

SAFENIGHT TECHNOLOGY INC.

"the safer smoke detector network"

2121 Electric Road SW
Roanoke, Virginia 24018
(703) 989-5738

January 31, 1996

Ms. Michelle Burgess, Mechanical Engineer
United States Nuclear Regulatory Commission
#2 Wide Flint North
11555 Rockville Pike T-8f5
Rockville, MD 20852

Re: Response to January 23rd letter

Dear Michelle:

In response to your letter:

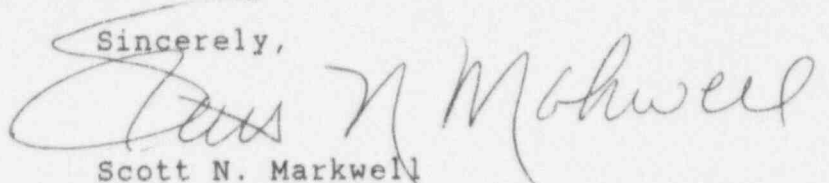
- 1) The referenced screw does penetrate the source support and not the source holder
- 2) Method "A" is the only method submitted. There is no other method with this submission.
- 3) Ion chamber label - attached is a scaled sample. The label in use may have either square or rounded corners or different font type text.

Point-of-purchasing markings - attached is one possible marketing scenario. While everything else on the package is subject to marketing revision, the NRC verbiage there will remain the same size.

- 4) Please replace the old section 12 "Audits" with the one attached.
- 5) Ditto #4
- 6) A copy of all testing and inspection and audit forms and records will be maintained at SafeNight Corporate. These will be on file within 7-10 working days from there occurrence.

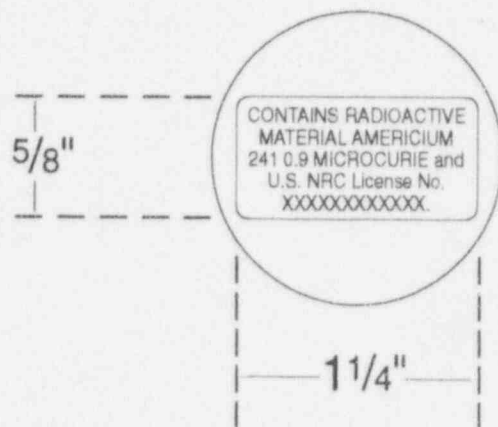
Also enclosed is a copy of a new "Form 3" to replace the old "Form 3". I hope this covers most everything. I am sure I will talk to you soon.

Sincerely,



Scott N. Markwell
President

SNM/ct



SafeNight™

SafeNight™

All alarm together as a system
when any SafeNight Detector
senses smoke.

NEW

Why
SafeNight

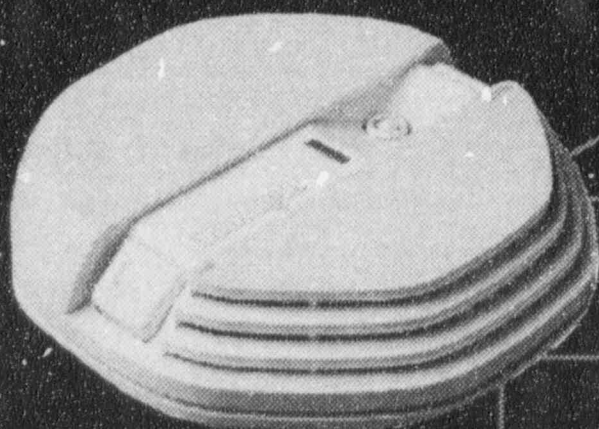
"At present, homeowners may have a false sense of security, believing their first-floor or basement smoke detector will awaken them."

—Charles H. Berry,
researcher, Fire Journal

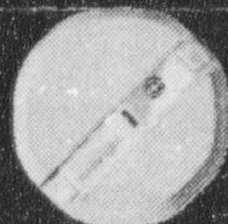
"Detectors located remote from the bedroom area may not be loud enough to awaken the average person."

—National Fire Protection Association Code

"Smoke detectors may not be heard. We recommend that smoke detectors be interconnected."
— a major smoke detector manufacturer

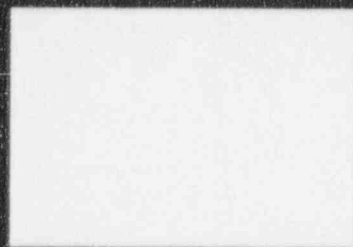


Wireless, Battery-Powered Smoke Detectors with RSA
(Repeating Signal Alert)



