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

February 9, 1995

Mr. Scott N. Markwell
Sleepsafe Corporation
2121 Electric Road
Roanoke, Virginia 24018

Dear Mr. Markwell:

This letter is in response to your application dated July 28, 1994, requesting a device evaluation and the registration of an exempt "E" distribution license for the 500S and 200P series smoke detectors. We are in the process of evaluating the information submitted in your report, "Application for Device Review." However, we need the following additional information and clarification to complete our evaluation:

1. Demonstration that the quality control (QC) program implemented by your manufacture contractor(s) meets the requirements of 10 CFR 32.26(b)(15) and as further discussed in Appendix C of Draft Regulatory Guide DG-6002. Please discuss Sleepsafe's quality assurance (QA) program to ensure that activities performed by other companies as discussed in Section 3.1.5 of the Application for Device Review (ADR) will meet your quality standard. Please also send in the QC procedure manual as stated in page 13 the ADR. The procedure manual should also denote the sample size and its justification for meeting the "SSSS" position on quality control. Copies of selected regulations and the draft Regulatory Guide are enclosed.

2. Results of prototype testing done on the detector. Please provide results of prototype testing of the detector, including drop tests, as stated in pages 7 and 12 of the ADR These tests must be performed, in accordance with 10 CFR 32.26(b)(11) and (12), to demonstrate the effectiveness of the construction and design of the containment, shielding, and other safety features of the detector.

3. Design and construction of the ionization chamber to deny human access to the sealed source. Paragraph 32.26(b)(7) of 10 CFR Part 32 requires the applicant to address the degree of access of human beings to the product during normal handling and use. In Fig. 1 of the ADR, please clarify how will the screw hold together the ionization chamber, the PCB, and the source cup. Also please explain how and where soldering will be applied to deny human access to the sealed source through non-destructive means. An enhanced version of Fig. 1 or equivalent will be useful.

4. Analysis to meet radiation safety criteria of 10 CFR 32.27. Section 3.3.6, "Radiation Profiles," of the ADR provides estimates of external doses and dose commitments under various scenarios. We assume that you used the information contained in NUREG/CR-1775 and NUREG/CR-1156 to arrive at the numbers to calculate doses. If this is not the case, please so indicate and provide basis for these numbers.

Please provide the requested information as soon as possible. If you have any questions, please contact me at (301) 415-5579 or Mr. Steven Baggett at (301) 415-7273.

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Sincerely,

Original Signed by

David T. Tang, Mechanical Engineer
Sealed Source Safety Section
Source Containment and Devices Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosures:
(1) Regulatory Guide 10.10
(2) Selected regulations
(3) Draft Regulatory Guide DG-6002

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