03033624 ORC

VOID SHEET

TO: License Fee Management Branch

FROM: Susan L. Greene

SUBJECT: VOIDED APPLICATION

Control Number: 021654

Applicant: SafeNight Technology, Inc.
(formerly Sleepsafe Corp.)

Date Voided: 11/ /96

Reason for Void: Application abandoned by licensee after license review.

310113

Susan L. Greene 11/13/96
Signature Date
IMAB/IMNS/NMSS

Attachment:
Official Record Copy of
Voided Action

FOR LFMB USE ONLY

Final Review of VOID Completed:

☐ Refund authorized and processed

☑ No Refund Due

☐ Fee Exempt or Fee Not Required

Comments:

Log completed ☑

Processed by:

d1

TNL-00
cy to Reg II

November 13, 1996

SafeNight Technology, Inc.
ATTN: Scott N. Markwell
2121 Electric Road SW
Roanoke, Virginia 24018

Dear Mr. Markwell:

This refers to your July 28, 1994, request for a device review and exempt distribution license, and NRC Registration Certificate NR-1005-D-101-E which was issued to SafeNight Technology, Inc. on August 5, 1996. After the issuance of the registration certificate, you were notified by telephone that additional information, in the form of a copy of your possession and use license, was required in order to complete our review of your licensing request and to issue an exempt distribution license.

As you indicated during our recent discussion, you have not yet determined a location from which distribution will be performed and, therefore, have not yet applied for a possession and use license. As I explained, since we have not received, as of the date of this letter, the information necessary to issue a distribution license, NRC must consider your application as having been abandoned by you and have voided your licensing action.

Note that should you decide to submit the necessary additional information within 1 year of the date of this notice, and provided there are no changes to your request, an additional fee will not be required. If you do decide to resubmit, you should reference your earlier submissions, note the fact that you included an application fee with your earlier submission, and reference Mail Control No. 021654.

If you have any questions concerning this action, please contact me at (301) 415-7843.

Sincerely,
Original signed by:

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

DISTRIBUTION:
Docket File
IMAB r/f
SBaggett

Docket No. 030-33624
DOCUMENT NAME: G:\SAFENITE.SLG C=COPY E=COVER/ENCLOSURE N=NO COPY

OFC	IMAB							
NAME	SLGreene							
DATE	11/13/96							

OFFICIAL RECORD COPY

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

August 7, 1996

MEMORANDUM TO: Susan Greene, License Reviewer
Commercial Section
Medical, Academic, and Commercial
Use Safety Branch

FROM: Michele L. Burgess, Mechanical Engineer MLB
Sealed Source Safety Section
Medical, Academic, and Commercial
Use Safety Branch

SUBJECT: SSD TECHNICAL ASSISTANCE REQUEST:
SAFENIGHT TECHNOLOGY, INC. (FORMERLY SLEEPSAFE CORP.)
CONTROL NO. - 021654

In response to your request dated August 4, 1994, for the need of a SSD review associated with Safenight Technology, Inc. (Formerly Sleepsafe Corp.) license application, we have completed the SSD review. Please find enclosed a copy of registration certificate NR-1005-D-101-E.

If you have any questions, please contact me at 415-5868 or Mr. Douglas Broaddus at 415-5847.

Attachment: As stated

cc: SKimberley, LFDCB

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: NR-1005-D 101-E DATE: August 5, 1996

DEVICE TYPE: Smoke Detector

MODEL: SN Series, PL Series

DISTRIBUTOR/MANUFACTURER: SafeNight Technology Inc.
2121 Electric Road
Roanoke, Virginia 24018

SEALED SOURCE MODEL DESIGNATION: NRD Model A001
Amersham Model AMM1001H

ISOTOPE: Americium 241

MAXIMUM ACTIVITY: 1.0 microcurie (37 kBq)

LEAK TEST FREQUENCY: Not Required

PRINCIPAL USE: (P) Ion Generators, Smoke Detectors

CUSTOM DEVICE: _____ YES ___X___ NO

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: NR-1005-D-101-E DATE: August 5, 1996

DESCRIPTION:

The SN Series and PL Series are different marketing names for the same smoke detectors. All models in both series are identical in construction to the base model, SN-100, with the exception of differences in electronic components. All models in both series incorporate the same ionization chamber. All models are battery powered and can be interconnected with radio signals so that when one detector alarms, then all connected detectors will alarm. The source holder is crimped into a source cup which is recessed into a polypropylene lower chamber. The lower chamber is fastened to the printed circuit board (PCB) by means of a screw passing through the PCB and anchored at the bottom of the source cup. The cover of the ionization chamber is snapped around the lower chamber and screwed and soldered to provide enclosure of the source cup. The detector housing is about 5.75 inches (14.4 centimeters) in diameter with a height of about 1.5 inches (3.8 centimeters).

REFERENCES:

The following supporting documents for the smoke detector SN Series and PL Series are hereby incorporated by reference and are made part of this registry document:

. SafeNight Technology Inc.'s application dated December 28, 1995, with enclosures thereto.

. SafeNight Technology Inc.'s letters dated May 21, 1996, February 8, 1996, and January 31, 1996, with enclosures thereto.

. SafeNight Technology Inc.'s facsimiles dated August 2, 1996, and June 24, 1996.

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: August 5, 1996 Reviewer: _____
Douglas A. Broaddus

Date: August 5, 1996 Concurrence: _____
Steven L. Baggett

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

May 28, 1996

MEMORANDUM TO: Susan Greene, License Reviewer
Commercial Section
Medical, Academic, and Commercial
Use Safety Branch

FROM: Michele L. Burgess, Mechanical Engineer MLB
Sealed Source Safety Section
Medical, Academic, and Commercial
Use Safety Branch

SUBJECT: SSD TECHNICAL ASSISTANCE REQUEST:
SAFENIGHT TECHNOLOGY, INC. (FORMERLY SLEEPSAFE CORP.)
CONTROL NO. - 021654

This is regarding your technical assistance request dated August 4, 1994. Please note that Sleepsafe Corporation has changed its name to SafeNight Technology, Inc. In addition, please be aware that SafeNight Technology resubmitted its application in its entirety on December 28, 1995. Contained in the resubmission package was material designated as an "Application for Exempt Distribution License". We are forwarding this material to you for your action.

If you have any questions, please contact me at 415-5868 or Mr. Douglas Broaddus at 415-5847.

Attachment: As stated

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

November 7, 1995

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

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 be aware that SafeNight will be considered the responsible entity to the NRC in all cases, regardless of any agreements that SafeNight may have with its contractors or manufacturers.

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,

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

cc: SKimberly, LFDCB
CBoyle, IMAB

BETWEEN:

Licensee Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 03255
Status Code: 3
Fee Category: _____
Exp. Date: 0
Fee Comments: _____
Decom Fin Assur Reqd: _

LICENSE FEE TRANSMITTAL

A. REGION HQ

1. APPLICATION ATTACHED
   Applicant/Licensee: SLEEPSAFE CORPORATION
   Received Date: 940802
   Docket No: 3033624
   Control No.: 021654
   License No.:
   Action Type: New Licensee

2. FEE ATTACHED
   Amount: $6100.00
   Check No.: 484

3. COMMENTS

SS + Drawer

Signed M. Moriarty
Date 8-2-94

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / ✓)

1. Fee Category and Amount: 3H $2400

2. Correct Fee Paid. Application may be processed for:
   Amendment
   Renewal
   License ✓

3. OTHER _____

Signed Lindsay Mitchell
Date 8-4-94

1994 AUG -3 AM 9:52

R1201021 LICENSING TRACKING SYSTEM DATE: 940802
PAGE: 1

LTS WORKSHEET

DOCKET NO : 03033624 LICENSE NO : _____ STATUS: ~~3~~ 4

MAIL CONTROL: 021654 RECEIPT DATE : 940802 ACTION TYPE: 2
DUE DATE : 941031

FED. GOVT : N INST. CODE : 23827 LICENSE REGION: 0

ISSUE DATE: _____ ORIGINAL DATE: _____ EXPIRATION DATE: _____

NAME : ~~SLEEPSAFE CORPORATION~~ DECOM FIN ASSUR REQD: _
SUBM: _
Safenight Technology Inc.

DEPT/BUREAU: _____ CONT PLAN REQD: _ APPRV: _

BUILDING : _____

STREET : 2121 ELECTRIC ROAD SW

CITY : ROANOKE STATE: VA ZIP: 24018

CONTACT PERSON: SCOTT N. MARKWELL, PRESIDENT PHONE: (703) 989-5738

PRIMARY PGM CODE : 03255 SECONDARY PGM CODE: _____

INSPECTION REGION: 2 PRIORITY CODE: _ INSPECTION CATEGORY: ___

RADIATION SAFETY OFFICER: _____

STATES WHERE USE IS AUTHORIZED: _
0 - ALL LISTED STATES
1 - SAME AS STATE IN ADDRESS
2 - ALL STATES
3 - NON-AGREEMENT STATES

AUTHORIZED STATES: _____ (USE ONLY IF ABOVE IS ZERO)

REPORTING IDENTIFICATION SYMBOL: _____

APPROVAL FOR: REDISTRIBUTION: STORAGE ONLY:
TEMPORARY JOB SITES: INCINERATION:
BURIAL:

EXEMPTIONS: (1)_____ (2)_____

POSSESSION LIMIT INFORMATION

MATERIAL TYPE : __________ FORM CODE: ___ AGGREGATE CODE: ___
MODEL NUMBER :
DESCRIPTION :
TOTAL QUANTITY : UNIT: ___
OTHER : _ # SOURCES: ___

MATERIAL TYPE : __________ FORM CODE: ___ AGGREGATE CODE: ___
MODEL NUMBER :
DESCRIPTION :
TOTAL QUANTITY : UNIT: ___
OTHER : _ # SOURCES: ___

MATERIAL TYPE : __________ FORM CODE: ___ AGGREGATE CODE: ___
MODEL NUMBER :
DESCRIPTION :
TOTAL QUANTITY : UNIT: ___
OTHER : _ # SOURCES: ___

MATERIAL TYPE : __________ FORM CODE: ___ AGGREGATE CODE: ___
MODEL NUMBER :
DESCRIPTION :
TOTAL QUANTITY : UNIT: ___
OTHER : _ # SOURCES: ___

MATERIAL TYPE : __________ FORM CODE: ___ AGGREGATE CODE: ___
MODEL NUMBER :
DESCRIPTION :
TOTAL QUANTITY : UNIT: ___
OTHER : _ # SOURCES: ___

MATERIAL TYPE : __________ FORM CODE: ___ AGGREGATE CODE: ___
MODEL NUMBER :
DESCRIPTION :
TOTAL QUANTITY : UNIT: ___
OTHER : _ # SOURCES: ___

MATERIAL TYPE : __________ FORM CODE: ___ AGGREGATE CODE: ___
MODEL NUMBER :
DESCRIPTION :
TOTAL QUANTITY : UNIT: ___
OTHER : _ # SOURCES: ___

INDIVIDUAL USERS PAGE: 3

NAME	AUTHORIZATION

ADDRESS WHERE MATERIAL IS USED OR POSSESSED

BUILDING:
ROOM:
STREET:
CITY:
STATE:

BUILDING:
ROOM:
STREET:
CITY:
STATE:

BUILDING:
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BUILDING:
ROOM:
STREET:
CITY:
STATE:

