

Enclosure

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

A. Items Regarding Registration Certificate

An active Sealed Source and Device Registration certificate is not required as part of your application to distribute your smoke detectors under 10 CFR 32.14 instead of 10 CFR 32.26. In order to inactivate your Registration Certificate NR-1047-D-101-E, please provide the following information:

- The total number of products sold under 10 CFR 32.26; the number of products still in use;
- Verification that no changes were made to the product since its initial registration or last amendment. If changes have been made, then the new information must be incorporated into the inactivated certificate.

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.

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.

C. Questions concerning specific regulatory requirements

Your application does not sufficiently address the requirements in Title 10 of the Code of Federal Regulations, Part 32, Section 32.14, “Certain items containing byproduct material; requirements for license to apply or initially transfer,” and Section 32.15, “Same: Quality assurance, prohibition of transfer, and labeling.”

- 1) Title 10, Code of Federal Regulations, Section 32.14(a) requires that the applicant satisfy the general requirements specified in § 30.33 of this chapter. The implication of this is that you must have a currently valid possession and use license from the State of North Carolina. Please provide a copy of this license.

- 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.

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

Your letter of June 17, 2015, stated: "The foil source used in the type 200 ion chamber is a laminated structure with the radioactive layer over plated with gold. See attached source information." Please clarify to which attachment you refer, and confirm that the information it contains accurately describes all smoke detectors in your application, including both those listed on the current license and those to be added to the license.

Your letter also stated: "The 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." NUREG-1556, "Consolidated Guidance About Materials Licenses," Volume 8, "Program-Specific Guidance About Exempt Distribution Licenses," states 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.

- 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.

- 5) Title 10, Code of Federal Regulations, Section 32.14(b)(6) requires a description of the proposed method of labeling or marking each unit and its container with the identification of the manufacturer or initial transferor and the byproduct material in the product.

Title 10, Code of Federal Regulations, Section 32.15(d)(2) further states: For ionization chamber smoke detectors, label or mark each detector and its point-of-sale package so that:

- (i) Each detector has a durable, legible, readily visible label or marking on the external surface of the detector containing:
 - (A) The following statement: "CONTAINS RADIOACTIVE MATERIAL";
 - (B) The name of the radionuclide ("americium-241" or "Am-241") and the quantity of activity; and
 - (C) An identification of the person licensed under § 32.14 to transfer the detector for use under § 30.15(a)(7) of this chapter or equivalent regulations of an Agreement State.
- (ii) The labeling or marking specified in paragraph (d)(2)(i) of this section is located where it will be readily visible when the detector is removed from its mounting.
- (iii) The external surface of the point-of-sale package has a legible, readily visible label or marking containing:
 - (A) The name of the radionuclide and quantity of activity;
 - (B) An identification of the person licensed under § 32.14 to transfer the detector for use under § 30.15(a)(7) or equivalent regulations of an Agreement State; and
 - (C) The following or a substantially similar statement: "THIS DETECTOR CONTAINS RADIOACTIVE MATERIAL. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS."

In response to these requirements, item number 5 of your letter of June 17, 2015, provided a partial description of the proposed method of labeling or marking the packaging (container) with the identification of the manufacturer or initial transferor and the byproduct material in the product; however, your letter did not appear to provide a complete description of the proposed method of labeling or marking each unit and its container with the identification of the manufacturer or initial transferor and the byproduct material in the product as required by Section 32.14(b)(6), nor did it appear to provide all of the information required by Section 32.15(d)(2). Please provide this information, or state where it can be found in your application.

- 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).

Your letter of June 17, 2015, in item number 4, misquoted the regulation in 10 CFR 32.14(b)(7) as it pertains to smoke detectors. Although you correctly quoted the first sentence ("The radiation level and method of measurement for each product for which limits on levels of radiation are specified in 10 CFR 30.15."), you continued: "10 CFR 30.15(a)(8) states that the levels of radiation from each electron tube containing byproduct material do not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber." Rather than 10 CFR 30.15(a)(8), the pertinent reference is 10 CFR 30.15(a)(7): "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."

In response to the requirement of Section 32.14(b)(7), you referred to the “Gerald D Rork Report.” This apparently is the “Evaluation of Safety Criteria per 32.27 10 CFR” (Appendix D), 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)(7), will be met.

- 7) Title 10, Code of Federal Regulations, Section 32.14(d) requires that the byproduct material is properly contained in the product under the most severe conditions that are likely to be encountered in normal use and handling.

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. Note: in the case of products for which prototype testing is not required, this requirement will be satisfied if sufficient information is provided about the details of the product submitted in accordance with 10 CFR 32.14(b)(1), (2), and (3). You may specify either the information from the referenced report that is applicable to this requirement, or refer to the responses to questions (C)(2), (C)(3), and (C)(4) above, or both.