

From: Seung Lee
To: Roger Mendez
Date: 05/14/2002 1:35:09 PM
Subject: Request for Additional Information

Good afternoon, Mr. Mendez!

This e-mail is in response to your submittal dated April 12, 2002, for amendment to registration certificate No. NR-0547-D-101-E to include 500B ion chamber series. We are in the process of evaluating your request. In order to continue our evaluation, we need additional information described below.

Please submit the requested information within thirty days of the date of this letter. If we have not received complete information within thirty days of the date of this letter, we will consider your application as having been abandoned by you. This is without prejudice to the resubmission of a complete application.

If you have any questions, please contact me at (301) 415-5787 or Dr. John Jankovich at (301) 415-7904.

1. Please provide the numerical values used in equation specified in Section IV, "Exposure Rate Calculations."
2. In Section III, "Prototype Testing and Evaluation," the application used Underwriters Laboratories Standard UL268, "Smoke Detectors for Fire Protective Signaling Systems," which did not perform the impact test as recommended in Nuclear Energy Agency standard "Recommendation for Ionization Chamber Smoke Detectors in Implementation of Radiation Protection Standards." Please provide the justification for not performing the impact test in your prototype testing.
3. In Section III, "Prototype Testing and Evaluation," the application stated that "Test described in this section are in addition to tests previously performed on the prototypes to verify compliance to the Underwriters Laboratories, Inc. (UL) standard..." Please provide the test results based on UL268 standard.
4. In Section III, "Prototype Testing and Evaluation," three tests of temperature, vibration, and drop are not comparable to those of Nuclear Energy Agency (NEA) standard "Recommendation for Ionization Chamber Smoke Detectors in Implementation of Radiation Protection Standards." Similarly, the prototype tests are not in compliance with ANSI N43.6-1997 which is usually used for prototype testing of smoke detectors for a Classification of 32222. Please provide information to describe how the results of tests, that you have performed, are comparable to the provisions of these standards. Specifically, please address how the requirements of the standards are satisfied regarding the four or five modes of testing, i.e., temperature, impact, drop, and vibration for NEA, or temperature, pressure, impact, vibration, and puncture for ANSI 43.6-1997, respectively. If you consider that some of the provisions of the standards are not applicable to your design, please provide your rationale.
5. In Section V, "Quality Assurance/Quality Control," the application stated that the receipt inspectors check the sources for critical dimensions to ensure that they conform to the drawing specifications. Please provide what the critical dimensions are.

6. In Subsection Radioactive Source Assembly in Section I, "Description of the Ionization Chamber," the application stated that "The foil is permanently assembled to the holder by the supplier." How can the receipt inspectors inspect the critical dimensions?
7. In Section V, "Quality Assurance/Quality Control," the application did not specify what measurements are performed prior to distribution. These measurements should be comparable to Appendix C to RG 6.9.
8. Please provide label information including contents, dimension, material, attachment, method of labeling, legibility for the working life for Model 200B and point-of-sale package complying with 10 CFR 32.29.
9. Engineering Drawings:
 - a. Drawing No. I87-008 is missing.
 - b. Drawing No. S23-024-000 did not specify dimensions and material information.
 - c. Drawing No. I56-1997-00 is in draft. Please provide complete and final version.
 - d. Drawing No. P87-247-02 specifies the activity of 0.7 microcurie. However, the maximum activity is 0.5 microcurie for Model 500B. Please clarify this discrepancy.
10. Please provide the location and address of the manufacturing facility.
11. Please clarify whether maintenance is required. Section III.4, "Maintenance Test," refers to cleaning once every two years. Exempt products do not require maintenance. If maintenance (blowing pressurized air for cleaning) is not a requirement, but a condition that you assumed for operation, please state so.

PS You can send your responses by e-mail if signature is included. Otherwise, send your responses through a private delivery carrier due to current problems with US Government mail delivery system to US NRC, Attn: Seung J. Lee, Two White Flint North, 11545 Rockville Pike, Rockville, MD 20852-2738.

CC: jpj2
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Subject: Request for Additional Information
Creation Date: 05/14/2002 1:35:09 PM
From: Seung Lee

Created By: SJL@nrc.gov

Recipients	Action	Date & Time
systemsensor.com Roger_Mendez (Roger Mendez)	Transferred	05/14/2002 1:35:22 PM
nrc.gov twf4_po.TWFN_DO	Delivered	05/14/2002 1:35:09 PM

JPJ2 CC (jpj2)

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6784

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Options

Auto Delete: No
Expiration Date: None
Notify Recipients: Yes
Priority: Standard
Reply Requested: No
Return Notification: None

Concealed Subject: No
Security: Standard

To Be Delivered: Immediate
Status Tracking: Delivered & Opened