

February 15, 2005

J. Emile Robichaux, P.E., PhD.  
President  
Brandywood Corporation  
409 Alpaca Dr  
Arabi, LA 70032

SUBJECT: NOTIFICATION OF DISCONTINUATION OF EXEMPT DISTRIBUTION LICENSE  
REVIEW AND SAFETY EVALUATION FOR A SMOKE DETECTOR CONTAINING  
AMERICIUM-241

Dear Dr. Robichaux:

This letter is in response to your application, dated November 15, 2004, for the exempt distribution license review and device registration of a smoke detector containing Americium-241. Upon initial review of the application, we find that it is lacking information required to conduct a complete license review and safety evaluation. Enclosure 1 provides a list of information needed to complete your application, as well as references to the regulatory requirements and guidance material available. You may view and attain a copy of the regulations and guidance material through the Electronic Reading Room of our main website: [www.nrc.gov](http://www.nrc.gov).

Due to insufficient information noted above, the U.S. Nuclear Regulatory Commission (NRC) staff is unable to complete a license review and safety evaluation at this time. We have therefore discontinued the review of your application, without prejudice to its re-submission upon addressing the missing information discussed in the enclosure. If you have any questions, or would like to meet to further discuss required information, please contact Dr. John P. Jankovich at (301) 415-7904, or Jonathan Rivera at (301) 415-5810, of my staff.

You have also requested that the application be expedited. Enclosure 2 discusses the criteria used by NRC to determine if a review should be expedited. Please address the requirements under this criteria upon re-submittal of your application if you again request that the application be expedited.

Sincerely,  
**/RA/**

Timothy E. Harris, Section Chief  
Materials Safety and Inspection Branch  
Division of Industrial and  
Medical Nuclear Safety  
Office of Nuclear Material Safety  
and Safeguards

Enclosure:

1. Information Needed, Regulatory Requirements, and Guidance Material
2. Expedited Reviews Criteria

Docket No. 030-36745  
Mail Control No. 022463

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Distribution: IMNS r/f JWard      MMoriarty

**ML050280143**

\*See Previous Concurrence

OFC	NMSS	NMSS	NMSS	NMSS	NMSS
NAME	JRivera*	AKirkwood*	JJankovich	NAshkeboussi*	THarris
DATE	1/26/05	2/8/05	2/14/05	2/9/05	2/15/05

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## **INFORMATION NEEDED, REGULATORY REQUIREMENTS, AND GUIDANCE MATERIAL**

### Regulatory Requirements

- 1) Title 10 of the Code of Federal Regulations (10 CFR), Section 32.26, "Gas and aerosol detectors containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer," contains the requirements for the issuance of a license to distribute, to persons exempt from regulatory requirements, gas and aerosol detectors containing byproduct material that are designed to protect life or property from fires and airborne hazards. 10 CFR 30.20, "Gas and aerosol detectors containing byproduct material," states the exemption from licensing requirements for those who receive, possess, use, transfer, own, or acquire byproduct material, in gas and aerosol detectors that have been manufactured or initially transferred in accordance with a specific license issued under 10 CFR 32.26.
- 2) 10 CFR 32.27, "Same: Safety criteria," and 10 CFR 32.28, "Same: Table of organ doses," contains the requirements for the applicant to demonstrate that dose limits set forth in 10 CFR 32.28 for individuals exposed to the radiation from, or the radioactive material in, the product, would not be exceeded during normal conditions of use, disposal, handling, storage, marketing, distribution, installation, and servicing, as well as under failure of the product, and that it would be unlikely that there would be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product.
- 3) 10 CFR 32.29, "Conditions of licenses issued under 32.26: Quality control, labeling, and reports of transfer" contains the requirements for carrying out quality control procedures, labeling the product and its point of sale package, reporting product transfers, and maintaining records of product transfers.
- 4) 10 CFR 30.33 contains the general requirements for the issuance of a license.
- 5) 10 CFR 32.210, "Registration of product information," contains the requirements for the evaluation and registration of products containing sealed sources.

### Guidance Material

- 1) NUREG-1556, Vol. 8, "Program-Specific Guidance About Exempt Distribution Licenses," provides guidance in preparing an exempt distribution license application, as well as NRC criteria for evaluating an exempt distribution license application. Section 9.8 specifically talks about gas and aerosol detectors for licensing under 10 CFR 32.26.
- 2) NUREG-1556, Vol. 3, Rev. 1, "Applications for Sealed Source and Device Evaluation and Registration," provides guidance on the information needed for a

device evaluation and registration. Sections 4.2 and 10 provide specific details on information needed for the review.