SafeNight™
Smoke Detector

Single Unit
Model No. SN-100

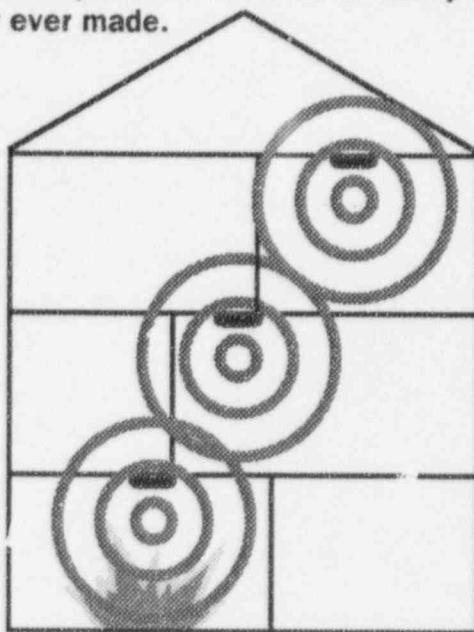


SafeNight™ Smoke Detectors. A lifesaving advantage.

SafeNight Smoke Detectors give your family a better chance to escape fire than any wireless smoke detector ever made.

Here's how:

A blaze breaks out in the basement of a home. The SafeNight smoke alarm located sounds in response to a fire. As family members sleep upstairs, the basement alarm sends radio signals to other SafeNight detectors. Quickly, all other SafeNight alarms that are part of the local network receive the radio signal and begin to sound, awakening the family. This family has up to 400% more time to escape the fire and smoke than conventional battery-powered alarms allow. The radio link in SafeNight makes our detectors a little more expensive. And a lot more valuable.



Exclusive SafeNight Features:

Computer Chip - A 44 pin custom integrated circuit.
Repeating Signal Alert (RSA™) - ensures the best possible radio signal reliability.
Transmitter/Ultra Sensitive Receiver.
LED - Indicates which detector originates the alarm.

Wireless, battery powered. 9-volt battery included.

Full one year manufacturer's warranty. Interconnectable up to 12 units.

Radio range accommodates most homes. 540/989-5738

HOME LOCATIONS

SafeNight recommends 3 or more per home

*Minimum standards
(National Fire Protection Association)*

- Outside of each separate sleeping area in the immediate location of the bedrooms
- On each additional story including basements but not unfinished attics
- In new construction, in each sleeping room

ADDITIONAL PROTECTION (National Fire Protection Association)

Basement, bedrooms, dining room, furnace room, utility room, and hallways not monitored by required smoke detectors.

*"Contains Radioactive Material
Americium 241 0.9 Microcuries"*

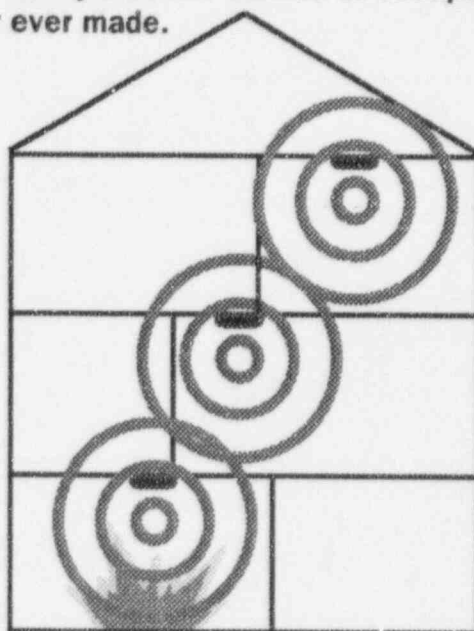
THIS DETECTOR CONTAINS RADIOACTIVE MATERIAL AND HAS BEEN MANUFACTURED IN COMPLIANCE WITH U.S. NRC SAFETY CRITERIA IN 10CFR 32.27. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS.

SafeNight™ Smoke Detectors. A lifesaving advantage.

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Here's how:

A blaze breaks out in the basement of a home. The SafeNight smoke alarm located sounds in response to a fire. As family members sleep upstairs, the basement alarm sends radio signals to other SafeNight detectors. Quickly, all other SafeNight alarms that are part of the local network receive the radio signal and begin to sound, awakening the family. This family has up to 400% more time to escape the fire and smoke than conventional battery-powered alarms allow. The radio link in SafeNight makes our detectors a little more expensive. And a lot more valuable.



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"Contains Radioactive Material
Americium 241 0.9 Microcunes"

"THIS DETECTOR CONTAINS
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HAS BEEN MANUFACTURED IN
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SAFETY CRITERIA IN 10CFR
32.27. THE PURCHASER IS
EXEMPT FROM ANY REGULA-
TORY REQUIREMENTS."

