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April 9, 2013

NUCLEAR REGULATORY COMMISSION
Attn: Richard K. Struckmeyer, Health Physicist
WASHINGTON, DC 20555 – 0001

Subject: REQUEST FOR ADDITIONAL INFORMATION - APPLICATION FOR EXEMPT DISTRIBUTION
LICENSE NO. 12-23809-01 E

Dear Mr. Struckmeyer:

This letter is a response to the NRC's letter dated March 12th, 2013. Each item from the NRC's letter is copied below with a response prepared by BRK Brands, Inc.

Item 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 Illinois.
Please provide a copy of this license.

BRK has a valid license to possess and use in Illinois. However, BRK does not distribute from Illinois. Distribution only takes place at BRK's facility in Texas under license L03725.

Item 2 - Title 10, Code of Federal Regulations, Section 32.14(b)(1) requires that the applicant submit information regarding the maximum quantity of byproduct material in each product. Please provide this information.

Each smoke alarm contains a maximum of 1 uCi (37 kBq) of Americium 241.

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

Every ionization smoke chamber is assembled as shown in drawing A1653XX. There are two types of "1000J" ionization chamber assemblies and the only difference is the outer chamber. The "1000J" ionization chamber is used in various smoke alarm models as detailed on drawing R12-30. Copies of drawing A1653XX and R12-30 included with this letter.

The ionization chamber is a tamper-resistant design. The chamber presents only two external surfaces: the outer active chamber and the printed circuit board. The outer chamber is soldered to the circuit board and can only be compromised through deliberate and determined physical attack.

The ionization chamber assembly cannot be disassembled to expose the radioactive source, and the radioactive source cannot be removed from its mounting under any normal or severe conditions of product handling, storage, use or disposal.



Item 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. Please provide the method of containment or binding of the radioactive byproduct material in the product.

The foil consists of Americium oxide uniformly distributed and sintered in a fine gold matrix. It is further contained between layers of gold, gold palladium alloy or palladium. The foil is mounted into a holder which is constructed of tin plated brass or stainless steel. The Americium source is then mounted into the 1000J ionization chamber mentioned in item 3.

Item 5 - Title 10, Code of Federal Regulations, Section 32.14(b)(4) requires procedures for and results of prototype testing to demonstrate that the byproduct material will not become detached from the product and that the byproduct material will not be released to the environment under the most severe conditions to be encountered in normal use of the product. Please provide these procedures and describe the prototype testing performed on the product.

The Americium source and the 1000J ionization chamber assemblies have been used for decades. The associated procedures and prototype test results are also from previous decades. Please clarify if procedures and prototype test results can be extracted from existing documentation. If not, due to the age of these documents, BRK requests an extension on item 5 to allow time for procedures to be updated and new test results generated.

Item 6 - Title 10, Code of Federal Regulations, Section 32.14(b)(5) requires that quality control procedures be followed in the fabrication of production lots of the product and a description of the quality standards the product will be required to meet. Please describe the quality control procedures to be followed in the fabrication of production lots of the product and provide a description of the quality standards the product will be required to meet.

All smoke alarms must meet the performance requirements described in ANSI/UL Standard 217, Single and Multiple Station Smoke Alarms. Every smoke alarm is factory adjusted to produce a smoke alarm signal when a sufficient amount of smoke is present. Every smoke alarm is electronically checked for function on the production line. Additionally, each alarm is marked with model number, company and date code for traceability.

Item 7 - 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. Please describe 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.

The nameplate and packaging of all ionization type smoke alarms are marked, "This smoke alarm contains a maximum of 1.0 microcuries of Americium 241, a radioactive material, distributed under U.S. NRC license 12-23809-01E and is made in compliance with U.S. NRC safety criteria in 10CFR32.27. The purchaser is exempt from any regulatory requirements." The outer packaging is marked UN2911 and shipped in limited quantities.

Item 8 - 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 not more than 1 microcurie (1-uCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires). Please provide this information.

The procedures in place at BRK's El Paso, TX facility require each shipment to be checked for visible damage. The radiation level of each shipment is monitored for contamination and required to be at background levels.



Item 9 - Title 10, Code of Federal Regulations, Section 32.14(c) requires that each product will contain no more than the quantity of byproduct material specified for that product in § 30.15 of this chapter. The levels of radiation from each product containing byproduct material will not exceed the limits specified for that product in § 30.15 of this chapter. Please specify that each product will contain no more than the quantity of byproduct material specified for that product in § 30.15 of this chapter, and that the levels of radiation from each product containing byproduct material will not exceed the limits specified for that product in § 30.15 of this chapter.