- 3) NUREG/CR-1156, "Environmental Assessment of Ionization Chamber Smoke Detectors Containing Am-241," provides guidance on the impact smoke detectors, containing Americium-241, would have on the environment.
- 4) Regulatory Guide 6.9, "Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources and Devices Containing Byproduct Material," provides guidance on QA programs that are acceptable to the NRC staff.
- 5) The Exempt Distribution Licensee Toolkit is available at the following link through the NRC website:  
<http://www.nrc.gov/materials/miau/product-manufac/exempt-toolkit.html>.

Information needed to complete application dated November 15, 2004

- 6) A detailed description and/or drawing that demonstrates the method in which the Americium-241 source is mounted into the source holder, and subsequently into the ionization chamber. Include the material of construction of the source holder and ionization chamber, as well as any adhesives and/or screws used.
- 7) A detailed description and/or drawing that demonstrates the method in which the ionization chamber is mounted into the 5190-0190-09, Assembly, Thermal Ionization Detector, as reference on Page 2 of the letter accompanying your application, as well as in Ref. 4 of your application. Include the material of construction, any adhesives and/or screws used, and any tamper resistant features.
- 8) A description of the normal, as well as any severe, conditions of handling, storage, use, and disposal the smoke detector would be subjected.
- 9) A description of the likely environments to which the smoke detector would be subjected to during normal use and likely accident conditions.
- 10) The maximum external radiation levels at 5 and 25 centimeters from the smoke detector, in accordance with 10 CFR 32.26 (b) (6).
- 11) The degree of access of human beings into the smoke detector during normal handling and use.
- 12) The total quantity of byproduct material expected to be distributed annually.
- 13) The expected useful life of the smoke detector.

- 14) Procedures for and results of the prototype testing of the smoke detector to demonstrate compliance with the requirements under 10 CFR 32.26 (b) (11) and (12).
- 15) Clear pictures or drawings of the detector and point-of-sale package labels, that demonstrate compliance with the requirements under 10 CFR 32.29 (b). Include a description of the material construction of the labels, and methods of attachment to the detector and point-of-sale package.
- 16) Demonstration that the smoke detector is designed and will be manufactured so that, during normal conditions of use, disposal, handling, storage, marketing, distribution, installation, and servicing, as well as during failure of the containment, shielding, or other safety features of the smoke detector, doses to individuals would not exceed the limits set forth in 10 CFR 32.27 (a), 32.27 (c), and 32.28.
- 17) Demonstration that the smoke detector is designed and will be manufactured so that it is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features from normal wear and abuse, in accordance with 10 CFR 32.27 (b).
- 18) Confirmation of your understanding of the record maintenance and material transfer reporting requirements specified under 10 CFR 32.29 (c).

## **EXPEDITED REVIEWS CRITERIA**

### **NRC–Expedited Reviews on the Basis of National Security**

NRC will give an application high priority and expedite the review if the product or device is necessary for protecting national security. The following criteria should be met for a review to be expedited:

1. The request for expedited review is made by a U.S. Military or Federal Agency (e.g., U.S. Customs, federal law enforcement agencies) directly to the U.S. Nuclear Regulatory Commission (NRC).
2. The request is made in writing (e-mail is acceptable) by the appropriate agency official to the appropriate Section Chief or higher level management.
3. The requesting agency should state that national security is at stake and briefly, and in general terms, describe what the product will be used for. A detailed description, which could disclose sensitive information, is not necessary. NRC will expedite the review for security reasons, not for business reasons.
4. There is no alternative product, an alternative product would be too costly, or pursuit of an alternative product would result in significant setbacks to plans or schedules.
5. The requesting agency commits to providing the necessary oversight of the applicant to ensure that:
  - a. the application is of sufficient quality and provides the necessary information to support an expedited review, and
  - b. the applicant is responsive to NRC request for information.

In conducting the review, NRC reviewers should be able to conclude, with reasonable assurance, that regulatory requirements are met. However, the rigor of the review should be commensurate with the risk that the product poses to public health and safety. The reviewer should exercise engineering judgement.

### **NRC–Expedited Reviews for Reasons Other than National Security**

An application may be assigned a higher priority based on one of the following reasons. Requests for higher priority must include adequate justification as indicated. Any request must be made by the Company President or CEO, in writing to the appropriate NRC manager, and include the following information:

1. On the dire need for the product to protect public health and safety, the product providing a currently unavailable benefit to society. The applicant must provide details of the need, including (a) who directly benefits from the use of the product, (b) how they benefit and how existing products fail to provide that benefit, (c) why the review must be accomplished in less than the normal review time, and (d) when is it needed.

2. Commercial hardship that is likely to be experienced by the applicant if the evaluation process is delayed. The applicant must provide details of the hardship, including (a) who is affected by the hardship, (b) how they are affected (e.g., bankruptcy, layoffs), and why completion of the action is the only way to avoid that effect, (c) why the review must be accomplished in less than the normal review time, and (d) when it is needed.