

Enclosure

Second Request for Information Needed for Amendment of
Exempt-Distribution License No. 32-23858-01E and
Sealed Source and Device Registration Certificate NR-1047-D-101-E

Questions in this enclosure are numbered to correspond to those in the enclosure to our Request for Additional Information (RAI) dated July 6, 2015. The original questions are presented in italics.

B. Questions concerning the information provided in your letter dated June 17, 2015.

1. You requested the addition of the following products to your license:

<u>Device Model</u>	<u>Maximum Quantity Per Device</u>
235 Series	1.00 microcurie (40.7 kBq)
305 Series	0.50 microcurie (20.4 kBq)
311 Series	0.77 microcurie (31.5 kBq)

Given that these products are characterized as "series," please explain how each series differs from the others, and describe the models of smoke detectors within each series, and how each model differs from the others within its series.

Follow up questions

You provided the following information on page 2 of your August 12, 2015, letter in reply to our RAI. Although not specifically identified as such, this information appears to be your answer to Question B.1:

"Only two models of Smoke Detectors will be distributed:
Series 200 chamber - Each unit contains 1.0 microcuries (37.0 kBq) of AM 241 per device
235 Series chamber- Each unit contains 0.14 microcuries (5.18 kBq) of AM 241 per device."

Your current license lists several additional models, namely 0905, 906, 908, 1225, and 1255. It is not clear whether these models are part of either of the 200 or 235 Series, nor is it clear whether you want to continue to distribute these models.

In addition, so as to eliminate any possible ambiguity, please restate the series and models that you intend to distribute, being careful not to use these terms interchangeably. Typically, models are considered to be a subset of series; however, if this is not how you specify your products, please explain the system by which your devices are organized.

2. You provided an attachment to your amendment request entitled "Evaluation of Safety Criteria per 32.27 10 CFR" (Appendix D) that is undated, but is accompanied by a letter dated July 18, 1991. Because of the apparent age of this report, please confirm that it is still valid with respect to the models of smoke detector that are authorized on your

current license, and indicate whether it applies to all detectors in the application, including those to be added. If it is applicable to models to be added, please explain why this information is valid.

Follow up question

It does not appear that you provided a response to this question in your letter dated August 12, 2015. Please indicate whether you intend to rely on the information in the above-referenced report, and if so, provide the requested information.

C. Questions concerning specific regulatory requirements

- 2) *Title 10, Code of Federal Regulations, Section 32.14(b)(1) requires that the applicant submit information regarding the chemical and physical form and maximum quantity of byproduct material in each product.*

In response to this requirement, your letter of June 17, 2015, stated: "See type 200 chamber evaluation report." This appears to be a reference to an attachment entitled "Evaluation of Ionization Chamber Design, Fyrnetics, Inc. Type 200," but you did not specify what information in that report is applicable with respect to this regulation. Please specify how the requirement of 10 CFR 32, Section 32.14(b)(1), will be met.

Follow up questions

You provided additional information in reply to this question in your letter dated August 12, 2015, but we do not see any indication as to whether you intend to reference the information in the document *"Evaluation of Ionization Chamber Design, Fyrnetics, Inc. Type 200."* Please clarify whether you intend to reference this report, and if so, provide the requested information.

As stated in the preceding paragraph, your letter dated August 12, 2015, contained additional information in reply to this question; however, some of this information appears to be outdated. For example, page 13 of your letter contains a "Certificate of Registration and Safety Analysis Summary" dated October 26, 1979, that lists a maximum activity of "up to 5 microcuries in 5 mm dia. disc." As another example, page 14 of your letter contains a reference to "radium sulphate" as a possible radioactive material that may be used in your products. Your amendment application requests authorization to distribute smoke detectors in accordance with the regulations in Title 10 of the Code of Federal Regulations, Chapter 32, Section 32.14 (10 CFR 32.14), which states: "An application for a specific license to apply byproduct material to, or to incorporate byproduct material into, the products specified in § 30.15 of this chapter or to initially transfer for sale or distribution such products containing byproduct material for use pursuant to § 30.15 of this chapter will be approved..." if the requirements of the ensuing subsections are met. Section 30.15(a)(7) specifies "ionization chamber smoke detectors containing not more than 1 microcurie (µCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires" as the only type of smoke detector that is authorized. Therefore, radionuclides other than americium-241, and quantities greater than 1 µCi cannot be approved for a license under 10 CFR 32.14.

Please review your response to this question and ensure that it contains current, relevant information that specifically addresses the requirements of the cited regulation. The use of older documents is acceptable only if they accurately describe your current program, including all products, methods, and commitments.

Subsequent pages (e.g., pages 17 – 20) appear to contain information relevant to the type of smoke detector specified in 10 CFR 30.15(a)(7); however, please clarify whether this information applies to all series and models of smoke detectors for which you are seeking authorization to distribute.

3) Title 10, Code of Federal Regulations, Section 32.14(b)(2) requires details of construction and design of each product.

