the entire surface area if it is less than 100 square centimeters. The amount of strontium-90 in the water used in the hermetic seal and waterproof test prescribed in paragraph (d) of this section shall also be measured. The detection on the filter paper of more than 2,200 disintegrations per minute of strontium-90 per 100 square centimeters of surface wiped or in the water of more than 0.1 percent of the original amount of strontium-90 in any device, shall be cause for rejection of the tested device.

Table with columns: Lot size, Sample size, Acceptance No. Rows include lot sizes from 1 to 180 up to 50,001 to 100,000.

(2) Lot Tolerance Percent Defective 1.0 percent:

Table with columns: Lot size, Sample size, Acceptance No. Rows include lot sizes from 1 to 120 up to 10,001 to 100,000.

Subpart C—Acceptance Sampling Procedures

§ 32.110 Acceptance sampling procedures under certain specific licenses.

(a) A random sample shall be taken from each inspection lot of devices licensed under §§ 32.14, 32.53, or 32.61 for which testing is required pursuant to §§ 32.15, 32.55, or 32.62 in accordance with the appropriate Sampling Table in this section determined by the designated Lot Tolerance Percent Defective. If the number of defectives in the sample does not exceed the acceptance number in the appropriate Sampling Table in this section, the lot shall be accepted. If the number of defectives in the sample exceeds the acceptance number in the appropriate Sampling Table in this section, the entire inspection lot shall be rejected.

(b) Single sampling tables for Lot Tolerance Percent Defective

(1) Lot Tolerance Percent Defective 0.5 percent

(3) Lot Tolerance Percent Defective 2.0 percent:

Table with columns: Lot size, Sample size, Acceptance No. Rows include lot sizes from 1 to 75 up to 10,001 to 100,000.

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