DOCKET: 03033624 LIC: NAME: SLEEPSAFE CORPORATION

PARTY ISSUING MECHANISM: ASSUR TYPE : _ (C=CERT D=DFP)
NAME : MECH TYPE : __
ADDR1: MECH AMOUNT:
ADDR2: APPROVED? _ DATE:
CITY : EXPIRES ? _ DATE:
STATE: __ ZIP:

PARTY ISSUING MECHANISM: ASSUR TYPE : _ (C=CERT D=DFP)
NAME : MECH TYPE : __
ADDR1: MECH AMOUNT:
ADDR2: APPROVED? _ DATE:
CITY : EXPIRES ? _ DATE:
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ADDR1: MECH AMOUNT:
ADDR2: APPROVED? _ DATE:
CITY : EXPIRES ? _ DATE:
STATE: __ ZIP:

PARTY ISSUING MECHANISM: ASSUR TYPE : _ (C=CERT D=DFP)
NAME : MECH TYPE : __
ADDR1: MECH AMOUNT:
ADDR2: APPROVED? _ DATE:
CITY : EXPIRES ? _ DATE:
STATE: __ ZIP:

PARTY ISSUING MECHANISM: ASSUR TYPE : _ (C=CERT D=DFP)
NAME : MECH TYPE : __
ADDR1: MECH AMOUNT:
ADDR2: APPROVED? _ DATE:
CITY : EXPIRES ? _ DATE:
STATE: __ ZIP:

LICENSE DATA, CONTINUED PAGE: 5

DOCKET NO: 03033624 LICENSE NUMBER: _____
NAME : SLEEPSAFE CORPORATION

MEDICAL QUALITY MANAGEMENT PROGRAM REQUIRED: N RECEIVED: _ APPROVED: _

DECOMMISSIONING FINANCIAL ASSURANCE REQUIRED: _ SUBMITTED: _

CONTINGENCY PLAN REQUIRED: _ APPROVED: _

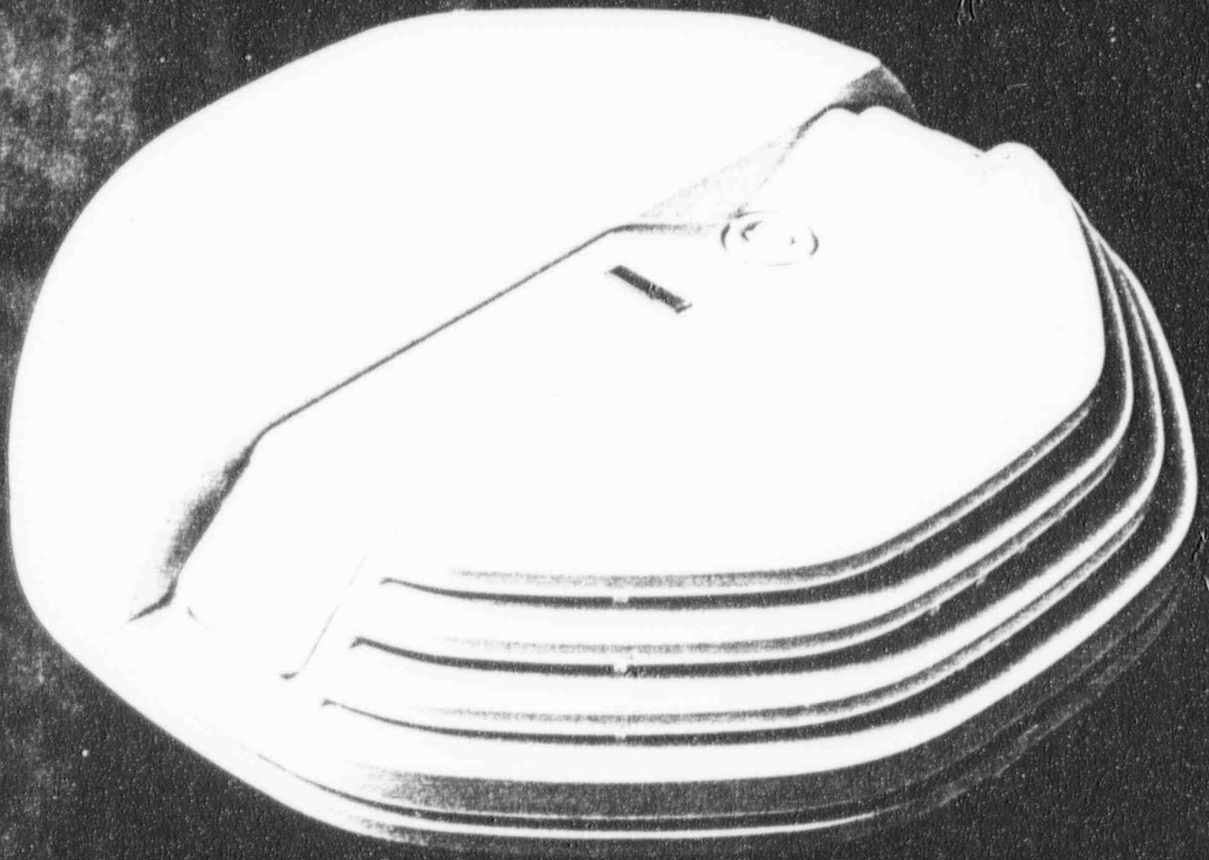
DECAY-IN-STORAGE APPROVED: N HOLDING FOR < 10 HALF-LIVES APPROVED: _

T 1/2 > 65 DAYS, ISOTOPE(S): _____ _____ _____
_____ _____ _____

INTERIM STORAGE UP TO 1996: N

SafeNight™

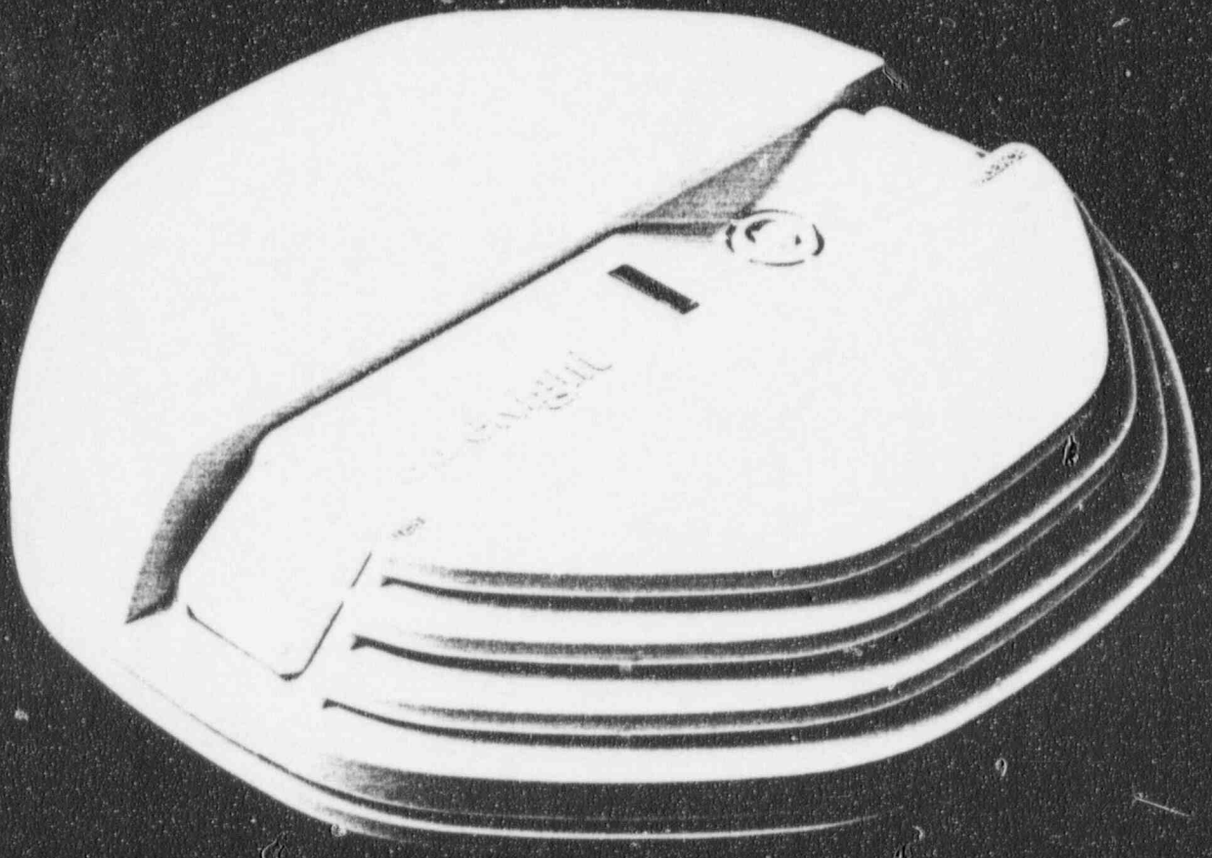
Wireless, Battery-Powered Smoke Detectors.



All alarm together when any SafeNight detector senses smoke.

Safe

Wireless, Battery-Powered Smoke Detectors.



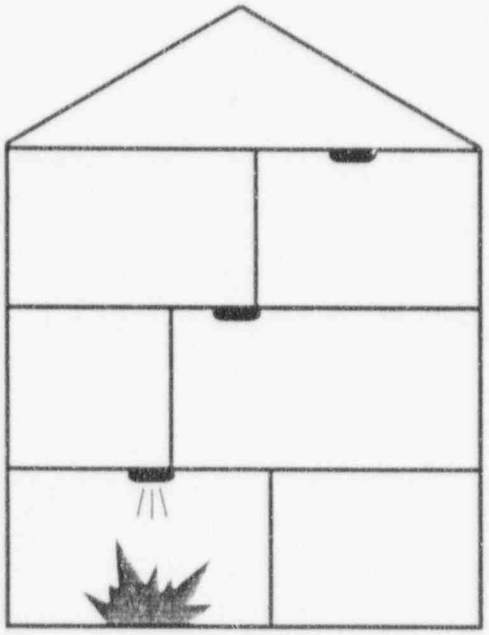
All alarm together when any detector senses smoke.

SafeNight™ Smoke Detec

All alarm together when any S

Conventional battery-powered smoke detectors are obsolete.

1. A basement smoke alarm sounds in response to a fire. This alarm wakes no one. Few people are awakened by fire alarms that are not in close proximity to where they are sleeping.



2. Two minutes into the fire. Flames are really starting to kick up. This fire will double in size every thirty seconds.

3. Three minutes. Fire and smoke roar toward the unsuspecting family. A second smoke alarm sounds but is still too distant, and no one hears.

4. Four minutes. The smoke and fire block some exits as the sleeping - level alarm sounds. Panicked, this family has only seconds to escape.

Conventional battery-powered smoke alarms, even when functioning perfectly, simply cannot deliver the protection families need.

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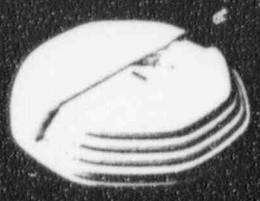
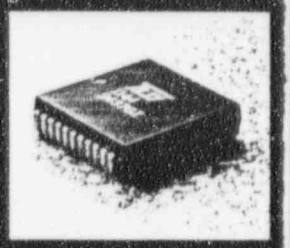
SafeNight Smoke Detectors.
All alarm when any one senses smoke.

