



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555 - 0001

March 12, 2013

BRK Brands, Inc.
ATTN: Mark H. Dippner
Radiation Safety Officer
3901 Liberty Street Road
Aurora, IL 60504

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

Dear Mr. Dippner:

This refers to your Application for Material License, NRC Form 313, dated December 17, 2012, and subsequent application dated February 27, 2013.

In an email dated February 4, 2013, you were informed that the Nuclear Regulatory Commission (NRC) revised its regulations in 2007 regarding distribution of smoke detectors. As stated in that email, these changes would apply to the smoke detectors you are authorized to distribute under your license. Section E of the final rule published in the Federal Register on October 16, 2007 (72 FR 58473), specially addressed smoke detectors. The entire final rule is available on the Federal Register's web site at: <http://edocket.access.gpo.gov/2007/pdf/E7-19944.pdf>. Please note that the final rule addressed more than just smoke detectors. An Addendum and Interim Staff Guidance dated November 2007, regarding the regulatory changes that was prepared to support NUREG-1556, Volume 8, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses," is available on NRC's web site at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v8/>.

This regulatory change provides a new licensing approach for smoke detectors containing no more than 1 microcurie of americium-241 in the form of a foil. As explained in the Federal Register Notice, smoke detectors which meet these criteria would no longer need to be licensed for distribution under 10 CFR 32.26, but instead could be authorized for distribution under 10 CFR 32.14. An important aspect of this change is that a sealed source and device (SSD) evaluation would not need to be conducted as part of the licensing process.

As your current license authorizes distribution of smoke detectors pursuant to 10 CFR 32.26 that would appear to meet the requirements and be acceptable for distribution under 10 CFR 32.14, it is possible to amend your license to make this change. Because the products covered under your current license may be subject to regulatory requirements that would not be applicable under 10 CFR 32.14, or because your current license may subject you to commitments that would no longer be necessary, you must submit a complete up-to-date application, without reference to any previously submitted information, addressing the applicable regulatory criteria specified in 10 CFR 32.14 and 10 CFR 30.15. As previously mentioned, the SSD certificate associated with your device(s) would no longer be necessary. Therefore, you should also request that the certificate be inactivated with issuance of the amended license.

This change will have impacts on your NRC fee obligations. Although we are requesting a complete, up-to-date application, because this license change is considered an amendment to your current license, it will not require a license application fee under Part 170. Your annual fee category would change in accordance with 10 CFR 171.16. You would no longer be subject to the annual fee for a sealed source device registration certificate. If you have any fee related questions, you may contact Brenda Brown at 301-415-6055, in the Accounts Receivable / Payable Branch, Division of the Controller, Chief Financial Officer.

In your application dated February 27, 2013, you indicated your intent to apply for a license pursuant to 10 CFR 32.14. However, you did not provide sufficient information to complete the review of your application according to the conditions described above. In order to continue our review we ask that you provide the following additional information:

- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.

- 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 (μCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires). Please provide this information.
- 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.
- 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.
- 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.
- 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.
- 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.

Our email of February 4, 2013, also addressed an issue concerning certain portions of your December 17, 2012, application that were marked as proprietary:

Please be aware that you may request that certain portions of your submittal to NRC be withheld from public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.390. You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate. While it is allowable, please refrain from submitting proprietary information in support of a license unless necessary. Keep in mind that all NRC licenses are considered to be in the public domain, and therefore may be viewed by any member of the public who requests to see them.

In order to request that NRC withhold information contained in an application from public disclosure, the applicant must submit the information and application, including an affidavit, in accordance with 10 CFR 2.390. The applicant should submit all of the following:

- A proprietary copy of the information. Brackets should be placed around the material considered to be proprietary. This copy should be marked as proprietary.
- A non-proprietary copy of the information. Applicants should white out or black out the proprietary portions (i.e., those in the brackets), leaving the non-proprietary portions intact. This copy should not be marked as proprietary.
- An affidavit that:
 - Is notarized.
 - Clearly identifies (such as by name or title and date) the document to be withheld.
 - Clearly identifies the position of the person executing the affidavit. This person must be an officer or upper-level management official who has been delegated the function of reviewing the information sought to be withheld and who has been authorized to apply for withholding on behalf of the company.
 - States that the company submitting the information is the owner of the information or is required, by agreement with the owner of the information, to treat the information as proprietary.
 - Provides a rational basis for holding the information in confidence.
 - Fully addresses the following issues:
 - Is the information submitted to and received by NRC in confidence? Provide details.
 - To the best of the applicant's knowledge, is the information currently available in public sources?
 - Does the applicant customarily treat this information, or this type of information, as confidential? Explain why.
 - Would public disclosure of the information be likely to cause substantial harm to the competitive position of the applicant: If so, explain why in detail. The explanation should include the value of the information to your company, the amount of effort or money expended in developing the information, and the ease or difficulty of others to acquire the information.

If you no longer consider your original renewal application of December 17, 2012, to be relevant, it may be possible to return it to you if you so request, and if you do not intend to reference any of the information contained therein with respect to your application pursuant to 10 CFR 32.14.

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.

In accordance with 10 CFR 2.390 of NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in NRC's Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC web site at <http://www.nrc.gov/NRC/ADAMS/index.html> (the Public Electronic Reading Room).

Any correspondence regarding your amendment application should reference the control number specified above.

If you have any questions, please feel free to contact me at (301) 415-5477 or electronic mail: richard.struckmeyer@nrc.gov.

Sincerely,

/RA/

Richard K. Struckmeyer, Health Physicist
Licensing Branch
Division of Materials Safety and
State Agreements
Office of Federal and State Materials and
Environmental Management Programs

Docket No. 030-38293
License No. 12-23809-01E

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Any correspondence regarding your amendment application should reference the control number specified above.

If you have any questions, please feel free to contact me at (301) 415-5477 or electronic mail: richard.struckmeyer@nrc.gov.

Sincerely,
/RA/
 Richard K. Struckmeyer, Health Physicist
 Licensing Branch
 Division of Materials Safety and
 State Agreements
 Office of Federal and State Materials and
 Environmental Management Programs

Docket No. 030-38293
 License No. 12-23809-01E

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