12. AUDITS

SafeNight Audit Procedures

A. Frequency

- audits will be conducted quarterly at the USA Test Location unless the test location is inactive during a given quarter. No audits will be conducted during inactive quarters. Should audits not be performed during inactive quarters, all attempts will be made to audit during an actual test cycle during an active quarter.
- an audit will be conducted yearly at the manufacturer

B. Scope

- 1) audit scope will include all NRC requested areas
- 2) will focus on received raw component (ion chamber) and finished goods from the manufacturer instead of individual suppliers

C. Who will conduct the audits?

- a person unrelated to the test or manufacturing process

D. Corrective action

- all deficiencies noted will be corrected in the proper responding time frame.

E. Follow up to deficiency

- depending on the severity of the deficiency of the audited item, SafeNight will insure corrective action by performing a follow up on-site audit if necessary

SafeNight On-Site Test Location Audit

Meets
Req'd
(y/n)

Organization

- 1) Is a copy of the QC/QA current hierarchy present with names and telephone numbers at the test facility?
- 2) Is the name of the current NRC contact listed in the QC manual?
- 3) Do the inspectors understand the importance of design conformity?

Personnel

- 4) Does test location maintain a employee file containing:
 - a) employee qualifications related to NRC licensing?
 - b) employee training related to NRC licensing?
- 5) Are employees qualified to do their jobs?

Equipment

- 6) Is a historical log maintained for each piece of equipment used in NRC related testing?
- 7) Does the location have a operators manual on each piece of equipment?
- 8) Are all calibrations current (less than on year old)?
- 9) Is there a process in place such that all equipment calibrations are kept current?

- 10) Do calibrations list the date and entity conducting the last calibration and is that calibration traceable to the NIST or equivalent?
- 11) Has all new equipment been calibrated prior to use?

Design and Document Control

- 12) Is the test location using only approved/ licensed NRC submitted specs for testing and inspection?
- 13) Is the filing system neat and orderly?
- 14) Are files set up for:
 - a) approved NRC drawings and specs
 - b) equipment instructions and history logs
 - c) employee NRC related records
 - d) QC manual
 - e) Verification of Conformance Report
 - 1) raw component testing
 - 2) finished goods testing
 - f) Nonconforming Material Report
 - g) Contract manufacturer chamber shipping document

Material and Service Procurement

- 15) (USA Test Location or SafeNight Corporate) Are certifications on file confirming sources are purchased in buttons from Amersham or NRD?

Inventory

- 16) Are inventory control procedures in place?
- 17) Are newly received contractor shipments segregated or tagged as to keep from previously tested, inspected, and approved samples and finished goods lots?
- 18) Are they kept separated until after the sample has been approved?

Inspection and Testing

I. Raw Component Testing

- 19) Is documentation present as to the size of the received lot of ion chambers/screws will be required with the sample shipment.
- 20) Is a Verification of Conformance form similar to Form 3 or a Nonconforming Material Form similar to Form 4 filled out and was one copy sent to SafeNight Corporate and one copy placed in file?
- 21) (SafeNight Corporate) Is correspondence present at SafeNight Corporate confirming pass/fail of raw material to contract manufacturer?
- 22) Are destroyed chambers either returned to the ion chamber manufacturer or the source and button manufacturer?

II. Finished Goods Testing

- 23) Are random samples drawn from newly received and untested finished goods lots?
- 24) Are all of the following testing and inspection points checked?
 - a) design conformity of point-of-purchase packaging
 - b) solder locks side chamber screw in place
 - c) chamber leads soldered to PCB and IC respectively
 - d) chamber is held snugly to the PCB by the screw on underside of the board
 - e) PCB size and thickness is within NRC submitted range
 - f) plastic housing is within NRC submitted range and are 4-5 plastic clips retaining the PCB
 - g) radiation wipe test on all 5% sampled units

- h) visually inspect the chamber for design conformity including labeling
- i) assuming 100% conformance of the sample, samples may move on to other non-NRC quality testing or be returned to inventory (except for disassembled samples)
- 1) a verification of conformance form similar to Form 4 filled out and placed on file

Nonconforming Materials

- 25) Are nonconforming device samples separated from conforming ones?
- 26) If any nonconforming items are found in a sample, is the entire finished goods lot tested or rejected?
- 27) If any nonconforming items are found, have corrective measures implemented?
- 28) Have nonconformance reports been filled out on each occurrence complete with remedy and on file?
- 29) Is the returned and corrected finished goods lot (from the contract manufacturer or other correction location) tested and inspected as a newly arriving finished goods lot?

Packaging and Transportation

- 30) Are there shipping records available?
- 31) Are shipments made in accordance to DOT regulations?

Deviations and Customer Complaints

- 32) Are customer complaints registered at the USA Test Location turned over to the SafeNight Customer Service Location?

33) (SafeNight Customer Service Location) Is the following process implemented on NRC related complaints?

- a) name, address, and telephone of the complainant taken
- b) nature of the complaint documented
- c) reply to the complainant
- d) corrective action taken
- e) root cause of the failure, if known
- f) sign-off of appropriate SafeNight official
- g) complaints held in computer database for periodic trend analysis

34) Is a form or computer record similar to Form 6 being used if the complaint is related to SafeNight's NRC license or registration?