SafeNight Smoke Detectors offer protection for your family no other battery-powered smoke detector can match. Though each unit is a wireless, battery-powered smoke detector, when one alarms, all alarm. Working together through an advanced system of radio transmitters and receivers, SafeNight provides the maximum warning of fire and the most reaction time for your family.



A new generation of technology.
A new level of protection.



The key is in a revolutionary computer chip and patented **Repeating Signal Alert (RSA)** that recognizes the presence of smoke and initiates radio signals, causing all other alarms in the network to sound.

Although SafeNight Smoke Detectors are a bold leap forward in terms of electronic sophistication, they are easy to use. In fact, one button on any unit can test or silence the entire network.

ors. When Minutes Count.

eNight detector senses smoke.

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Fire Protec-
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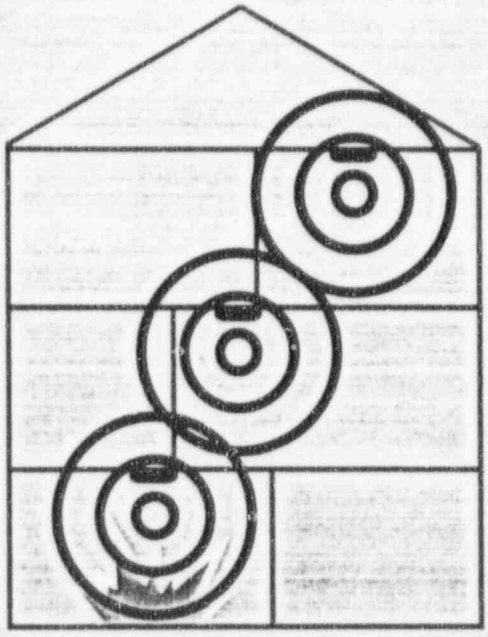
oke detector
anufacturer

SafeNight All-Alarm Smoke Detectors deliver unsurpassed protection.

1. The SafeNight smoke alarm located in the basement sounds in response to a fire. As family members sleep upstairs, the basement alarm sends radio signals to other SafeNight detectors.



2. Quickly, all other SafeNight alarms that are part of the local network receive the radio signal and begin to sound, awakening the family.

3. Time is still precious, but this family has up to 400% more time to escape the fire and smoke than conventional battery-powered alarms allow.

4. The family exits quickly to the safety and comfort of a neighbor's home.

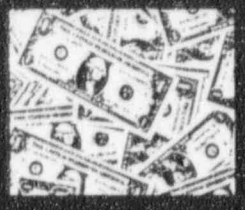
This family is safe because of the superior protection provided by SafeNight All-Alarm Smoke Detectors.

When minutes count.
Earlier warning means better protection.

SafeNight's all-alarm protection is a concept that has been enthusiastically endorsed by fire and safety experts as well as insurance professionals.

Contrasted with conventional battery - operated smoke detectors, our all-alarm feature could allow up to four times more warning time to react to a fire...time that can be used to save lives and property.

The advantages of a hard-wired alarm system.
Without the expense.



Since 1989, virtually all new construction codes have required wired interconnected smoke alarm systems so all detectors sound when there is a fire. It's an idea that saves lives. Yet the vast majority of owners of homes built prior to this regulation have not installed these systems because of the expense of wiring. In fact, wiring a system into an existing home can cost thousands of dollars.

SafeNight Smoke Detectors make the superior protection of interconnected alarms affordable.

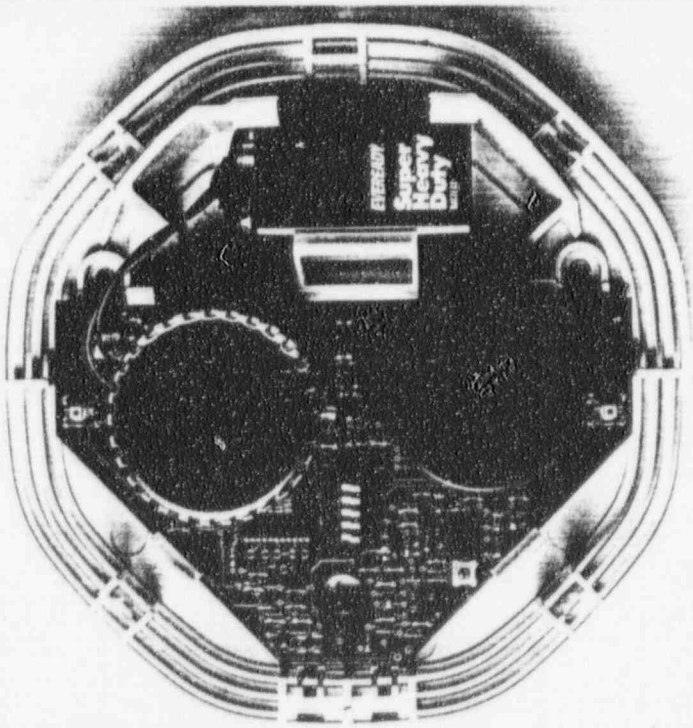
When Minutes Count.

SafeNight smoke detectors undergo rigorous UL smoke detector testing and meet the highest manufacturing quality standards.

Repeating Signal Alert (RSA) - A patented communications protocol that ensures the best possible radio signal reliability.

Test/Silence Control Buttons - In the event of a false alarm (or testing), one button on any unit can silence and control the entire network.

Low Power Usage Circuitry - High technology circuitry that uses very little power. A single 9-volt battery provides power far longer than for conventional radio products.



Smoke Sensing Chamber - A proven, high performance smoke sensing device.

Computer Chip - A 44-pin custom integrated circuit incorporating C-Mos circuitry and thousands of transistors.

Piezoelectric Horn - High quality, loud warning horn.

LED Light - Indicates which detector originates the alarm.

ABS Housing - An attractive, heavy duty housing.

Intelligent Command Controller - A custom manchester encoder/decoder design allows each SafeNight detector to control all others in your system.

Transmitter/Ultra Sensitive Receiver - Detectors communicate through a very reliable multiplexed radio communication network.

SafeNight Smoke Detectors feature a world-class design that is the result of a joint effort between a leading U.S. military defense contractor and other commercial firms.

Patent Pending, U.S. Patent Number 4,363,031

SafeNight Technology, Inc.

2121 Electric Road SW
PO Box 21847
Roanoke, Virginia 24018
703/989-5738
After 8/1/95, 540/989-5738

SafeNight

phone
540 989 5738

fax
540 989 5248

APPLICATION FOR DEVICE REVIEW

APPLICATION FOR EXEMPT DISTRIBUTION LICENSE

QUALITY CONTROL PROGRAM

RE-Submitted by
SafeNight Technology Inc.
(formerly Sleepsafe Corp.)
2121 Electric Road
Roanoke, VA 24018
Scott Markwell, President
(540)-989-5738
(540)-989-5248 FAX
12/29/95

APPLICATION FOR DEVICE REVIEW

Submitted by

SafeNight Technology Inc.
(formerly Sleepsafe Corp.)
2121 Electric Road
Roanoke, VA 24018
Scott Markwell, President
(540)-989-5738
(540)-989-5248 FAX

TABLE OF CONTENTS

3.1) SUMMARY DATA

3.3.1 Date

The date of the original application was July 28, 1994

3.1.2 Applicant

SafeNight Technology Inc.
(formerly Sleepsafe Corporation)
2121 Electric Road
Roanoke, Virginia 24018
Contact: Scott Markwell, President
540-989-5738

SafeNight Technology Inc. is the distributor of the device. It owns the design and will contract with a contract manufacturer to produce the device.

3.1.3 Device Type

The device type used by industry is a smoke alarm or smoke detector.

3.1.4 Model

The smoke detector consists of series designated as the Model SN, PL, RS, MA, AM, MN, CT, JS, TS, DS, KT, HM series.

SN-100. The base model.
SN-500. A/C model. No significant changes affecting the integrity of the chamber from the SN-100.
PL, RS, MA, AM, MN, CT, JS, TS, DS, KT, HM - 100. Redistribution or different marketing models of the SN-100
PL, RS, MA, AM, MN, CT, JS, TS, DS, KT, HM - 500. Redistribution or different marketing models of the SN-500

3.1.5 Other Companies Involved

Other companies directly involved will include a contract manufacturer. Given that we do not maintain our own manufacturing facilities, this party is subject to change depending on favorableness of terms. Regardless, we will

maintain relations with a contract manufacturer achieving generic U.S.N.R.C. requirements.

3.1.6 Radioactive Source Model Designation

The radiation source model designation will be either:

a) Amersham model AMM.1001 source and holder
or
b) NRD model A-001 source in model A-1056 holder

Both sources and their testing are well documented by the NRC.

3.1.7 Radionuclides and Maximum Activity

The radionuclide is Americium 241 - 1.0 microcurie or less.

3.1.8 Leak Test Frequency

Their will be no scheduled leak testing of these devices after they are distributed. Amersham and NRD have previously leak tested the sealed sources of our devices, and we will guarantee our devices not leaking prior to distribution per 10 CFR and the "SSSS" position.

3.1.9 Principal Use Codes

The Principal Use Code is "P", Ion Generators, Smoke Detectors. Applicant is applying for an exempt distribution license.

3.2) SUMMARY DESCRIPTION

3.2.1 Written Description

SafeNight smoke detectors are designed to safe lives by giving the earliest possible warning of fire to the residential consumer. While most battery-powered smoke detectors are single station only the Model SN-100 is interconnected with radio signals. When one detector senses smcke, it will signal all others and all will alarm as a multi-station system. Thus, the consumer will get early notification of fire from remote or hard to hear locations such as basements.

The detector is designed for ceiling or wall installation with screws and anchors. It is not portable and will be installed in a fixed location.

