

UNITED STATES NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

March 11, 2020

Mr. Brett Byers EHS Specialist/RSO DRS Training & Control Systems, LLC 645 Anchors Street Fort Walton Beach, FL 32548

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. Byers:

This letter refers to your license renewal application request dated January 15, 2020 for U.S. Nuclear Regulatory Commission (NRC) exempt-distribution license number 09-23977-01E.

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 32.26 through 32.29. To ensure that the documentation supporting a renewed license 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, including renewals, 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 renewal application should reference control number 618179.

B. Byers 2

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. 030-38022 License No. 09-23977-01E

Enclosure: As stated

B. Byers 3

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

DATED: <u>March 11, 2020</u>

DISTRIBUTION: MSST r/f

ADAMS Accession: ML20070T401 (Letter) ML20064C897 (pkg.)

<u> </u>			
OFC	NMSS/MSST/MSTB	NMSS/MSST/MSTB	NMSS/MSST/MSTB
NAME	R Struckmeyer	T Brockington	R Struckmeyer
DATE	03/11/2020	03/10/2020	03/11/2020

OFFICIAL RECORD COPY

DRS Training & Control Systems, LLC Application dated January 15, 2020 Request for Additional Information

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the DRS Training & Control Systems, LLC, application for exempt-distribution license renewal dated January 15, 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), 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 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. Paragraph 32.26(b)(1) requires a description of the product and its intended use or uses.
- 2. Paragraph 32.26(b)(2) requires information concerning the type and quantity of byproduct material in each unit.
- 3. Paragraph 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. Paragraph 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. Paragraph 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. Paragraph 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. Paragraph 32.26(b)(7) requires the applicant to submit information concerning the degree of access to human beings during normal use.
- 8. Paragraph 32.26(b)(8) requires the applicant to submit information concerning the total quantity of BPM expected to be distributed annually.
- 9. Paragraph 32.26(b)(9) requires the applicant to submit information concerning the expected useful life of the product.
- 10. Paragraph 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 10 CFR 32.29(b).
- 11. Paragraph 32.26(b)(11) requires the applicant to submit information concerning the <u>procedures</u> 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. Paragraph 32.26(b)(12) requires the applicant to submit information concerning the <u>results</u> of prototype testing including any change in form, extent of release to environment, increase in radiation levels and changes in safety features.
- 13. Paragraph 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 10 CFR 32.28.
 - a. Paragraph 32.26(b)(13) requires the estimated dose commitments relevant to the safety criteria in 10 CFR 32.27 and the basis for such estimates.
 - b. Paragraph 32.26(b)(14) requires a determination that the probabilities in 10 CFR 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 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 in 10 CFR 32.27(c) and will not exceed the dose commitments in 10 CFR 32.28, Column II.

14. Paragraph 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. Paragraph 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