Follow up questions

You provided information that was intended to address this requirement in your letter dated August 12, 2015; however, in our RAI of July 6, 2015, we stated (per the guidance in NUREG-1556, "Consolidated Guidance About Materials Licenses," Volume 8, "Program-Specific Guidance About Exempt Distribution Licenses") that applicants should provide detailed engineering drawings of each basic device in each series with a list of the differences between the models in that series. The drawings should clearly show all dimensions and tolerances, describe or identify the construction materials, and provide the details of the source mounting.

As noted above in Question B.1, it is not clear whether the models listed on your current license are part of the 200 or 235 Series, nor is it clear whether you want to continue to distribute these models. Furthermore, it is not clear whether the 200 and 235 series will be sold under multiple model names or numbers. In order to fully address the intent of this requirement, please indicate whether the 200 and 235 series will be sold under various model names or numbers, and if so, provide a list of the differences between the models in these series.

Furthermore, you provided information on pages 13 through 20 of your letter of August 12, 2015, in response to our RAI of July 6, 2015; however, you did not clearly explain how this information is relevant; for example, whether it is applicable to one series or both; whether it is applicable to all models within these series; and whether (as noted in Question C.2 above) all or just some of the documentation remains valid. Only currently valid information should be submitted.

Also, the drawings that you provided on pages 22, 23, 25, and 26 are partially illegible, and are unaccompanied by any explanatory text. Please provide legible copies of these or new drawings, including at least one for each series you plan to distribute, as well as sufficient description of each drawing to show how the requirements of 10 CFR 32.14(b)(2) will be met.

It is acceptable to include documents that were previously provided in support of your Sealed Source and Device registration certificate no. NR-1047-D-101-E for any series and models that are listed in it and that are included in this amendment request. You must also provide additional documents (including drawings) for any series and models that you are requesting to have added to your license. Please ensure that you provide sufficient documentation to describe the construction and design of each series of detector that you plan to distribute, and to describe the differences in the various models (if any) within each series.

- 4) *Title 10, Code of Federal Regulations, Section 32.14(b)(3) requires that the method of containment or binding of the radioactive byproduct material in the product be described.*

In response to this requirement, item 3 in your letter of June 17, 2015 provided information about the housings within the type 200 smoke detectors, including information that we interpret as the results of prototype testing. Prototype testing is not required for smoke detectors under 10 CFR 32.14. However, your letter contains information that appears to respond to the requirement of Section 32.14(b)(3), but this information was provided in item 2 in response to the requirement of Section 32.14(b)(2) rather than Section 32.14(b)(3). Item 2 stated "[t]he source is riveted into the source holder which is also riveted into the chamber insulator assembly. The same source and source holder are used in all Kidde ionization smoke alarms." Please state whether this information is applicable to the requirement of Section 32.14(b)(3), and provide any relevant additional information that describes the method of containment or binding of the byproduct material (i.e., the Am-241 source) within the housings.

Follow up question

Your letter dated August 12, 2015, provided a paragraph on page 26 of 44 that is apparently intended to respond to the requirement of 10 CFR 32.14(b)(3). However, this paragraph does not provide sufficient information, and you did not provide an answer to Question C.4. As indicated in the original question, "your letter [of June 17, 2015] contains information that appears to respond to the requirement of Section 32.14(b)(3), but this information was provided in item 2 in response to the requirement of Section 32.14(b)(2) rather than Section 32.14(b)(3)." In order to provide a complete response to the requirement of Section 32.14(b)(3), a possible approach would be to move some of the information you included in item 2 (i.e., in response to 32.14(b)(2)) to develop a more complete response to Section 32.14(b)(3).

- 6) *Title 10, Code of Federal Regulations, Section 32.14(b)(7) requires that the radiation level and the method of measurement for products for which limits on levels of radiation are specified in § 30.15; 10 CFR 30.15(a)(7) specifies such limits for ionization chamber smoke detectors (must contain no more than 1 microcurie (μCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires).*

Follow up question

Your letter of August 12, 2015, provided a method of measurement, but did not specify the radiation level that was measured. Please provide the result(s) of measurements taken with the specified measuring equipment.

Additional Information

With regard to the information concerning quality control procedures that was provided on pages 31 – 39 of your August 12, 2015, letter, please note that 10 CFR 32.15(a) is not applicable to smoke detectors authorized under 10 CFR 30.15(a)(7) because quality control procedures are required only for ionizing radiation measuring instruments and timepieces containing tritium in the form of paint, but not for smoke detectors, according to 10 CFR 32.14(a)(5).

However, in the case of these smoke detectors, section 32.15(b)(1) requires that the applicant / licensee commit not to transfer any part or product tested and found defective unless the defective part or product has been repaired or reworked, retested, and found by an independent inspector to meet the applicable acceptance criteria. (Note also that section 32.15(b)(2) refers back to 32.15(a)(2), and therefore is not applicable to these smoke detectors.)

Therefore, some of this information you provided in response to 10 CFR 32.15(a) may be applicable to meet the intent of 10 CFR 32.15(b)(1). Please provide appropriate information to satisfy the requirement of 10 CFR 32.15(b)(1).