

DIVISION 117

REGULATION AND LICENSING OF NATURALLY OCCURRING RADIOACTIVE MATERIALS (NORM)

333-117-0010 [PURPOSE]

This Division establishes radiation protection standards for the possession, use, transfer and disposal of naturally oc

333-117-0040 [EXEMPTIONS]

- (1) Persons who receive, possess, use, process, transfer, distribute and dispose of NORM are exempt from the requirements of these Rules if: The materials contain or are contaminated at concentrations 5 pCi/gm (185 Bq/kg) of radium, 0.05% by weight of uranium or thorium or 150 pCi/gm (5.55 kBq/kg) of any other NORM radionuclide, provided that these concentrations are not exceeded at any time.
- (2) Persons who receive products or materials containing NORM distributed in accordance with a specific license issued by the Agency pursuant to § [0220\(2\)](#) or an equivalent license issued by another Licensing State are exempt from these rules.
- (3) The manufacturing, distribution, use and disposal of the following products/materials are exempt from the requirements of these rules:
 - (a) Potassium and potassium compounds which have not been isotopically enriched in the radionuclide K^{40} ; and
 - (b) Brazil nuts.
- (4) The wholesale and retail distribution (including custom blending), possession and use of the following products/material are exempt from the requirements of these:
 - (a) Phosphate and potash fertilizer;
 - (b) Phosphogypsum for agricultural uses; and
 - (c) Materials used for building construction if such materials contain NORM which has not been technologically enhanced.
- (5) The possession and use of natural gas and natural gas products as a fuel are exempt from the requirements of these rules. The distribution of natural gas and the manufacturing and distribution of natural gas products are exempt from the specific license requirements of this Division but are subject to the general license requirements in §§ [0100](#) and [0130](#).

333-117-0050 [EFFECTIVE DATE]

The provision and requirements of this Division shall take effect January 1990 and shall apply to all facilities or sites owned or controlled by a person on that date. Products distributed and disposals made prior to that date are not subject to the provisions of this Division.

GENERAL LICENSE

333-117-0100 [GENERAL LICENSE]

- (1) A general license is hereby issued to mine, extract, receive, possess, own, use, process and dispose of NORM not exempted in § [0040](#) without regard to quantity. This general license does not authorize the manufacturing or distribution of products containing NORM in concentrations greater than those specified in § [0040\(1\)](#).

- (2) Facilities and equipment contaminated with NORM in excess of the levels set forth in TABLE 1 of this Division shall not be released for unrestricted use. The decontamination or maintenance of such equipment and facilities shall only be performed by persons specifically licensed by the Agency or another Licensing State to conduct such work. Each general licensee shall establish written procedures for the evaluation (or screening) of equipment and components to ensure that the levels in TABLE 1 of this Division are not exceeded.
- (3) No person shall transfer land for unrestricted use where the concentration of Ra²²⁶ or Ra²²⁸ in soil averaged over any 100 m² exceeds the background level by more than:
 - (a) Five pCi/gm, averaged over the first 15 cm of soil below the surface; and
 - (b) Fifteen pCi/gm, averaged over 15 cm thick layers of soil more than 15 cm below the surface.
- (4) Equipment contaminated with NORM in excess of the levels set forth in TABLE 1 of this Division may be released for maintenance and/or overhaul provided the recipient is specifically licensed to perform the activity on contaminated equipment. The decontamination or maintenance of equipment, facilities and land, as described in § [0200\(2\)](#) shall only be performed by persons specifically licensed by the Agency or another Licensing State to conduct such work.

333-117-0110 [PROTECTION OF WORKERS DURING OPERATIONS]

Each person subject to the general license in § [0100](#) shall conduct operations in compliance with the standards for radiation protection set out in divisions [111](#)² and [120](#),³ except for releases of radioactivity in effluents, which shall be governed by § [0120](#) and disposal, which shall be governed by § [0130](#).

333-117-0120 [PROTECTION OF THE GENERAL POPULATION FROM RELEASES OF RADIOACTIVITY]

Concentrations of radioactive material which may be released to the general environment in groundwater, surface water, air, soil, plants and animals shall not result in an annual dose above background exceeding an equivalent of 25 mrem (0.25 mSv) to the whole body or 75 mrem (0.75 mSv) to the critical organ of any member of the public. Doses due to Ra²²⁰, Ra²²² and their respective decay products, are excluded from these limits. Effort shall be made to maintain releases of radioactivity in effluents to the general environment as low as is reasonably achievable.

