



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

August 15, 1995

Seatt Corporation
ATTN: Mr. Tom Barakat
Radiation Safety Officer
2820 Thatcher Road
Downers Grove, Illinois 60515-4040

Dear Mr. Barakat:

This is in reference to your application dated September 26, 1994, requesting renewal of NRC License No. 12-15537-02E.

In reviewing your request, I noted that your license references letters and applications dating back to 1975, and the information is often disjointed and confusing. Therefore, in order to create an up-to-date license file, a complete application concerning your current distribution activities and products must be submitted for review.

Please review your distribution program and previous application, and submit a complete application concerning your current distribution activities. This application will supersede all previously submitted information. Please note that it is appropriate to resubmit or reference previously submitted information as long as it pertains to your current distribution activities. Your application should only include information that pertains to the products you distribute.

During my review, it was also discovered that the models listed on your registration certificate differ from those authorized in your license. Please advise me of any models to be deleted, and verify all models that are currently being distributed.

Note: All basic models may be registered as a "series" based on such differences as size, construction, and source activity. For example, the Series 200 is larger in size than the basic Series 100, and the Series 300 has a larger source activity than either the 100 or 200.

Models contained within each series are the same basic model with "cosmetic" differences, such as lights and timers. For example, a basic model designated as the Series 100 is registered to include the 100A model with a three second timer, and the 100B with a five second timer.

As part of your submission, you should list all models that are part of a series and all models that differ in size, construction, and source activity as different basic models or series. Any models that are not listed on the

registration sheet (unless they are part of a series that has already been reviewed and registered) may require a device review. This review and amendment to your registration sheet would be for administrative purposes; therefore, no fee would be required for this review and amendment.

The product information to be submitted is outlined in Sections 32.26, 32.27, and 32.29 of 10 CFR Part 32. Your submission should include, but is not limited to, the following specific information:

1. Provide detailed engineering drawings of each smoke detection device model or series. The drawings should clearly show all dimensions and tolerances, describe or identify the construction materials, and provide the details of the source mounting. Also describe the differences between the different models, and include the varying activities.

Two or more models may be the same basic model with different model numbers for different distributors. In this case, submit only one set of drawings and indicate the different models concerned. If you plan to register any series, only one set of drawings is needed for each "basic" series with a list of the differences between the models in that series (e.g., light, whistle, etc.).

2. Confirm that you are still using Amersham and NRD foil sources. ✓
3. Pursuant to §32.26(b), provide details of construction, design, shielding, and safety features.
4. Paragraph 32.29(b) requires that each detector contain a legible, durable, and readily visible label on the external surface of the detector. The label must contain the statement: "CONTAINS RADIOACTIVE MATERIAL," name of byproduct material, quantity of activity, and identification of the person authorized under Section 32.26 to transfer the detector.

Provide an example of the label meeting the above criteria and indicate the location of the label on the device. It is not necessary to provide a label for each model of detector; one basic, generic example showing how you meet the regulations in Section 32.29 will be sufficient.

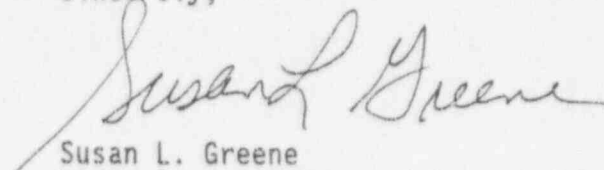
5. While it is not necessary that you provide a sample of the smoke detector(s), you should submit an example of the typical or generic point-of-sale package showing how you meet the requirements as listed in §32.29(b)(3).
6. Paragraph 32.26(b)(15) requires that the quality control procedures to be followed in the fabrication of the product, and the quality control standards the product will be required to meet, be submitted for review. Your QA/QC program should ensure that the devices have been manufactured and labelled in accordance with the information, drawings, and

specifications provided to the NRC; the detectors and their packages are free of radioactive contamination and the detectors are not leaking radioactive material. For your information and help in reviewing your QA/QC program, I have enclosed a copy of Regulatory Guide 6.9, "Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources and Devices Containing Byproduct Material," issued February 1995. This guidance provides the elements of a QA/QC program that have been deemed essential for an acceptable program. Specifically, Appendix C of this document contains the "QC Program Specifications for the Manufacture and Distribution of Smoke Detectors." You may follow these specifications or, if desired, you may submit an equivalent alternate program.

- ✓ Please describe your QA/QC program showing how it meets the requirements as outlined in the above document, "QC Program Specifications for the Manufacture and Distribution of Smoke Detectors."
7. Please confirm the points of distribution as 2820 Thatcher Road, Downers Grove, Illinois, and 28 Leigh Fisher Boulevard, Butterfield Trail Industrial Park, El Paso, Texas.
 8. Please provide a copy of your current State of Illinois and Texas possession licenses.

My review of your request will continue upon receipt of the above information. Please reply within 30 days, in duplicate, and reference Mail Control No. 021679. If you have any questions, please feel free to contact me at (301) 415-7843.

Sincerely,



Susan L. Greene
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Docket No. 030-11357

Enclosure: Regulatory Guide 6.9