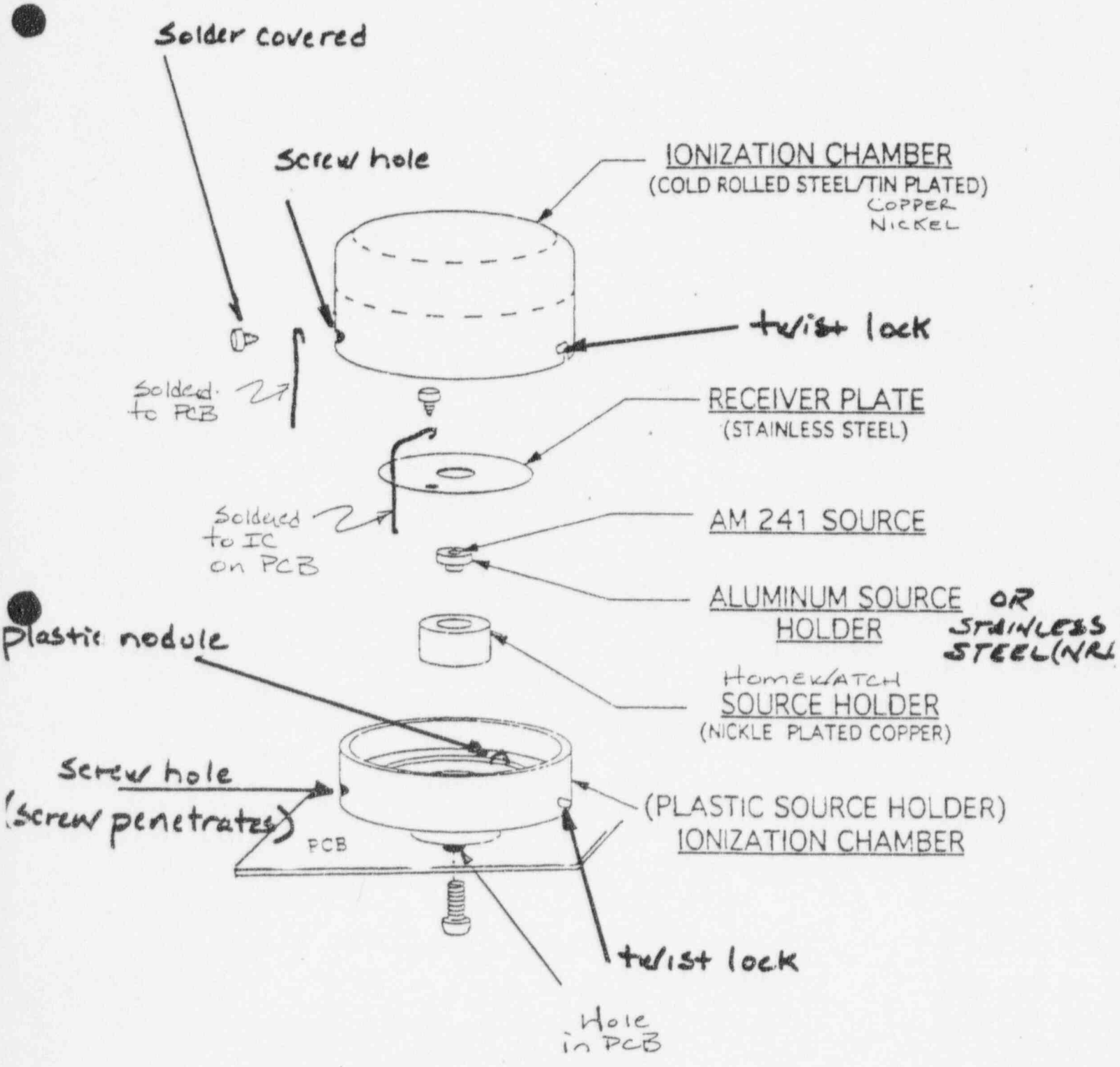
The source housing does not move during use.

The ionization chamber includes a sealed source (Americium 241) and source holder from Amersham or NRD with certification that they have been leak tested in accordance with USNRC leak test requirements. The source holder is crimped into a nickel plated source cup which is recessed into a hard plastic lower chamber and then attached to the printed circuit board by screw. The other part of the ionization chamber consisting of a steel/tin (perforated and insect proof) cover is screwed, soldered, and snapped around and over the source cup for security.

3.2.2 Drawing

Drawings of our chamber are detailed in the Following Figures 1,2,3,3A,4. Further detail as to the Amersham and NRD source and source holders are included in Appendix A.

FIGURE 1



CONTAINMENT OF SOURCE WITHIN DETECTOR

FIGURE 1

CHAMBER CONSTRUCTION

Pg(5)

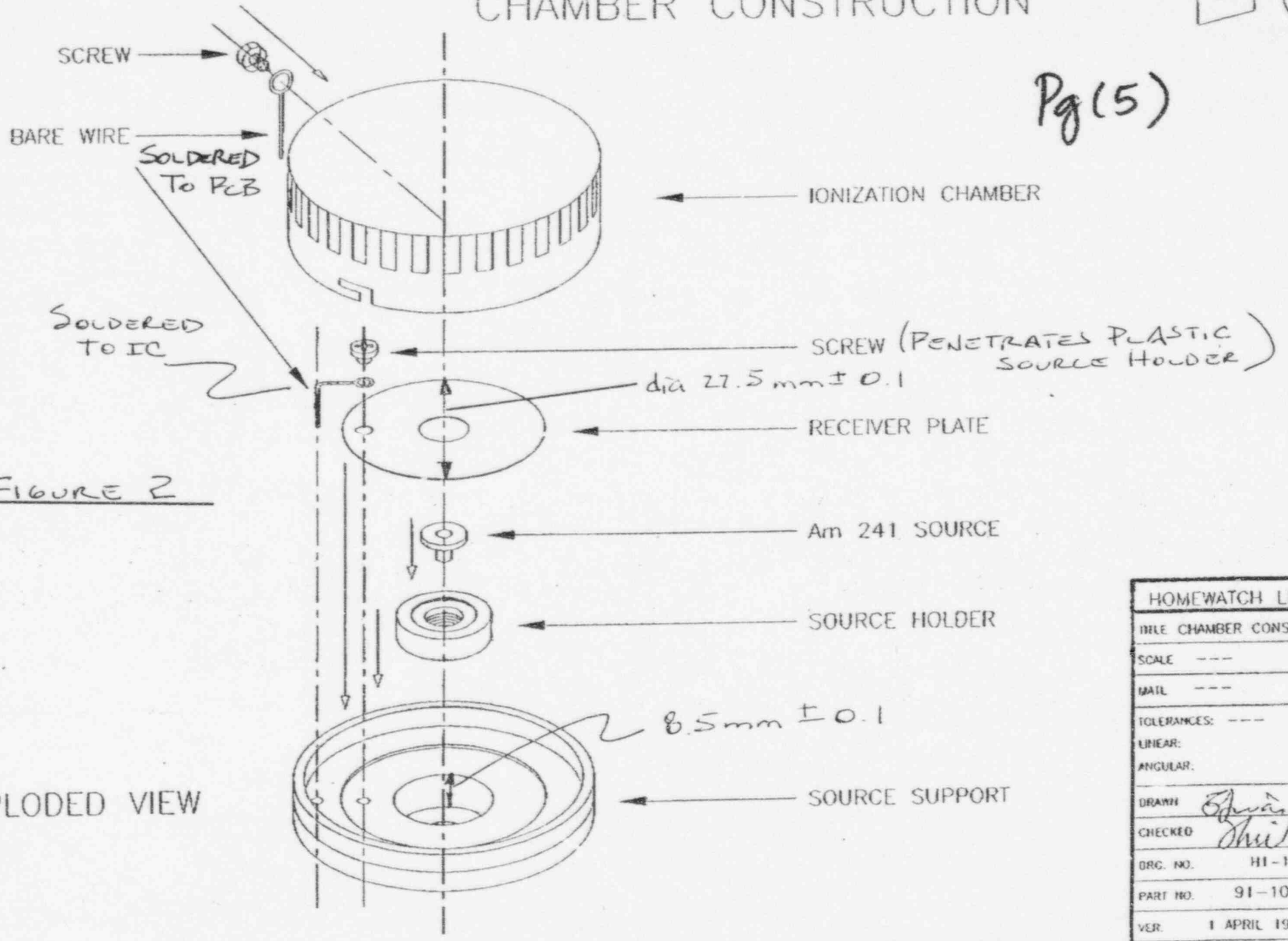


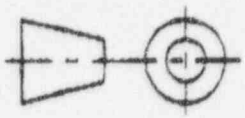
FIGURE 2

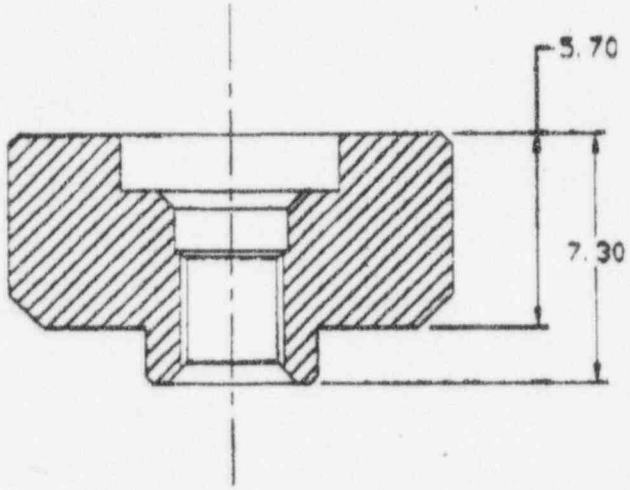
EXPLODED VIEW

HOMEWATCH LIMITED	
TITLE	CHAMBER CONSTRUCTION
SCALE	---
MATL	---
TOLERANCES:	---
LINEAR:	
ANGULAR:	
DRAWN	
CHECKED	
DRG. NO.	H1-100C
PART NO.	91-101001
VER.	1 APRIL 1991 (A)
SHEET	ONE ONLY

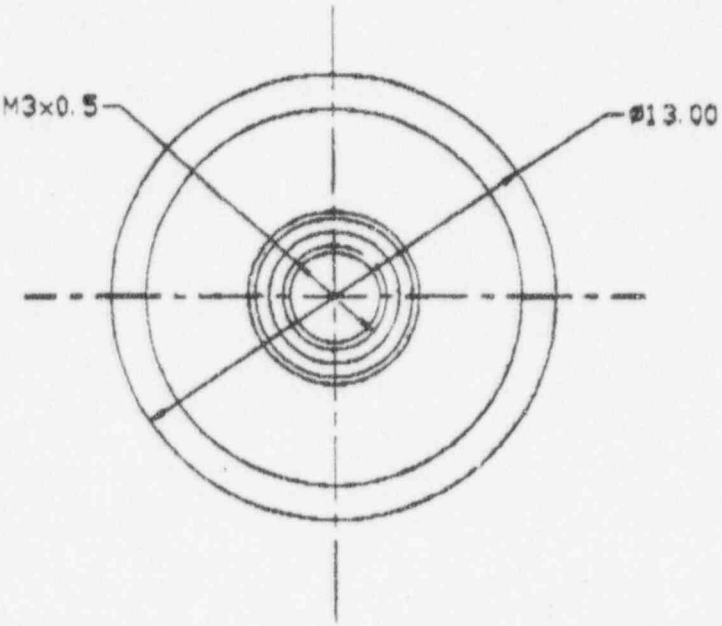
HCW

Pg (4)





SECTION AA FRONT



BASE

FIGURE #3

HOMEWATCH LIMITED	
TITLE	NRD SOURCE HOLDER
SCALE	NOT TO SCALE (mm)
MAT.	BRASS plated with Ni
TOLERANCES:	
LINEAR:	±0.2
ANGULAR:	±0.2
DRAWN	
APPROVED	
DWG. NO.	HW-M18
DATE	1 APR 92
VER.	
PART NO.	