333-117-0130 [DISPOSAL AND TRANSFER OF WASTE FOR DISPOSAL]

Each person subject to the general license in § [0100](#) shall manage and dispose of wastes containing NORM in accordance with the applicable requirements of the U.S. Environmental Protection Agency for disposal of such wastes or in a manner equivalent to the requirements for uranium and thorium byproduct materials in [40 CFR 192](#) or shall transfer wastes for disposal to a land disposal facility licensed by the U.S. [Nuclear Regulatory Commission](#) or an Agreement State or a Licensing State. Records of disposal including manifests, shall be maintained pursuant to the

² Notices, instructions and reports to workers: inspections

³ Standards for protection against radiation

provisions of division [120](#).⁴ Transfers of waste containing NORM for disposal shall be made only to a person specifically licensed to receive such waste.

SPECIFIC LICENSE

333-117-0200 [SPECIFIC LICENSE]

- (1) Unless otherwise exempted under the provisions of division [102](#),⁵ the manufacturing and distribution of any material or product containing NORM shall be specifically licensed pursuant to the requirements of this Division or pursuant to equivalent regulations of another Licensing State.
- (2) Persons conducting the following activities involving equipment and facilities contaminated with NORM in excess of the levels set forth in TABLE 1 of this Division shall be specifically licensed pursuant to the requirements of this Division:
 - (a) Decontamination of equipment, facilities and land;
 - (b) Maintenance of equipment and facilities involving the exposure of individuals to radiation or radioactive materials; or
 - (c) Disposal of the resulting waste.

333-117-0210 [FILING APPLICATION FOR SPECIFIC LICENSES]

- (1) Applications for specific licenses shall be filed in a manner and on a form prescribed by the Agency.
- (2) 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) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.
- (4) An application for a license may include a request for a license authorizing one or more activities.
- (5) In an application, the applicant may incorporate by reference information contained in previous application, statements or reports filed with the Agency provided such references are clear and specific.
- (6) 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.

333-117-0220 [REQUIREMENTS FOR THE ISSUANCE OF SPECIFIC LICENSES]

- (1) A license application will be approved if the Agency determines that:
 - (a) The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these

⁴ Standards for protection against radiation

⁵ Licensing of radioactive material

- rules in such a manner as to minimize danger to public health and safety or property;
- (b) The applicant's proposed equipment, facilities and procedures are adequate to minimize danger to public health and safety or property;
 - (c) The issuance of the license will not be inimical to the health and safety of the public; and
 - (d) The applicant satisfies any applicable special requirement in this Division.
- (2) An application for a specific license to decontaminate or perform maintenance on equipment and facilities contaminated with NORM in excess of the levels set forth in TABLE 1 of this Division and to dispose of the resulting waste will be approved if:
- (a) The applicant satisfies the general requirements specified in § [0220\(1\)](#); and
 - (b) The applicant has adequately addressed the following items in the application:
 - (A) Procedures and equipment for protection of workers;
 - (B) An evaluation of the radiation levels and concentrations of contamination expected during normal operations;
 - (C) Operating and emergency procedures, including procedures for waste reduction and quality assurance of items released for unrestricted use; and
 - (D) Method of disposing of the radioactive material removed from contaminated equipment and facilities.
- (3) An application for a specific license to manufacture and/or initially transfer products or materials containing NORM to persons exempted from these rules pursuant to § [0040\(2\)](#) will be approved if:
- (a) The applicant satisfies the general requirements specified in § [0220\(1\)](#);
 - (b) The NORM is not contained in any food, beverage, cosmetic, drug or other commodity designed for ingestion or inhalation by or application to, a human being; and
 - (c) 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 NORM material or product to demonstrate that the material or product will meet the safety criteria set forth in § [0230](#). The information shall include:
 - (A) A description of the material or product and its intended use or uses;
 - (B) The type, quantity and concentration of NORM in each material or product;
 - (C) The chemical and physical form of the NORM in the material or product and changes in chemical and physical form that may occur during the useful life of the material or product;
 - (D) An analysis of the solubility in water and body fluids of the NORM in the material or product;

- (E) The details of manufacture and design of the material or product relating to containment and shielding of the NORM and other safety features under normal and severe conditions of handling, storage, use, reuse and disposal of the material or product;
 - (F) The degree of access of human beings to the material or product during normal handling, use and disposal;
 - (G) The total quantity of NORM expected to be distributed annually in the material or product;
 - (H) The expected useful life of the material or product;
 - (I) The proposed method of labeling or marking each unit of the material or product with identification of the manufacturer and/or initial transferor of the product and the radionuclide(s) and quantity of NORM in the material or product;
 - (J) Procedures for prototype testing of the material or product to demonstrate the effectiveness of the containment, shielding and other safety features under both normal and severe conditions of handling, storage, use, reuse and disposal;
 - (K) Results of the prototype testing of the material or product, including any change in the form of the NORM contained in it, the extent to which the NORM may be released to the environment, any change in radiation levels and any other changes in safety features;
 - (L) The estimated external radiation doses and dose commitments relevant to the safety criteria in § [0230](#) and the basis for such estimates;
 - (M) A determination that the probabilities with respect to doses referred to in § [0230](#) meet the criteria;
 - (N) Quality control procedures to be followed in the production of production lots of material or product and the quality control standards the material or product will be required to meet; and
 - (O) Any additional information, including experimental studies and tests, required by the Agency to facilitate a determination of the safety of the material or product.
- (4) Notwithstanding the provisions of § [0230\(2\)](#) the Agency may deny an application for a specific license if the end uses of the product are frivolous or cannot be reasonably foreseen.

333-117-0230 [SAFETY CRITERIA]

An applicant for a license under § [0220\(3\)](#) shall demonstrate that the product is designed and will be manufactured so that:

- (1) In normal use and disposal it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material, excluding radon and radon decay products, in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the material or product, will exceed the doses in COLUMN 1 OF TABLE 2.

- (2) In normal handling and storage of the quantities of the material or product likely to accumulate in one location during marketing, distribution, installation and servicing of the material or product it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material, excluding radon, in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the material or product, will exceed the doses in COLUMN 2 OF TABLE 2.
- (3) In normal use, disposal, handling and storage, it is unlikely that the radon released from the material or product will result in an average radon concentration in air of more than 0.4 pCi/l (14.8 Bq/m³).
- (4) It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding or other safety features of the material or product from wear and abuse likely to occur in normal handling and use of the material or product during its useful life.

333-117-0240 [ISSUANCE OF SPECIFIC LICENSES]

- (1) Upon a determination that an application meets the requirements of the Act and rules 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.
- (2) The Agency may incorporate in any license at the time of issuance or thereafter by amendment, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material subject to this Division as it deems appropriate or necessary in order to:
 - (a) Minimize danger to public health and safety or property;
 - (b) Require such reports and the keeping of such records and to provide for such inspections of activities under the license as may be appropriate or necessary; and
 - (c) Prevent loss or theft of material subject to this Division.

333-117-0250 [CONDITIONS OF LICENSES ISSUED UNDER § [0220](#)]

- (1) General Terms and Conditions:
 - (a) Each license issued pursuant to this Division 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;
 - (b) No license issued or granted under this Division and no right to possess or utilize radioactive material granted by any license issued pursuant to this Division 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;

- (c) Each person licensed by the Agency pursuant to this Division shall confine use and possession of the material licensed to the locations and purposes authorized in the license;
 - (d) Each person licensed by the Agency pursuant to this Division is subject to the general license provisions of §§ [0110](#), [0120](#) and [0130](#);
 - (e) 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 (11 U.S.C.) by or against:
 - (A) A licensee;
 - (B) An entity [as that term is defined in [11 U.S.C. 101\(14\)](#)] controlling a licensee or listing the license of licensee as property of the estate; or
 - (C) An affiliate [as that term is defined in [11 U.S.C. 101\(2\)](#)] of the licensee.
 - (f) The notification indicated in § [0250\(1\)\(e\)](#) must:
 - (A) Indicate the bankruptcy court in which the petition for bankruptcy was filed; and
 - (B) The date of the filing of the petition.
- (2) [QUALITY CONTROL, LABELING AND REPORTS OF TRANSFER] Each person licensed under § [0220\(2\)](#) shall:
- (a) Carry out adequate control procedures in the manufacture of the material or product to assure that each production lot meets the quality control standards approved by the Agency;
 - (b) Label or mark each unit so that the manufacturer, processor, producer or initial transferor of the material or product and the NORM in the material or product can be identified; and
 - (c) Maintain records identifying, by name and address, each person to whom NORM is transferred for use under § [0040\(2\)](#) or the equivalent regulations of another Licensing State and stating the kinds, quantities and uses of NORM 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 December 31, and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to § [0220\(2\)](#) during the reporting period, the report shall so indicate.

333-117-0260 [EXPIRATION AND TERMINATION OF LICENSES]

- (1) Except as provided in §§ [0270\(2\)](#) and [0260\(4\)\(c\)](#), each specific license shall expire at the end of the specified day in the month and year stated therein.
- (2) Each licensee shall notify the Agency immediately, in writing, and request termination of the license when the licensee decides to terminate all activities involving materials authorized under the license. This notification and request for termination of the license must include the reports and information specified in § [0260\(4\)\(d\)-\(f\)](#). The licensee is subject to the provisions of § [0260\(4\)-\(5\)](#), as applicable.

