



*Stayed just a  
bb call*

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

Mr. Scott N. Markwell  
SafeNight Technology Inc.  
2121 Electric Road SW  
Roanoke, VA 24018

Dear Mr. Markwell:

This letter is in reference to our May 2, 1996, telephone conversation. As we discussed, we are in the process of re-evaluating your request. However, in order to continue our evaluation, the following information or clarification is necessary:

General issues

- ✓1. Please verify that you are using the AMM1001H source holder as registered by Amersham.
- ✓2. What is initial distribution point for the finished detectors?

Prototype testing

- ✓3. You state that after the drop and impact tests, "no removable contamination was observed above background levels and did not exceed 0.005 uCi". Are you referring to the dose rates around the ion chamber ("above background") or to removable contamination?
- ✓4. In addition, the prototype tests should demonstrate source containment integrity over normal use conditions. Your drop test results indicate that you chose to perform seven drops, and that the ion chamber cover came off on drop number four. This seems to indicate that the ion chambers did not pass the drop test. You stated that the tests were performed from a height that you did not believe would be encountered in typical usage, and that you intend to re-perform the drop tests on the detector to better demonstrate the integrity of the detector under the actual use conditions. Please submit procedures and results for this re-testing and provide support for your decision to disregard the original tests in favor of the new tests.

Design

- 7
- ✓5. There are several apparent contradictions in the drawings and descriptions submitted. For example, the ion chamber cover is described as steel/tin in section 3.2.1 of your application and is described as steel/tin or steel/copper or steel/nickel on one of the drawings. Another example is that the Homewatch source holder is listed as nickel plated copper in one place and nickel plated brass on one of the drawings. There were also discrepancies in the dimensions listed. For example, section 3.3.2 4(a) states that the diameter of the housing is

5+/-2 inches, which results in a range of 3-7 inches. In contrast, the drawing of the PCB layout lists the larger dimension of the PCB as 5+/-1 inches, which results in range of 4-6 inches. This range does not allow for a circuit board that would fit in the smallest requested diameter of the housing. Another example is section 3.3.2 states that the height of the cover is 2+/-1 inches, which results in a range of 1-3 inches. Based on measurements submitted for the ion chamber, the apparent height of the ion chamber is 1.01 inches, which would not fit into the smallest requested cover height. In view of these and other apparent discrepancies, please review the information your drawings and descriptions, and resubmit corrected information as necessary.

6. Please verify that you will remove the word "and" on your smoke detector label.

Quality Assurance/Quality Control

7. Please specify what drawing will be used in #9(b) of "II Finsihed Goods Testing".
8. In question #24(g) in the "SafeNight On-Site Test Location Audit" checklist, please verify that the 5% indicated is inteded to be a sample from modified LTPD 5% tables. Please verify that all references to LTPD 5% are intended to be to the modified LTPD 5% tables, where the acceptance number is equal to zero. *NOT DONE but OK*
9. The guidance in Regulatory Guide 6.9 states that all failed units must pass the test criterion before release. The procedures described in section 9) Nonconforming Material seem to contradict this. Please describe how your procedures meets the guidance.

Please provide the requested information as soon as possible. If you have any questions, please contact me at (301) 415-5868 or Mr. Douglas Broaddus at (301) 415-5847.

Sincerely,

*Michele L. Burgess*

Michele L. Burgess, 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

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Michele L. Burgess, Mechanical Engineer  
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Source Containment and  
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