HCW

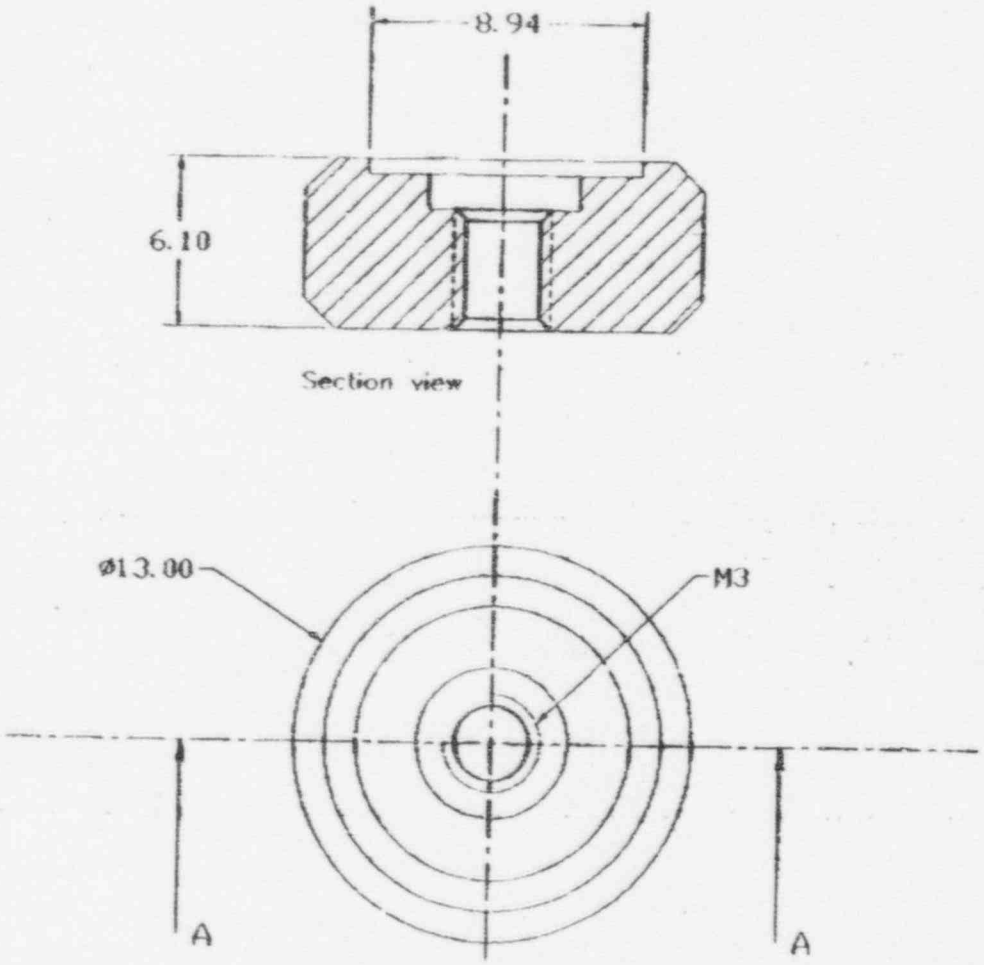


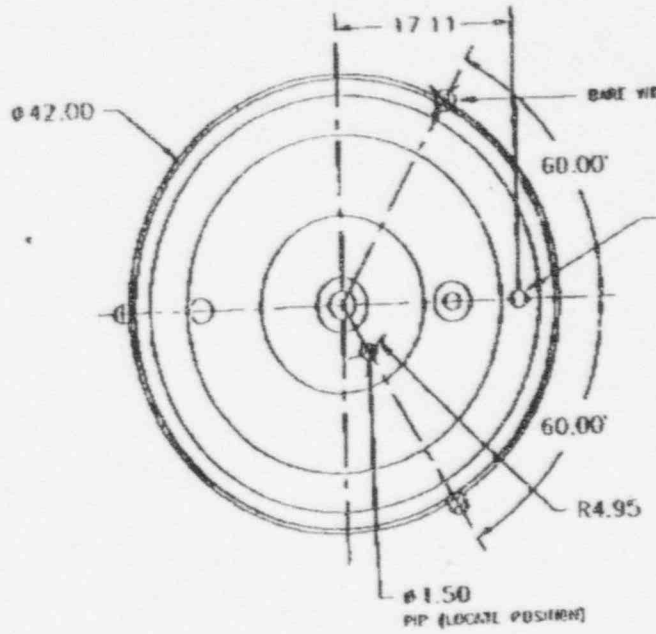
FIGURE 3A

7

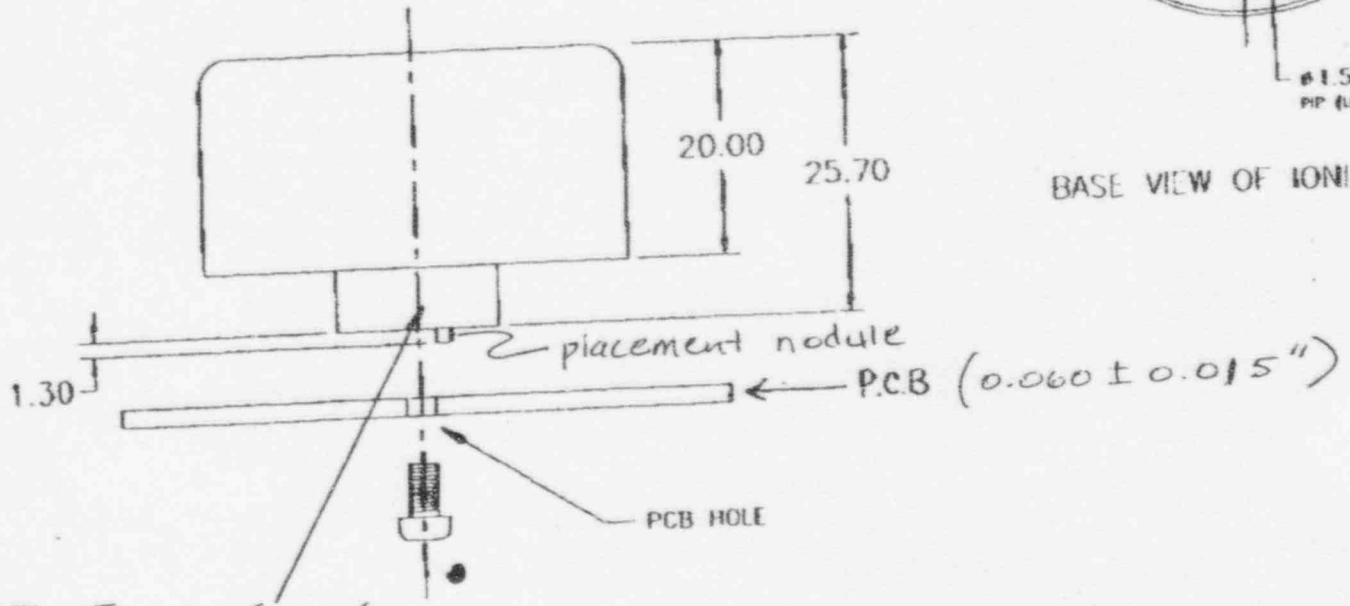
HOMEWATCH LIMITED	
TITLE	Source Holder (Amersham)
SCALE	4 : 1
MAT'L	Brass plated with Nickel
TOLERANCES: LINEAR: ANGULAR:	
DRAWN	Edwin Wong
APPROVED	
DWG. NO.	H1-008C
DATE	1/4/1991
REVISION	

JCW

FIGURE 4



BASE VIEW OF IONIZATION CHAMBER



HOMEWATCH LIMITED	
TITLE	DIMENSION OF IONIZATION CHAMBER
SCALE	1:0.7 (UNIT=mm)
MATL	Unless noted
TOLERANCES:	
LINEAR	
ANGULAR	
DRAWN	
CHECKED	
DRG. NO.	
PART NO.	
VER	13 NOV 1993
SHEET	ONE ONLY

NO ALTERATIONS WITHOUT DRAWING OFFICE APPROVAL

JCW

3.3) DETAILS OF CONSTRUCTION AND USE

3.3.1 Conditions of Use

Planned Use of the Device:
The planned use of the device is a single or multi-station residential smoke alarm/detector.

Extremes of Environmental Operating Conditions:
As a residential smoke detector typically, the device will enjoy a very controlled environment. In any case the device will have to undergo and pass several vigorous U.L. environmental tests. Since the detector will be mounted only once during its useful life, there should be little vibration of the device during its use. Regardless, the unit will have to undergo a U.L. vibration test.

Types of Users:
Since the detectors will be mounted at a height of seven feet or more, the users primarily will be adults. Again, these will be residential users.

Locations of Use:
Being a residential smoke alarm, the SN-100 will be installed according to NFPA 72 and local building codes:

1) On the Ceiling. This is the preferred mounting location. Best nearest the center of ceiling.
2) On the Wall. This location is recommended for rooms where ceiling installation is not practical.
3) Minimum standards (National Fire Protection Association)
   a) Outside of each separate sleeping area in the immediate vicinity of the bedrooms
   b) On each additional story including basements but excluding unfinished attics
   c) In new construction, in each sleeping room
4) ADDITIONAL protection (National Fire Protection Association)
   a) Basement, bedrooms, dining room, furnace room, utility room, and hallways not protected by required smoke detectors

Occasions the Consumer will be near the device:
The initial installation of the device will take less than twenty minutes and should be a one-time event. We will recommend weekly testing which will require less than one minute for the system. The device will require a new battery once per year. It is estimated that this will take 2 minutes or less per unit. Should the unit go into alarm, the alarm is latching and will have to be reset. Reset will take less than one minute for the system. Of course, alarming whether real or false should be an unusual event. Lastly, we will recommend once per year vacuuming the outside of the unit, and this should take less than one minute per unit.

Possibility the Device Used as a Component of Another Product:
It is not expected that the device could be used as a component of anything other than as an independent unit of a fire or security system.

Expected Useful Life:
The expected useful life is 10 years.

3.3.2 Details of Construction

1) Engineering Details of the Chamber and Contents:

Please see Figures 1,2,3,3A,4 in section 3.2.2.

Method of Fabrication:
The nickel plated copper source holder is fabricated with a female plug in the bottom of it. The aluminum or stainless steel source holder from NRD or Amersham is crimped around the edge into the source holder. Both are then pressed down inside a snug fitting plastic source holder. The process does not contact the sealed source.

There is a gap between the top of the source holder and the bottom of the receiver plate. The receiver plate is placed on top of a plastic ledge in the plastic source support above the source holders and held in place by a screw and plastic nodule present on the plastic source holder. The screw penetrates all the way down to the plastic holder. The steel tin/copper/nickel-plated cup is then placed over the plastic source holder (again a snug fit) and twist-locked. A screw is applied that penetrates

both the steel/tin cup and the plastic source holder. This screw will be covered with solder to prevent tampering and untwisting action.

The chamber is aligned on the PCB using a nodule present at the bottom of the plastic holder and a small hole in the PCB. Then it is screw connected from the other side. The lead wire from the receiver plate is soldered to the smoke detector chip and the other lead wire is soldered to the board. Both will prevent the screwing of the chamber from the board short of destruction.

2) Dimension and Materials of the Circuit board:

See Figure 5. The circuit board will be of a standard PCB material.

3) Attachment of the chamber to the board:

Please see Figures 1,2,4 in section 3.2.2.

4) Housing:

Materials - the material of the outer housing will be ABS meeting U.L. 94-HB.

a) diameter of the housing: 5.0 inches +/- 2.0 "
b) thickness of the housing: 2.0 inches +/- 1.0 "
d) method of attachment of the board to the housing: four or five plastic snaps
e) method of opening/closing: hinged cover
f) color: varies

3.3.3 Labeling

1) Device Labeling Description:

All models will include a durable paper label fastened to the top of the ion chamber. It will contain the verbiage "CONTAINS RADIOACTIVE MATERIAL AMERICIUM 241 0.9 MICROCURIE" and "U.S. NRC License No. XXX".

