**UNITED STATES**
**NUCLEAR REGULATORY COMMISSION**
**WASHINGTON, D.C. 20555-0001**

March 12, 2020

Mr. Steven Ellingson
Abbott Transfusion EHS Manager
Abbott Laboratories
Abbott Diagnostics Division
200 Abbott Park Road
Abbott Park, IL 60064

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. Ellingson:

This letter refers to your application dated February 24, 2020 for a new U.S. Nuclear Regulatory Commission (NRC) exempt-distribution license.

We do not have sufficient information to complete the review of your application. In order to continue our review, please address the issues listed in the enclosure to this letter. This information is required by Title 10 of the *Code of Federal Regulations* (10 CFR) Sections 32.18 through 32.19. To ensure that the documentation supporting your request is based on current and accurate information, you should respond to all of the regulatory requirements in the enclosure. You may provide previously submitted documents as long as they are current. These should be provided as attachments to your response to this letter.

Please note that an application for an exempt-distribution license should not contain information concerning the possession and use of radioactive material since that is covered in your separate possession license.

We will continue our review upon receipt of this information. If we do not receive your reply within 30 calendar days from the date of this letter, we will consider your application as having been abandoned by you. This action would be without prejudice to the resubmission of another application with the required information.

Please be aware that 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 Paragraph 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).

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Any correspondence regarding this application should reference control number 618178.

If you have any questions, please feel free to contact me at (301) 415-5477 or by electronic mail: Richard.Struckmeyer@nrc.gov.

Sincerely,

***/RA/***

Richard K. Struckmeyer
Materials Safety and Tribal Liaison Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Docket No. 030-39221

Enclosure: As stated

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

DATED: March 12, 2020

DISTRIBUTION: MSST r/f

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| **DATE** | 03/12/2020 | 03/12/2020 | 03/12/2020 |

**OFFICIAL RECORD COPY**

**Abbott Laboratories**
**Application dated February 24, 2020**
**Request for Additional Information**

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Abbott Laboratories application for an exempt-distribution license dated February 24, 2020, 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* (10 CFR), Part 32, Sections 32.18 through 32.19, 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 Paragraph 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 provide previously submitted documents as long as they are current. 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. 10 CFR 32.18(d) requires the applicant to submit copies of prototype labels and brochures, and that the Commission approve such labels and brochures, in order to demonstrate compliance with 10 CFR 32.19(c) and (d). Please provide copies of the labels on the immediate container of check sources, and the accompanying brochure, if any, that may be distributed along with the byproduct material.

2. 10 CFR 32.19(b) requires that each quantity of byproduct material set forth in Section 30.71, Schedule B of this chapter 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 Section 30.18 of this chapter. The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour. Although you paraphrased this requirement in your application, you did not explicitly describe how you would comply. Please describe how you shall meet the requirements of 10 CFR 32.19(b), including how the dose rate at the external surface of the package is determined.

3. 10 CFR 32.19(c) requires that the immediate container of each quantity or separately packaged fractional quantity of byproduct material shall bear a durable, legible label which (1) identifies the radioisotope and quantity of radioactivity, and (2) bears the words "Radioactive Material." Your application does not appear to provide a description of how this requirement will be met. Please describe and provide a sample or copy of the labels you plan to use in meeting this requirement. The description should include the factors that ensure the labels' durability, including the type of material used for the label and how it is attached.