- (3) No less than 30 days before the expiration date specified in a specific license, the licensee shall either:
 - (a) Submit an application for license renewal under § [0270](#); or
 - (b) Notify the Agency in writing, under § [0260\(2\)](#), if the licensee decides to discontinue all activities involving NORM.
- (4) If a licensee does not submit an application for license renewal under § [0270](#), the licensee shall on or before the expiration date specified in the license:
 - (a) Terminate use of NORM;
 - (b) Remove radioactive contamination to the extent practicable;
 - (c) Properly dispose of NORM;
 - (d) Submit a record of disposal of radioactive material and radiation survey(s) to confirm the absence of NORM or to establish the levels of residual radioactive contamination, unless the licensee demonstrates the absence of residual radioactive contamination in some other manner. The licensee shall, as appropriate;
 - (e) Report levels of radiation in units of $\mu\text{rad/hr}$ of **E** and **J** radiation at 1 cm and **J** radiation at 1m from surfaces and report levels of radioactivity in units of dpm/cm^2 (or $\mu\text{Ci/cm}^2$) removable and fixed on surfaces, $\mu\text{Ci/ml}$ in water and pCi/gm in contaminated solids such as soils or concrete; and
 - (f) Specify the instruments(s) used and certify that each instrument is properly calibrated and tested.
- (5) If no radioactivity attributable to activities conducted under the license is detected, the licensee shall submit a certification that no detectable radioactive contamination was found. If the Agency determines that the information submitted under § [0260\(4\)\(d\)-\(f\)](#) is adequate and surveys confirm the findings, the Agency will notify the licensee in writing that the license is terminated.
- (6) If detectable levels of residual radioactivity attributable to activities conducted under the license are found, the license continues in effect beyond the expiration date, if necessary, with respect to possession of residual NORM until the Agency notifies the licensee in writing that the license is terminated. During this time, the licensee is subject to the provisions of § [0260\(5\)](#) and OAR [333-103-0010](#).⁶ In addition to the information submitted under § [0260\(4\)\(d\)-\(f\)](#), the licensee shall submit a plan, if appropriate, for decontaminating the location(s) and disposing of the residual NORM.
- (7) Each licensee who possesses residual radioactive material under § [0260\(4\)\(c\)](#) shall:
 - (a) Be limited to actions involving NORM related to preparing the location(s) for release for unrestricted use; and
 - (b) Continue to control entry to restricted areas until the location(s) are suitable for release for unrestricted use and the Agency notifies the licensee in writing that the license is terminated.

⁶ Annual fee for specific licenses

333-117-0270 [RENEWAL OF LICENSES]

- (1) Applications for renewal of specific licenses shall be filed in accordance with § [0210](#).
- (2) In any case in which a licensee, not less than 30 days prior to expiration of his existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until final action by the Agency.

333-117-0280 [AMENDMENT OF LICENSES AT REQUEST OF LICENSEE]

Applications for amendment of a license shall be filed in accordance with § [0210](#) and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

333-117-0290 [AGENCY ACTION ON APPLICATIONS TO RENEW AND AMEND]

In considering an application by a licensee to renew or amend the license, the Agency will apply the criteria set forth in § [0220](#).

333-117-0300 [MODIFICATION AND REVOCATION OF LICENSES]

- (1) The terms and conditions of all licenses shall be subject to amendment, revision or modification or the license may be suspended or revoked by reason of amendments to the Act or by reason of rules, regulations and orders issued by the Agency.
- (2) Any license may be revoked, suspended or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Act or because of conditions revealed by such application or statement of fact or any report, record or inspection or other means which would warrant the Agency to refuse to grant a license on an original application or for violation of, or failure to observe any of the terms and conditions of the Act or of the license or of any rule, regulation or order of the Agency.
- (3) Except in cases of willfulness or those in which the public health, interest or safety requires, otherwise, no license shall be modified, suspended or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

RECIPROCITY

333-117-0370 [RECIPROCAL RECOGNITION OF LICENSES]

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

- (1) The licensing document does not limit the activity authorized by such document to specified installations or locations.
- (2) The out-of-state licensee notifies the Agency in writing at least three days prior to engaging in such activity. Such notification shall indicate the location, period and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the three 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 engaged in activities under the general license provided in § [0370\(1\)](#).
- (3) The out-of-state licensee complies with all applicable rules 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 rules of the Agency.
- (4) The out-of-state licensee supplies such other information as the Agency may request.
- (5) The out-of-state licensee shall not transfer or dispose of NORM possessed or used under the general license provided in § [0370\(1\)](#) except by transfer to a person:
 - (a) Specifically licensed by the Agency or by another Licensing State to receive such material; or
 - (b) Exempt from the requirements for a license for such material under § [0040](#).