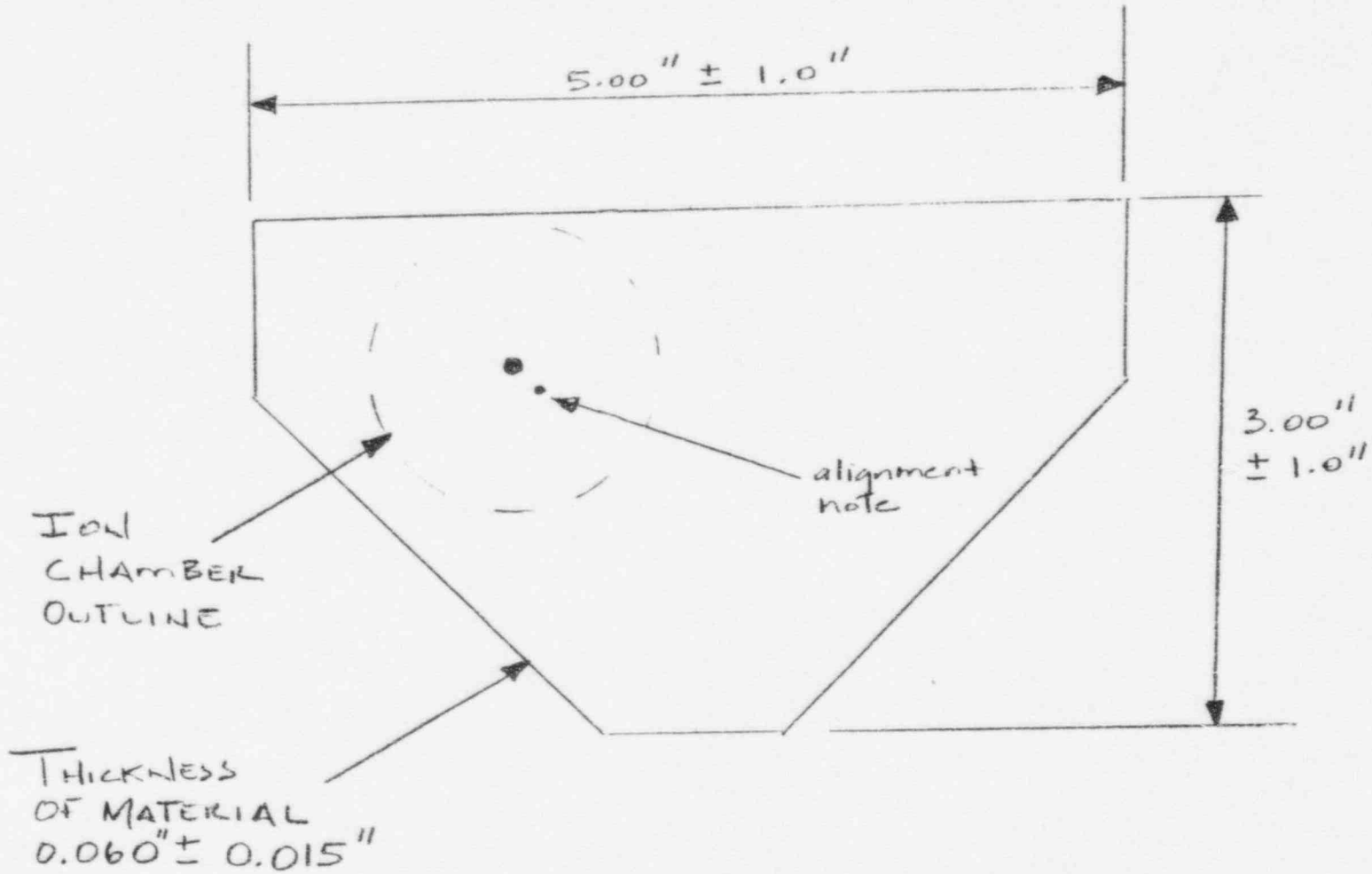


FIGURE 5

PCB LAYOUT
NOT TO SCALE

2) Point of Sale Packaging Marking

All model packaging will contain the following or equivalent:

a) "Contains Radioactive Material Americium 241 0.9 Microcuries"

b) "U.S. NRC License No. XXX"

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

3.3.4 Testing of Prototypes

1) Amersham and NRD testing. Amersham and NRD sealed sources have been evaluated many times for the U.S. NRC with temperature, pressure, impact, vibration, and puncture tests conducted in accordance with ANSI 524 and ISO 2919 and found suitable for licensing purposes in the United States. Appendix A details some Amersham and NRD information.

Testing by Amersham and NRD should be considered worst case testing since surrounding sealed source and holder with other components and casing would provide some shielding.

2) Prototype testing. On June 9, 1995 and November 13, 1995, we conducted prototype tests on two prototypes at the office of Physics Associates in Roanoke, Virginia.

Drop test. In the first test, we took a SafeNight Model SN-100 PCB with ion chamber mounted (no plastic housing) and dropped it seven times from a height of 4 meters onto a concrete floor. During the course of the testing, the steel ion chamber cover came off on drop four. The source remained in place in its source holder(s) and remained attached to the PCB throughout the testing. Wipe tests were taken from the AM-241 source and the immediate environs thereof. A calibrated PC/3 NAI multi-channel analyzer gamma ray spectroscopy system was used to analyze the wipes. No removable contamination was observed above background levels and did not exceed 0.005 uCi.

Impact Test. In the second test, we took a SN-100 PCB with ion chamber mounted (no plastic housing) and dropped a 1 pound hammer onto the ion chamber 2 times from a height of 36 inches. The steel ion chamber cover was dented. Wipe tests were done from the ion chamber. Using the same multi-channel analyzer, no removable contamination was observed above background levels and did not exceed 0.005 uCi.

3.3.5 Quality Control Program

See Appendix B

3.3.6 Radiation Profiles

Background:
The Americium 241-gold matrix is not very insoluble in water or bodily fluids. In ICRP Publication 30, Part 1, entitled "Limits for Intakes of Radionuclides by Workers", the fractional rate at which all ingested compounds of Americium are translocated to body fluids was taken as 5 X 10-4, based on animal studies reporting values <10-4. It also noted that greater gastrointestinal absorption might be expected for complex forms of Americium and that enhanced absorption has been reported in very young rats. In a case study involving the ingestion of two Americium 241-gold matrix foils that were accidentally swallowed by a worker, less than 1% of the Americium was lost to body fluids after being exposed within the gastrointestinal tract of the worker for more than 16 days. Further, the activity that was released under these circumstances was so inert that there was negligible (much less than 1.5%) absorption into the blood.

R.G. Niemeyer (ORNL-TM-2684) performed a total of 23 twenty four water leach tests and 15 three-week water leach tests on eight Am 241 foils which had been removed from five-six year old smoke detectors. The sources contained approximately 15 microcuries of Am 241 each and half of the sources were deliberately damaged by drawing a sharp tool along the entire length of the foil before leach tests. The maximum activity leached in these tests was 0.0045 microcuries, which was less than the 0.005 microcuries of leakage allowed by NRC's standard leak test condition for alpha sources. The average leached during the 38 tests was 0.9 nanocuries and 11 of the 38 tests leached less than 0.02 nanocuries.

Dale H. Denham, Batelle Pacific Northwest laboratory, (Health Physics 16, 480 (196) stated , with a literature citation to ICRP Report II,"Because most of the compounds of the transplutonium elements are insoluble in biological fluids, ingestion and percutaneous absorption are unlikely to result in significant body burdens. For example, less than 0.01% of the Americium taken into the gut ultimately reaches the critical organ, bone. Hence, at least 500 uCi of insoluble AM 241 must be ingested to produce one bone burden (0.05 uCi)."

Since the AM 241 used in the SN-100 is AMO2 intimately bound in precious metals and is of much lower activity than these tests, leaching of Am 241 into the body from

smoke detector sources would be much less than stated by ICRP for insoluble compounds of Americium.

(a) Normal Use:
The intake of Americium 241 into the blood system of a user of the unit would be negligible, and the likelihood of such an occurrence would be less than a one in a million chance. The dose commitment result from such a negligible uptake would be much less than 0.005 Rem or 5 Millirem to the whole body, all the blood forming organs, other organ or bodily parts. The information given in background section above would serve as a basis for such a claim.

The external dose equivalent to the head and the lens of the eyes of a seven foot individual (possibly at a distance of a foot from the wall in the vicinity of the smoke detector) with these portions of his/her whole body approximately 25 centimeters from the ion chamber (for a full year, his/her dose equivalent would be 0.003 Rem/year.

This is clearly less than a 0.005 Rem or 5 Millirem whole body dose. Since the limbs of the body, the skin of the entire body, and other organs would be at greater distances from the smoke detector during it use, the dose equivalent to these portions of the body would be less than 5 millirem.

In the above example, it is extremely unlikely that an individual would remain in the vicinity of a smoke detector for such a long time. It is more likely that only 20 minutes are spent in the initial installation and a similar period of maintenance for the other years. So the whole body dose equivalent could be lower than 0.004 percent of the calculated dose equivalent.

If during the twenty minute period of installation or maintenance the individual placed his/her hand on the surface of the smoke detector directly above the ion chamber. At a 5 centimeter distance, the annual dose was measured as 0.05 Rem/year. The surface of the smoke detector is at least 1.5 centimeters away from the ion chamber. The exposures rates at different distances are related in an inversely proportionate relationship to the squares of their distances from the source. Since the top of the ion chamber is more than 1.5 centimeters from the source, the distance from the source is moved from 6.5

centimeters to 3 centimeters. The dose equivalent would then be expected to be 4.7 times the original value of 0.05 Rem/year, resulting in a value of 0.24 Rem/year. So for twenty minutes the total dose equivalent to the hand would be 0.01 Millirem. This is much less than the 75 Millirems allowed to the hand and forearms.

As far as the safety involved in the disposal of a single smoke detector or a number of smoke detectors from consumer use to the natural environment, please refer to the information given in NuReg CR-1775 and CR-1156, "Environmental Assessment of Exposures"

(b) Safety over useful life:
In the normal handling and use of the smoke detector during its useful life of ten years, it is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product from wear and abuse. Representative samples of smoke detectors have been subjected to and passed recognized physical, mechanical and chemical tests designed to indicate their ability to withstand adverse environmental conditions. This unit is rugged in construction materials used and in the manner in which it has been bound together as a unit. In addition, it would be isolated on a wall subjected to extreme conditions only in the event of a fire, in which case if it does function, it more than serves its purpose. If the unit does burn up, with the very, very large volume of air and other gases which might be associated with such a burn-up, the large dilution and subsequent decrease in the concentration of any released Americium 241 would probably be insignificant in its effect on the environment.

(c) Worst Case:
In order for dose equivalents to be received that are a factor of one hundred larger than those of 5 millirems listed in column I of the table in Section 32.28, then a failure must occur in both the smoke detector housing and in the ionizatic chamber. A failure in the ion chamber may mean exposing an individual to the source foil. The radiation exposure would now increase markedly due primarily to the characteristic x-rays which have a combined exposure constant of 14.4 microroentgens per microcurie-hour. In addition, the 26 keV and 33 keV gammas would also present some additional exposure of 0.3 microroentgens/microcurie-hour. The total gamma constant to which an individual would then be exposed would be 16 microroentgens per microcurie-hour. The resulting dose

equivalent levels would be 12.5 times higher. In other words, the .003 Rem/year levels that existed at a distance of 25 centimeters from the outer cap of the ion chamber (26.5 centimeters from the source) would now be 0.0375 Rem or 37.5 millirem. If an individual kept such a sealed source at this distance from their eyes and head for a year, they would receive this dose. The probability of such a failure and occurrence is low - probably less than one in ten thousand. For a hand placed on top of the sealed source for this duration, only a small area slightly larger than a 3 mm diameter would receive a large dose and, if not moved at all during the year, would certainly exceed the 7.5 Rem limit. If the sealed source were to be manipulated in the hand, then the localized maximum intensities would be shared by most of the other portions of the hand so that the average effect is to receive a dose equivalent not nearly as large as a maximum localized dose. Since it is very improbably that the sealed source would be handled continuously for an entire annual period and probably much less so, the expected dose equivalent would be less than the 7.5 Rem limit. The probability of such as occurrence is probably much less than one in ten thousand. In judging the possibilities of receiving an uptake of Americium 241, the chance of such as occurrence is less than a one in a million chance.

