



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

September 26, 2016

Mr. Thomas Kent, President
SEE Co.
5255 Edina Industrial Blvd.
Edina, MN 55439

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION, SEE CO. APPLICATION DATED
JULY 7, 2016

Dear Mr. Kent:

This letter is in response to your application dated July 7, 2016, for a new Sealed Source and Device Registration Certificate for the models GBa3.061.4, XBa3, XCd9, and XFe5 as a series. In reviewing your request, we find that additional information is required to complete our review. In the enclosure to this letter, we have summarized the issues not addressed in your application.

Please be aware that you may request that certain portions of your submittal to the NRC be withheld from public disclosure as proprietary information. To do this, you must execute an affidavit as specified in Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390. You must list all portions that you wish to be withheld as proprietary, along with your reasoning as to why that is appropriate.

Please submit the requested information within 30 calendar days of the date of this letter. If we have not received complete information within 30 days, we will consider your request as having been abandoned by you. This is without prejudice to the submission of a complete new request.

If you have any questions, please contact me at Lymari.Sepulveda@nrc.gov or at (301) 415-5619.

Sincerely,

/RA/

Lymari Sepulveda
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal,
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Request for Additional Information

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Enclosure:
Request for Additional Information

SSD Case: 16-29

Certified Mailing No. 7015 0640 0003 2910 1405

ADAMS Accession No.: ML16265A555

| OFC | NMSS/MSLB | NMSS/MSLB | NMSS/MSLB | NMSS/MSLB | NMSS/MSLB |
|------|------------|-----------|-----------|-----------|------------|
| NAME | LSepulveda | DMiller | THerrera | HGonzalez | LSepulveda |
| DATE | 9/26/2016 | 9/21/2016 | 9/26/2016 | 9/26/2016 | 9/26/2016 |

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SEE Co. Application dated July 7, 2016 Request for Additional Information

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the SEE Co. application dated July 7, 2016, and determined that additional information is needed. In order to continue with our review, please address the issues listed below. This information is required by Title 10 of the *Code of Federal Regulations* (10 CFR) 32.210 and described in the relevant guidance document NUREG-1556, Volume 3, Revision 1, titled, "Applications for Sealed Source and Device Evaluation and Registration."

General

1. Please indicate if the model XBa3.06 and GBa3.06(061.4) are part of a model series XBa3 series and GBa3 series respectively or individual models.
2. Your application requested the registration of the XCd9 series and the XFe5 series. Page 3 of your application indicates that each series of sources will include different models; the XCd9 series will include the XCd9.06, XCd.07, and XCd9.08 models and the XFe5 series will include the XFe5.21, XFe5.22, XFe5.23, and XFe5.24 models. Please explain the differences and similarities between each of the models in the series.

Description of the Product/Construction

3. Page 6 of your application includes "Table 3. Materials of Construction." The table lists the materials that will be used, but also includes the statement "or similar." Please explain what is meant by "or similar." If it is anticipated that different materials may be used in the construction of the sources, please explain why the prototype testing submitted will continue to be valid for different materials.

Labeling

4. In your application you indicated that the sources will be engraved with RITVERC logo which simulates the radiation symbol. Please note that, at a minimum, the trefoil symbol or the words "CAUTION-RADIOACTIVE MATERIAL" should be displayed on the label. While the stylized symbol is intended to simulate the trefoil, it may not be apparent that the logo is supposed to represent the trefoil symbol. Therefore, the proposed method of labeling will not be sufficient. Please confirm that the sources will be labeled with the trefoil symbol or the words "CAUTION-RADIOACTIVE MATERIAL" and confirm that the symbol or the words will be laser or mechanically engraved and stated in the application.

Prototype Testing

5. The prototype testing results provided in Appendix C indicate that only source capsules 06, 21, and 24 were tested. However, your application requests that source capsules 07, 08, 22, and 23 also be included in the registration certificate. Please provide the prototype test results for capsules for 07, 08, 22, and 23 or provide a justification as to why the prototype tests conducted on source capsules 06, 21, and 24 are also applicable to the source capsules 07, 08, 22, and 23.

Enclosure

Radiation Profiles

6. On page 10 of your application, you provided the radiation profiles for the sources you are seeking to register. If the radiation levels were measured, please identify the equipment that was used, including the type, window thickness, sensitivity, and calibration. If the radiation levels were calculated, please submit the calculations used to develop the radiation levels.