Each smoke alarm will contain no more than the quantity of byproduct material specified in § 30.15. In addition, the levels of radiation from each smoke alarm containing byproduct material will not exceed the limits specified in § 30.15.

Item 10 - 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. Please describe how 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.

The ionization chamber is a tamper-resistant design. The chamber presents only two external surfaces: the outer active chamber and the printed circuit board. The outer chamber is soldered to the circuit board and can only be compromised through deliberate and determined physical attack. Refer to drawing A1653XX.

Item 11 – Title 10, Code of Federal Regulations, Section 32.15(a){1} requires that each person licensed under § 32.14 shall maintain quality assurance practices in the manufacture of the part or product, or the installation of the part into the product. Please describe your quality assurance practices in the manufacture of the part or product, or the installation of the part into the product.

All smoke alarms must meet the performance requirements described in ANSI/UL Standard 217, Single and Multiple Station Smoke Alarms. Every smoke alarm is factory adjusted to produce a smoke alarm signal when a sufficient amount of smoke is present. Every smoke alarm is electronically checked for function on the production line. Additionally, each alarm is marked with model number, company and date code for traceability.

Item 12 – Title 10, Code of Federal Regulations, Section 32.15(a){3} requires that each person licensed under § 32.14 shall visually inspect each unit in inspection lots. Any unit that has an observable physical defect that could affect containment of the byproduct material shall be considered as a defective unit. Please describe how you shall visually inspect each unit in inspection lots for defects.

BRK requests a minor extension while these documents are being translated. The documents are expected to be available by April 19, 2013.

Item 13 – Title 10, Code of Federal Regulations, Section 32.15(c) requires that no person licensed under § 32.14 shall transfer to other persons for use under § 30.15 of this chapter or equivalent regulations of an Agreement State any defective part or product. Please describe how you shall prevent transfer to other persons for use under § 30.15 of this chapter or equivalent regulations of an Agreement State any defective part or product.

Possession and distribution of assembled smoke alarms, intended for sale to the end-user, is limited to BRK's Texas facility. The Texas facility is not open to the public and has restricted access. Assembled smoke alarms are shipped directly to retailers for sale to end-users.



Sincerely,

Mark H. Dippner
Compliance Engineer, RSO
First Alert/BRK Brands, Inc.
Aurora, IL 60504-8122

DRAWING NUMBER: **R12-30**FILE NAME: **R1230R.doc**

REVISION: R

PRODUCT: **DISTRIBUTORS AND MODEL NUMBERS OF SMOKE ALARMS USING 1000J CHAMBER ASSEMBLIES (SINGLE SOURCE-DUAL CHAMBER)**

DISTRIBUTORS AND MODEL NUMBERS OF SMOKE DETECTORS USING 1000J CHAMBER ASSEMBLIES (SINGLE-SOURCE-DUAL CHAMBER)

DISTRIBUTOR'S NAME AND ADDRESS	MODEL NUMBERS
BRK Brands, Inc. 3901 LIBERTY STREET ROAD AURORA, IL 60504	SA340 FG200, FG225, FG250 SA300, SA303, SA304 SC9120B 9120B, 9120 SA302 3120B, SA320

	70647		12/13/10	N/A	Add 3120B and SA320.	MD	R
	69215	MD	11/5/09	N/A	Revised names and models. Removed obsolete models.	MD	Q
	65792	VM	5/22/07	N/A	Revised addresses and models	DL	P
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N/A	THIS PRINT AND INFORMATION HEREIN ARE PROPRIETARY TO BRK BRANDS, INC., AND SHALL NOT BE USED IN WHOLE OR IN PART WITHOUT ITS WRITTEN CONSENT					BRK BRANDS, INC. 3901 LIBERTY STREET ROAD AURORA, ILLINOIS 60504-8122	
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DO NOT SCALE DRAWING SCALE: N/A	TITLE: DISTRIBUTORS AND MODEL NUMBERS OF SMOKE ALARMS USING 1000J CHAMBER ASSEMBLIES (SINGLE SOURCE-DUAL CHAMBER)					DRAWING NUMBER R12-30	SHEET 1-1 REV R