In another worst case example, if a sealed source were to be accidentally swallowed by a youngster after successfully prying open the smoke detector and the ion chamber, the source might lodge in his/her throat for a period of time, perhaps two weeks, in which case he/she might receive 50 Rems of dose to this area. If the source were to continue on instead of lodging in the throat, and spend a week in the gastrointestinal tract, chances are that for the source being as inert as it is, that less than 1 percent would get into the bodily fluids and less than 0.1 percent of the latter would get into the blood system. So beginning with less than one microcurie, then only 10 picocuries may expose the whole body blood, but the dose equivalent would be less than 15 Rems.

Further, lets assume a maximum storage at any one location at any time of 25,000 units. Lets also assume a carton contains 24 smoke detectors with a conservatively calculated surface dose of 9.1 uR/hr (hand) and 2.9 uR/hr at 6 inches (body). If a warehouse worker directly handled cartons 10 hours per week, the hand does would be 4.7 mr/yr and body would be 1.5 mr/yr. In actual practice, such handling would be much more intermittent

given the use of fork-lifts etc., and the calculations would be much smaller.

Lastly, there have been a vast number of other scenarios generated showing many different probabilities of hypothetical accidents. A number of these scenarios are in Amersham Corporation's radioactive material license files in your office. Please refer to them as part of our demonstration of creditable accidents beyond the one mentioned in the background to this section.

3.3.7 Installation

The detector is designed for ceiling or wall installation with screws and anchors. It is not portable and will be installed in a fixed location. The consumer will install the units.

We will provide two plastic anchors and screws for installation. First, the anchors will be installed (if drywall). Next the screws will be screwed into the anchors but not tightened. The detector will be hung on the screws and then the screws will be tightened down. At this point, it is permanently affixed.

Being a residential smoke alarm, the SN-100 series will be installed according to NFPA 72 and local building codes. Minimally, it will be installed at seven feet high on a wall (or higher on a ceiling) which typically will limit accessibility and exposure.

3.3.8 Radiological Safety Instructions

Nothing in addition to what has already been provided.

3.3.9 Documentation Accompanying the Device

Nothing in addition to what has already been provided.

3.3.10 Servicing

Not applicable

3.3.11 Leak testing

Not applicable except what has already been mentioned in Section 3.1.8.

3.3.12 Safety Analysis

All radiological elements of the SN-100 Series smoke detector are well documented. The Amersham and NRD sealed sources have been evaluated many times for the U.S. NRC with temperature, pressure, impact, vibration, and puncture tests conducted in accordance with ANSI 524 and ISO 2919 and found suitable for licensing purposes in the United States.

APPENDIX A

NRD INC.
2937 Alt Boulevard North, Grand Island, New York 14072-1292
Telephone: (716) 773-7634
FAX # (716) 773-7744

CERTIFICATE OF RADIOACTIVE SOURCE INTEGRITY

Specification: Americium-241 Alpha Foil Model NRD A001
Drawing Number: 85B026
Nuclide & Radiotoxicity Gp.: Americium-241 Group A
Maximum Activity: 0.9 microCuries
Classification Designation: ANSI/ISO C32222
Test Sources: Foil in source holder A-1056

Test	Temperature	Pressure	Impact	Vibration	Puncture
1					
2		Pass <0.05	Pass <0.05	Pass <0.05	Pass <0.05
3	Pass <0.05				
4					
5					
6					

Test carried out in accordance with ANSI-542 International Standard ISO 2919.

Leak Test: Immersion and Wipe

Additional information: Figures in Table denote activity (nCi) measured in liquid after immersion.

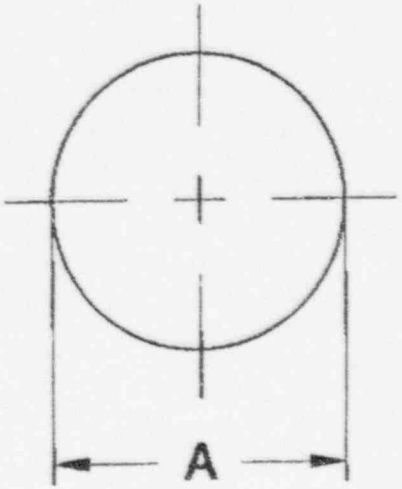
Lawrence Keating
Quality Control Department

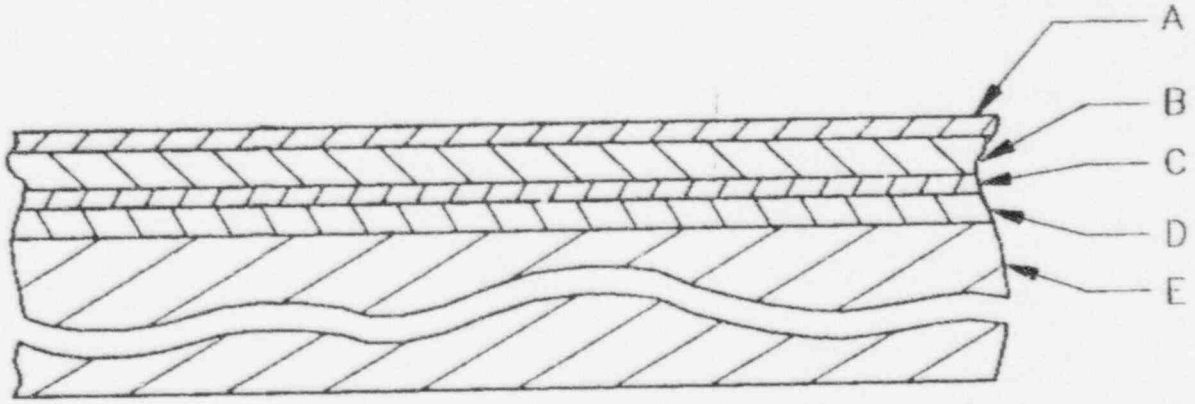
7/21/94
Date

Donald McGlynn
Source Department

A FOIL DIAMETER	
METRIC ±0.03 mm	DECIMAL ±0.001"
2.3 mm	0.092 in.
5.0 mm	0.197 in.
6.0 mm	0.236 in.
16.0 mm	0.629 in.

REVISIONS					
REV.	DATE	DESCRIPTION	AUTH	DR	CK
1	01MR91	REDRAWN ON AUTOCAD		CDD	
2	30JA92	LAYER A CHANGED: YELLOW GOLD WAS GOLD	J.J.	CDD	
3	04MR94	LAYER "B" CHANGED: GOLD OR PALLADIUM WAS GOLD	J.C.	CDD	JCJ





A. YELLOW GOLD PLATE 0.00002"
B. GOLD OR PALLADIUM 0.00004"
C. AMERICIUM 241 AND GOLD 0.00002"
D. GOLD 0.00003"
E. SILVER 0.004" TO 0.007"

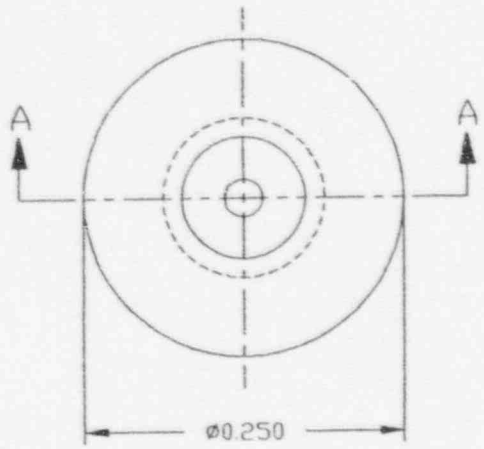
UNLESS OTHERWISE SPECIFIED	SIGNATURES	DATE
DIMENSIONS ARE IN INCHES	DRAWN R. BIDELL	
TOLERANCES ON:	CHECKED	
2 PL DECIMALS ±	APPROVED	
3 PL DECIMALS ±	APPROVED	
ANGLES ±	THIRD ANGLE PROJECTION	
FRACTIONS ±		
DO NOT SCALE PRINT		

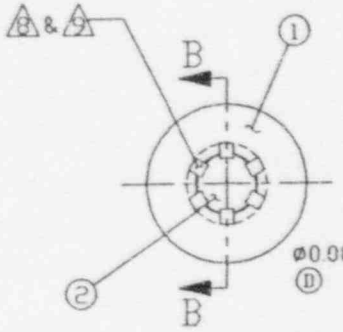
NRD INC.
A SUBSIDIARY OF MARK IV INDUSTRIES, INC.
2937 ALT BOULEVARD GRAND ISLAND, NEW YORK 14072

A-001 SINGLE FACE FOIL

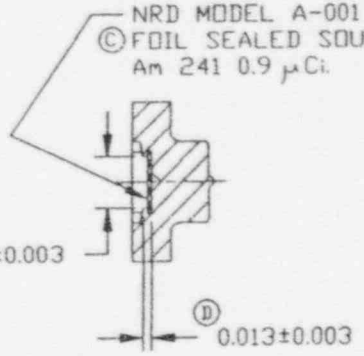
MATERIAL & FINISH	Am 241, GOLD, SILVER			
A	DATE 13AP79	SCALE NA	DWG NO 79A045	REVISION 3

DATE	SYM	REVISION RECORD	AUTH.	DR	CK.
05JUL85	A	ADD NOTE 4	TC	JES	
29APR87	B	CHANGE .030 +.005 -.003 TO .030 +.002 -.001		JES	
01DEC88	C	ADD FOIL NOTE		JES	
26AUG90	4	REDRAWN ON AUTOCAD		CDD	
27NOV90	D	DIM Ø0.096 WAS Ø0.098, Ø0.080 WAS Ø0.083, DIM 0.013 WAS 0.015, CHANGED TO A 6 STAKE ASSY	JES	CDD	
07JA91	6	SPEC 10 CALLOUT ADDED	DH	CDD	
16JA91	E	DIM 0.063 +0.001 -0.002 WAS 0.060 +0.002 -0.002	TC	CDD	

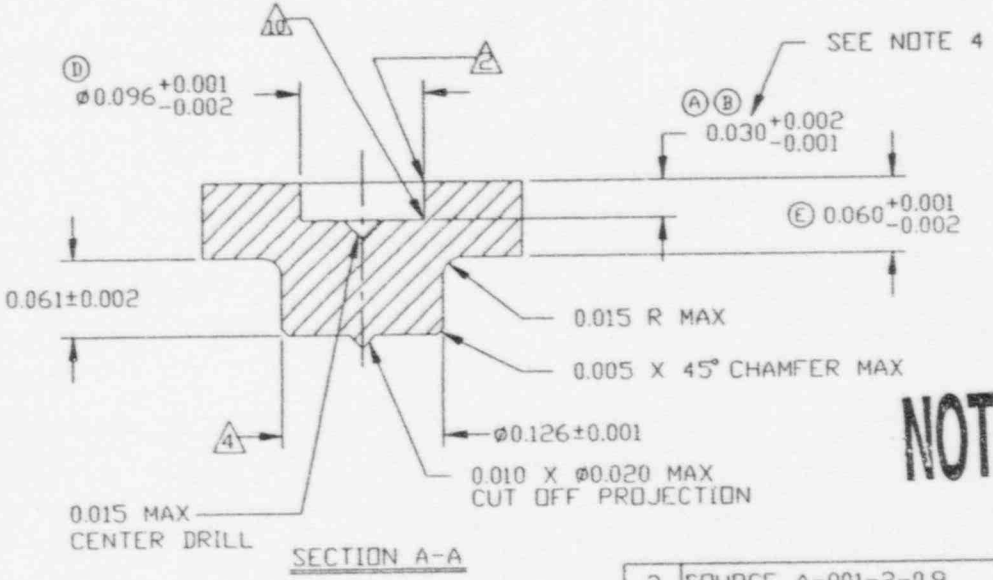




SOURCE AND SOURCE HOLDER IN THE ASSEMBLED STATE.