SafeNight On-Site Manufacturer Location Audit

Inventory - Ion Chambers and Screws Only

- ___ 1) Are inventory control procedures in place?
- ___ 2) Are newly received supplier shipments segregated or tagged as to keep from previously tested, inspected, and approved lots?
- ___ 3) Are samples properly taken?

CONTRACT MANUFACTURER CHAMBER
CONTROL SHIPPING DOCUMENT

DATE CHAMBERS/SCREWS RECEIVED FROM
CHAMBER/SCREW MANUFACTURER: _____

CHAMBERS AND SCREWS(Y/N): _____

CHAMBERS ONLY(Y/N): _____

SCREWS ONLY(Y/N): _____

LOT/NUMBER IDENTIFICATION: _____

SIZE OF SHIPMENT: _____

SIZE OF SAMPLE SHIPPED TO
SAFENIGHT USA TEST LOCATION: _____

DATE THIS SHIPMENT: _____

Contract Manufacturer Chamber Control Agreement:

I agree that I have sampled the above incoming shipment of ion chambers and or screws. Our sampling technique included taking roughly an equal number of samples from each shipping container and from different places in that container. The entire shipment will stay segregated from other shipments of ion chambers and out of production until notification comes from SafeNight Technology Inc. that this sample has passed design conformity testing.

Contract Manufacturer Inventory Person

Date

F O R M 3

B22

November 7, 1995

45 days is Dec 22

Mr. Scott N. Markwell
SafeNight Technology Inc.
2121 Electric Road SW
Roanoke, VA 24013

Dear Mr. Markwell:

This letter is in response to our telephone conversation on November 6, 1995, in which you stated that SafeNight intends to resubmit its request for registration of the Model SN Series and PL Series smoke detectors in its entirety, without reference to previously submitted materials, in an effort to better address the range of detectors SafeNight proposes to distribute. In addition, you intend to completely revise your QA/QC procedures to address the testing commitments for design conformity. This will include providing details regarding any manufacturing or testing procedures that SafeNight will require its contractors or manufacturers to perform and the auditing plans that SafeNight will establish to ensure that those procedures are satisfactorily executed.

Please provide the complete resubmittal within forty-five (45) days of the date of this letter. If we do not receive the resubmittal within forty-five (45) days we will have considered 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) 415-5868 or Mr. Steven Baggett at (301) 415-7273.

Sincerely,

/s/

6.15 42 days

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

45

cc: SKimberly, LFDCB
CBoyle, IMAB

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SSD-94-49

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DATE	11/07/95		11/7/95					

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UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

January 23, 1996

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

Dear Mr. Markwell:

This letter is in response to your resubmittal dated December 28, 1995, requesting registration of the Model SN-100 Series and SN-500 Series smoke detectors. We are in the process of re-evaluating your request. However, in order to continue our evaluation, the following information is necessary:

1. The exploded view of the ion chamber on page 5 of the section titled "Application for Device Review", indicates that the screw inside the ion chamber passes through the receiver plate and penetrates the plastic source holder. From the drawing, it appears that this screw penetrates the source support and not the source holder. Please clarify this discrepancy.

2. The first sentence on page B2 states that SafeNight's quality checks will occur in one of two ways. The text contains only method "A", and does not reference a second method. Please provide details concerning the second method.

Please provide samples or full-scale drawings of the ion chamber and point-of-sale package labels.

4. Your application proposes an annual audit of your contractors. Based on the information provided and in order to provide an adequate level of confidence, the audits of the testing contractor should be performed on a more frequent basis.

5. The auditing procedures provided appears to combine both the audit of the testing contractor and the audit of the manufacturing contractor pulling the samples. Please indicate the procedures for auditing at each type of facility.

6. Please clearly indicate where copies of each record will be maintained.

Your application contained information that was not needed for a device review. We are returning the following to you from the "Application for a Device Review" section: part A) 2 Personnel, part A) 3 Equipment, Form 1 "Employee Training", and Form 2 "Equipment Log". In addition, we have forwarded the section entitled "Application for Exempt Distribution License" to the appropriate licensing reviewer.

4/29/96
Scott Markwell
says maybe line
item 4 takes 3.
per year
quicker
which no
activity.
Take a look at
what he
submitted.

being in the
package must contain
the person licensed under 32.26 to transfer
the label
the name
SafeNight
and the
list of the
letters
which is not
the

9601240162 2 pp.

S. Markwell

-2-

Please provide the requested information as soon as possible. If you have any questions, please contact me at (301) 415-5868 or Mr. Steven Baggett at (301) 415-7273.

Sincerely,

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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DATE	1/22/96	<input type="checkbox"/>	1/23/96	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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