

December 20, 1999

Mr. Steven Rakiec
Hemisphere Forwarding, Inc.
7 Cerro Street
Inwood, New York 11096.

Dear Mr. Rakiec

You requested via a facsimile, dated May 5, 1999, to include Smoke Detector Model SS 668 to your registration certificate number NR-1040-D-101-E. We find your information submitted to date lacking significant amounts of the required information for us to reach a decision. We have listed in the Enclosure to this letter the issues which were not fully addressed in your application. With incomplete documents and inadequate information we are not able to complete our evaluation. Therefore, we have discontinued our review of your request to add Model SS 668 to your registration certificate NR-1040-D-101-E.

Our discontinuance of the review is without prejudice to a re-submission of your application. If you decide to resubmit your application for registration, please ensure that you have included sufficient information to allow NRC to evaluate your device in a timely manner. Enclosure, is a summary of our major areas of concern that you need to address. A copy of NUREG-1556, Vol. 3 is enclosed which will assist you in the completion of your application.

If you have any questions, please call me on (301)415-7273 or Ujagar S. Bhachu of my staff at (301)415-7894.

Sincerely,

/s/

Frederick Sturz, Section Leader
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosures: As stated.

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Hemisphere Forwarding, Inc.

Enclosure

Hemisphere Forwarding Inc. requested in a facsimile, dated May 5, 1999, to include Smoke Detector Model SS 668 in registration certificate number NR-1040-D-101-E. Your request was based on the assertion of the manufacturer that the model SS668 is substantially similar in design to the models currently appearing on the registration certificate. The NRC's review of your request indicated that sufficient information was not available to continue the registration process. We presented our concerns to you by phone. We received additional information from you on September 09, 1999. We still find areas that are deficient. To complete the review and safety evaluation we need the following information or clarifications:

1. On September 09, 1999, Garvan Enterprises Associates Ltd., (Manufacturer) submitted the Underwriters Laboratories Inc. Report File number S4964, Project 91NK4560, dated December 19, 1991. Page 1 ILL 11 of this file makes a reference to a source Model AMMK1235 received from Amersham. We have no record that this sealed source has been previously approved and registered. Please submit to us a valid source registration number, or the necessary information as outlined in the NUREG 1556 Volume 3.
2. Please provide a set of mechanical and electrical diagrams that show the device safety-related features, overall dimensions, where the source is held in the device, how the source is secured in the device and the materials of construction for a registered model and the model to be added to the registry.
3. Please supply a description or illustration of the proposed labels or markings on the source, the device and the point of a sale package to satisfy the requirements of 10 CFR 32.29 (b).
4. Please provide the expected quantity of byproduct material to be distributed annually and expected useful life of the product.
5. We need the maximum external radiation levels at 5, 25, and 100 cm from any external surface of the product.
6. Please submit estimates of the external radiation doses and dose commitments to demonstrate that the Smoke Detector Model SS668 is designed and will be manufactured so that it meets the safety criteria in 10 CFR Section 32.27. These estimates must also include a discussion of the basis of such estimates.
7. Please provide details of procedures of prototype tests performed on the device to demonstrate the effectiveness of the containment and other safety features. If the integrity of the device to withstand normal and accident conditions was established through engineering analysis, please submit such analysis.

Hemisphere Forwarding, Inc.

8. The information submitted made no mention of the manufacturer's Quality Assurance and Quality Control programs to be used for, manufacture and USA receipt inspection. Please have the manufacture submit a copy of the manufacturer's Q/A and Q/C manual or a list of QA/QC procedures to be performed on the device and /or source.
9. Please ensure that the application for amendment of the registration certificate is signed by an authorized Officer of your corporation.
10. NUREG-1556 Vol. 3, Section10.1 requires that the applicant must include the name, complete mailing address, and function of all other companies involved in the manufacture and distribution of the product.