3701:1-43-10 General requirements for the issuance of specific licenses.

(A) An application for a specific license will be approved if:

(1) The application is for a purpose authorized by Chapter 3748. of the Revised Code and the rules adopted thereunder;

(2) The applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property or the environment;

(3) The applicant is qualified by training and experience to use the TENORM in question for the purpose requested in such manner as to protect health and minimize danger to life or property or the environment;

(4) The applicant satisfied all applicable special requirements in rule 3701:1-38-02, Chapter 3701:1-40, and Chapter 3701:1-43 of the Administrative Code;

(5) For an application that involves an activity that could potentially affect the quality of the environment, the director has:

(a) Reviewed the information filed and evaluations made pursuant to rule 3701:1-40-30 of the Administrative Code;

(b) Weighed the environmental, economic, technical, and other benefits against environmental costs and considered available alternatives; and

(c) Concluded that the proposed activity, along with any appropriate conditions to protect the environment, would be acceptable.

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.

(6) The applicant has met the financial assurance requirements of rule 3701:1-43-13 of the Administrative Code;

(7) The applicant has adequately addressed the following items in the application:

(a) Procedures and equipment for monitoring and protecting 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) A method for managing the radioactive material removed from contaminated equipment, facilities, and land.

(8) For each location to be listed on the license as an authorized use location, the applicant shall submit either:

(a) A statement that the applicant owns the facility where radioactive material is to be used or stored; or

(b) A statement verifying that the facility owner has been informed, in writing, of the use or storage of radioactive material at the facility, and that the use of such material is subject to the rules of the director.

(B) An application for a specific license to decontaminate equipment, land, or facilities contaminated with TENORM in excess of the levels set forth in rule 3701:1-43-15 of the Administrative Code, as applicable, and to dispose of the resulting waste will be approved if the applicant satisfies the general requirements specified in paragraph (A) of rule 3701:1-43-10 of the Administrative Code.

(C) An application for a specific license to transfer or manufacture or distribute consumer or retail products containing TENORM to persons exempted from these rules pursuant to paragraph (B) of rule 3701:1-43-07 of the Administrative Code will be approved if:

(1) The applicant satisfies the general requirements specified in paragraph (A) of rule 3701:1-43-10 of the Administrative Code;

(2) The TENORM 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

(3) 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 TENORM product to demonstrate that the product will meet the safety criteria set forth in rule 3701:1-43-11 of the Administrative Code. The information shall include:

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

(b) The type, quantity, and concentration of TENORM in each product;

(c) The chemical and physical form of the TENORM in the product and changes in chemical and physical form that may occur during the useful life of the product;

(d) An analysis of the solubility in water and body fluids of the radionuclides in the product;

(e) The details of manufacture and design of the product relating to containment and shielding of the TENORM and other safety features under normal and severe conditions of handling, storage, use, reuse, and disposal of the product;

(f) The degree of access of human beings to the TENORM product during normal handling, use, and disposal;

(g) The total quantity of TENORM expected to be distributed annually in the product;

(h) The expected useful life of the product;

(i) The proposed method of labeling or marking each unit of the product with identification of the manufacturer or initial transferor of the product and the radionuclides and quantity of TENORM in the product;

(j) The 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, reuse, and disposal;

(k) The results of the prototype testing of the product, including any change in the form of the TENORM contained in it, the extent to which the TENORM 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 committed dose equivalent relevant to the safety criteria in rule 3701:1-43-11 of the Administrative Code and the basis for such estimates;

(m) A determination that the probabilities with respect to doses referred to in rule 3701:1-43-11 of the Administrative Code meet the safety criteria;

(n) The quality control procedures to be followed in the processing of production lots of the product, and the quality control standards the product will be required to meet; and

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

(D) Notwithstanding the provisions of paragraph (B) of rule 3701:1-43-11 of the Administrative Code, the director may deny an application for a specific license if the end uses of the product are frivolous or cannot be reasonably foreseen.

(E) Upon a determination that an application meets the requirements of Chapter 3748. of the Revised Code and the rules adopted thereunder, the director will issue a specific license authorizing the possession and use of TENORM.

Five Year Review (FYR) Dates: 07/11/2017 and 07/01/2022

CERTIFIED ELECTRONICALLY

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Certification

07/11/2017

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Date

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