ENCLOSURE

Dynalec Corporation Application dated February 20, 2019
Request for Additional Information

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Dynalec Corporation application for exempt-distribution license renewal dated February 20, 2019, and has determined that additional information is needed. In order to continue with our review, please address the issues listed below.

The information related to review of your exempt distribution license application is required by Title 10 of the *Code of Federal Regulations*, Chapter 32 (10 CFR 32), Sections 32.26 through 32.29, and is described in the relevant guidance document NUREG-1556, Volume 8, Rev. 1, titled "Program-Specific Guidance about Exempt Distribution Licenses," available on the NRC public web site (https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v8/).

Please be advised that an application for an exempt distribution license should not contain: information concerning the possession of radioactive material because that is covered in your separate possession license; and personally identifiable information such as resumes and certificates of training. As stated in the accompanying letter, upon your request, proprietary information submitted to the NRC may be withheld from public disclosure. To do this, you must follow the procedures in 10 CFR 2.390(b) including requesting withholding at the time the information is submitted and complying with the document marking and affidavit requirements set forth in 10 CFR 2.390(b)(1).

Please provide the information required by each of the following regulations. Please clearly identify any document(s) that respond(s) to each of the requirements listed below. You may need to obtain some of this information from your supplier(s). Documents, or portions of documents, that are intended to satisfy any particular requirement should be in English, or should be accompanied by an English translation. Note that it is the applicant's responsibility to confirm the validity of all information. The regulations cited below are provided for completeness and clarity; they are not necessarily intended to imply that you omitted the required information.

1. Section 32.26(b)(1) requires a description of the product and its intended use or uses;

2. Section 32.26(b)(2) requires information concerning the type and quantity of byproduct material in each unit;

3. Section 32.26(b)(3) requires the applicant to submit information concerning the 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. Section 32.26(b)(4) requires the applicant to submit information concerning the solubility in water and body fluids of the forms of the byproduct material contained in the product.

5. Section 32.26(b)(5) requires the applicant to submit information concerning details of construction and design as related to containment and shielding and other safety features under normal and severe conditions of handling, storage, use, and disposal.

6. Section 32.26(b)(6) requires the applicant to submit information concerning maximum external radiation levels at 5 and 25 cm from external surface of product and the method of measurement.

7. Section 32.26(b)(7) requires the applicant to submit information concerning the degree of access to human beings during normal use.

8. Section 32.26(b)(8) requires the applicant to submit information concerning the total quantity of BPM expected to be distributed annually.

9. Section 32.26(b)(9) requires the applicant to submit information concerning the expected useful life of the product.

10. Section 32.26(b)(10) requires the applicant to submit information concerning the proposed method of labeling or marking the product and its point of sale package to satisfy the requirements of §32.29(b).

11. Section 32.26(b)(11) requires the applicant to submit information concerning the procedures for prototype testing (containment, shielding and other safety features) under both normal and severe conditions of handling, storage, use, and disposal of the product.

12. Section 32.26(b)(12) requires the applicant to submit information concerning the results of prototype testing including any change in form, extent of release to environment, increase in radiation levels and changes in safety features.

13. Sections 32.26(b)(13) and (14) require the applicant to provide a detailed evaluation which demonstrates that the product will meet the safety criteria of 10 CFR 32.27 and 32.28. These sections require that the applicant demonstrate that under normal conditions of handling, storage, use, and disposal, it is unlikely that the dose commitments for an exposed individual would exceed the values in 32.28.

    a. Section 32.26(b)(13) requires the estimated dose commitments relevant to the safety criteria in Section 32.27 and the basis for such estimates.

    b. Section 32.26(b)(14) requires a determination that the probabilities in Section 32.27(c) (related to scenarios such as bulk storage and fires) will not be exceeded with respect to the dose commitments referred to in Section 32.28, Column II. This is usually done using a methodology and scenarios similar to those found in Section 2, Exemptions for Byproduct Material, of NUREG-1717, “Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials.”

    Please provide an evaluation which demonstrates that the product will not exceed the probabilities in10 CFR 32.27(c) and will not exceed the dose commitments in 32.28, Column II.

14. Section 32.26(b)(15) requires the applicant to submit information concerning the Quality Control procedures followed in fabrication of production lots of product and Quality Control standards product must meet. Section 10.7, “Quality Assurance and Quality Control,” of NUREG-1556, Vol. 3, Rev. 2, states that an applicant must provide details of the QA program that will be implemented to ensure that the product is manufactured and distributed in accordance with the representations made in the application, and the statements contained in the registration certificate for the product.

15. Section 32.29(b) requires the applicant to submit the following information concerning product labeling:

    With regard to items “a” and “c”, below, please provide copies of the labels showing the required information.

    a. Each detector must contain a durable, legible, readily visible label or marking on the external surface of the detector containing:

        i. The statement "CONTAINS RADIOACTIVE MATERIAL"
        ii. Name and quantity of activity of BPM
        iii. Identification of the person licensed to transfer the product

    b. Describe how the label or marking is located where it will be readily visible when the detector is removed from its mounting.

    c. The external surface of the point-of-sale package has a legible, readily visible label or marking containing:

        i. Name and quantity of activity of BPM
        ii. Identification of the person licensed to transfer the product
        iii. The following or similar statement:

        THIS DETECTOR CONTAINS RADIOACTIVE MATERIAL AND HAS BEEN MANUFACTURED IN COMPLIANCE WITH U.S. NRC SAFETY CRITERIA IN 10 CFR 32.27. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS