

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

August 29, 2019

Mr. Timothy Stickler Radiation Safety Officer Federal Resources Supply Company Director of Critical Infrastructure Protection 235-G Log Canoe Circle Stevensville, MD 21666

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. Stickler:

This letter is in response to your application, U.S. Nuclear Regulatory Commission (NRC) Form 313, dated August 16, 2019, requesting a new Exempt Distribution License.

We do not have sufficient information to complete the review of your application. In the enclosure to this letter you will find the list of the questions and items not addressed in your application.

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 Title 10 of the *Code of Federal Regulations* (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).

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.

In accordance with 10 CFR Section 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.

Your application for a distribution license should not contain information concerning the possession and use of radioactive material because that is covered in a separate possession license.

Any correspondence regarding your amendment application should reference Mail Control Number 613950.

T. Stickler

If you have any questions, please contact me at (301) 415-5477, or email <u>Richard.Struckmeyer@nrc.gov</u>.

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. 030-39193 Mail Control No. 613950

Enclosure: Request for Additional Information

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

DATED: <u>August 29, 2019</u>

ADAMS Accession No.: ML19233A130 Pkg ML19241A379 Ltr.

OFFICE	MSST/MSTB	MSST/MSTB	MSST/MSTB
NAME	RStruckmeyer	TBrockington	RStruckmeyer
DATE	8/29/2019	8/22/2019	8/29/2019

OFFICIAL RECORD COPY

FEDERAL RESOURCES SUPPLY COMPANY APPLICATION DATED AUGUST 8, 2019 REQUEST FOR ADDITIONAL INFORMATION

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Federal Resources Supply Company application dated August 8, 2019 and determined that additional information is needed. In order to continue with our review, please address the issues listed below.

The information related to the review of your exempt-distribution license application is required by Title 10 of the Code of Federal Regulations (10 CFR) Sections 32.18 and 32.19 and is described in the relevant guidance document NUREG-1556, Volume 8, Rev. 1, "Program-Specific Guidance About Exempt Distribution Licenses," by responding to the following questions:

- Paragraph 32.18(a) of 10 CFR requires the applicant to satisfy the general requirements specified in 10 CFR 30.33. To do so, please provide a copy of your possession and use license from the state(s) in which possession will occur prior to initial distribution. Please note that an Exempt Distribution License will not be issued until we receive a copy of your possession and use license(s). If locations are in non-Agreement States, you may need to apply to the appropriate NRC regional office for possession license(s).
- 2) Paragraph 32.18(b) of 10 CFR requires the applicant to ensure that the byproduct 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. Please describe how you shall ensure that this requirement is met.
- 3) Paragraph 32.18(c) of 10 CFR requires the applicant to ensure that the byproduct 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. Please describe how you shall ensure that this requirement is met.
- 4) Paragraph 32.18(d) of 10 CFR requires the applicant to submit copies of prototype labels and brochures, and that the Commission approve such labels and brochures. Please provide copies of the labels to be used on these products, and the accompanying brochure, if any, that may be distributed along with the byproduct material.
- 5) Paragraph 32.19(a) of 10 CFR requires that no more than 10 exempt quantities set forth in Section 30.71, Schedule B of this chapter shall be sold or transferred in any single transaction. For purposes of this requirement, an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Section 30.71, Schedule B of this chapter, provided that the sum of such fractions shall not exceed unity. Please describe how you shall prevent the sale or transfer of more than 10 exempt quantities in any single transaction.
- 6) Paragraph 32.19(b) of 10 CFR 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. Please describe how you shall ensure that this requirement is met.

- 7) Paragraph 32.19(c) of 10 CFR 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 the quantity of radioactivity, and (2) bears the words "Radioactive Material." Please describe and provide samples or copies of the labels you plan to use in meeting this requirement.
- 8) Paragraph 32.19(d) 10 CFR requires, in addition to the labeling information required by paragraph (c) of this section, that the label affixed to the immediate container, or an accompanying brochure, shall also (1) state that the contents are exempt from NRC or Agreement State licensing requirements; (2) 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 (3) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material. Please describe and provide a sample or copy of the labels and/or brochures you plan to use in meeting this requirement.