SECTION B-B
FIVE TIMES SIZE



SECTION A-A

NOTES:

1. SOURCE HOLDER AND SOURCE HOLDER ASSEMBLY MUST COMPLY WITH NRD SPECIFICATION 2016 DATED 2/8/85.
2. NUMBERED △ REFER TO SPECIFIC NOTES.
3. ALL DIMENSIONS ARE IN INCHES.
4. (A) EACH SHIPMENT, 0.030 DIMENSION MUST BE HELD TO ±0.001 WITHIN THE +0.002 -0.001 TOLERANCE.

NOT TO SCALE

NO.	DESCRIPTION	DWG.	REQ'D	MAT'L
2	SOURCE A-001-2-0.9	79A045	1	COMB.
1	SOURCE HOLDER A-1056	85B026	1	S. STEEL

NRD DIV. MARK IV IND. INC.
2937 ALT BOULEVARD GRAND ISLAND, NEW YORK 14072

TOLERANCES (EXCEPT AS NOTED)	TITLE: SOURCE HOLDER MODEL A-1056		
DECIMAL ± 0.005	MATERIAL & FINISH: SEE NRD SPEC 2016	SCALE: 10 : 1	DRAWN BY: JES
FRACTIONAL ±			APPROVED BY:
ANGULAR ± 1°	DATE: 07FE85	DWG. NUMBER: 85B026	R.

DATE	SYM	REVISION RECORD	AUTH.	DR.	CK.
29NO90	1	NOTE 3 & 6 CHANGED: Ø0.096 WAS Ø0.098, Ø0.094 WAS Ø0.096		CDD	
04JA91	2	NOTE 2 CHANGED: 0.001 WAS 0.003	JES	CDD	
07JA91	3	NOTE 10 ADDED	DM	CDD	
22NO91	4	NOTE 1 CHANGED: B90 WAS B100	JS	CDD	
12DE91	5	NOTE 1 CHANGED: B100 WAS B90 NOTE 11 ADDED	DM	CDD	
23JN92	6	HARDNESS SPEC REVISED; PAGE 1 OF 2 REMOVED FROM TITLE; NOTE 3 REVISED	T.C.	CDD	JA

GENERAL NOTES FOR STAINLESS STEEL SCREW MACHINE HOLDERS:

1. MATERIAL: 303 STAINLESS STEEL
   FINISHED SOURCE HOLDER HARDNESS: ROCKWELL B100 MAX.
2. COUNTERBORE TO HAVE SHARP CORNERS, 0.001" MAX. COUNTERBORE SURFACE TO BE FLAT AND FREE FROM PROJECTIONS.
3. CONCENTRICITY TO BE WITHIN 0.003" ON ALL DIAMETERS.
4. ROUNDNESS TO BE 0.001" MAX.
5. SURFACE FINISH TO BE NO GREATER THAN 90 MICRO INCHES UNLESS OTHERWISE SPECIFIED. SHARP CORNERS NOT TO EXCEED 0.005" RADIUS.
6. SOURCE HOLDER CAVITY MUST PASS A Ø0.094" PLUG GAUGE CHECK.
7. AFTER MACHINING, PARTS SHOULD BE DEBURRED, PASSIVATED, AND THEN DEGREASED.
8. AFTER ASSEMBLING, CRIMPED TABS SHOULD HOLD FOIL FIRMLY TO THE BOTTOM OF THE FOIL CAVITY. CRIMPED SURFACES SHOULD BE FREE FROM CRACKS OR FLAWS.
9. SOURCE MUST REMAIN FLAT AND FREE OF DISTORTIONS AFTER CRIMPING.
10. CORNERS TO BE SHARP, 0.003" MAX.
11. CUT OFF BURR NOT TO EXCEED 0.003" HIGH X Ø0.015".

FOIL MODEL	A-001
RIVET MODEL	A-1056
ASSEMBLY MODEL	———
ENCAPSULATION CODE	I-405
PROTOTYPE TESTS	11211111
Q.C. TESTS	AGRSVW

NRD INC.
A SUBSIDIARY OF MARK IV INDUSTRIES, INC.
2937 ALT BOULEVARD GRAND ISLAND, NEW YORK 14072

TOLERANCE (EXCEPT AS NOTED)	TITLE: NRD SPECIFICATION 2016		
DECIMAL ±	MATERIAL & FINISH	SCALE	DRAWN BY
FRACTIONAL ±			APPROVED BY J.M.
ANGULAR ±	DATE 08FE85	DWG. NUMBER SPEC FOR 85B02E	6

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

(Corrected Copy)

NO.: NR1365174U DATE: October 26, 1979 PAGE 1 OF 4

SEALED SOURCE TYPE: Foil Source

MODEL: AMM1001, AMM1001H

MANUFACTURER/DISTRIBUTOR: Amersham Corporation
2636 S. Clearbrook Drive
Arlington Heights, IL 60005

MANUFACTURER/DISTRIBUTOR:

ISOTOPE: Americium-241 MAXIMUM ACTIVITY: 50 microcuries per square cm of foil

LEAK TEST FREQUENCY:

PRINCIPAL USE: Ion Generators, Smoke Detectors

CUSTOM SOURCE: ___ YES _X_ NO

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

NO.: NR136S174U DATE: October 26, 1979 PAGE 2 OF 4

SEALED SOURCE TYPE: Foil Source

DESCRIPTION:

The Model AMM 1001 sealed source consists of americium oxide uniformly distributed and sintered in a pure gold matrix which is further contained between a backing of gold coated pure silver and a front covering of either gold or gold-palladium alloy and fabricated by hot forging methods. The continuously welded metal layers are rolled so that the minimum thickness of the layers are:

gold-palladium alloy	0.0015 mm
americium oxide plus gold	0.0001 mm
gold	0.0001 mm
substrate	0.20 mm

Sub-division of the rolled foil is accomplished by cutting or punching into discs of 5 mm diameter or strips of say 2 mm x 10 mm diameter. At the activity loading specified above, there is no loose or wipable contamination above the wipe test limit of 0.005 microcuries.

The Model AMM 1001H mounted sealed source consists of a sized foil mounted in a "T" shaped standard holder constructed of tin plated brass. Lips of the source holder are rolled over the edge of the foil so the cut edges of the foil are not exposed. The larger diameter of the holder is approximately 5 mm and the length is approximately 6 mm. The useful life is 20 years.

LABELING:

Neither the foils nor mounts are labeled. This evaluation does not describe possible A/S foil sources distributed under other model designations nor sources previously distributed under "AMM" designation.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

NO.: NR136S174U DATE: October 26, 1979 PAGE 3 OF 4

SEALED SOURCE TYPE: Foil Source

DIAGRAM:

A - (i) Palladium ~ 0,002 mm
(ii) Gold ~ 0,0002 mm
B - Americium Oxide plus Gold ~ 0,002 mm
C - Gold ~ 0,001 mm
D - 0,20 - 0,25 mm
E - Gold - < 0,001 mm

PROTOTYPE TESTING:

Prototype Model AMM 1001 blanked sealed sources and Model AMM 1001H mounted sources have been tested to conditions described by USASI standard N5.10-1968 and respective classifications of C54545 and C44444 have been demonstrated. Results of wipe tests of the tested foils were acceptable to less than 0.005 microcuries. In addition, AMM 1001 samples have successfully passed "special form" testing conditions.

Model AMM 1001 foils have experienced the following additional tests:

1. Immersion in water of prototype foils for 3 weeks at room temperature: less than 0.001 microcurie per foil loaded at maximum activity was found in the water.

2. Immersion in 0.1 N hydrochloric acid for 24 hours at room temperature: less than 0.004 microcurie activity was leached out.

3. Foils were subjected to tests in moist air, dry air, sulfur dioxide fumes, hydrochloric acid fumes, ammonia vapor, to repetitive wipe tests (5000X) and welding tests: less than 0.005 microcurie wipable contamination was found. Shelf-life tests of foils with 50 microcuries/cm² loading show no deleterious aging effects after 6 years.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

NO.: NR1365174U DATE: October 26, 1979 PAGE 4 OF 4

SEALED SOURCE TYPE: Foil Source

PROTOTYPE TESTING (CONT'D):

Foils and mounted foils have been subjected to ozone at 0.75 ppm for a period of 60 days and salt spray for 16 days without deleterious results.

QUALITY ASSURANCE AND CONTROL:

Not less than 10 percent of the Model AMM 1001H sources are checked by gamma counting to ensure that the activity in each foil is within specified limits. Each product is visually inspected to check that the rolled-over edge is satisfactory and that the alpha emitting surface is free from surface defects. Each source is wipe tested to an acceptance limit of 0.005 microcuries.

In addition to the above, each Model AMM 1001 foil is checked by alpha spectrometry to determine the adequacy of the gold cover.

REFERENCES:

Date October 26, 1979 Reviewed By /s/
Joseph M. Brown, Jr.

Date October 26, 1979 Concurrence /s/
Earl G. Wright

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

2|2

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

AMENDMENT NO. 1
CERTIFICATE OF REGISTRATION
AND SAFETY ANALYSIS SUMMARY
SEALED SOURCE

Manufacturer and Distributor

Amersham Corporation
2636 S. Clearbrook Drive
Arlington Heights, IL 60005

Sealed Source Model Designation

(Foil) AMM 1001
(Mounted Foil) AMM 1001H

Isotope

Americium-241

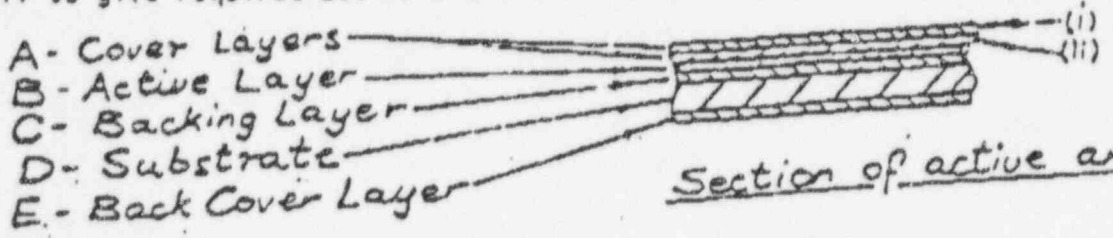
Maximum Activity

Up to 5 microcuries in 5 mm dia. disc. and up to 50 microcuries/cm^2 of foil

In accordance with request dated September 20, 1979 this certificate is amended as follows:

Description of Foil Source

The general construction of foil, identified as model AMM 1001 is typically as shown in the sketch below. The radionuclide as americium oxide is uniformly distributed and sintered in a matrix of fine gold at temperatures in excess of 800°C. It is further contained between a backing of gold or gold/palladium alloy or palladium and gold by hot forging. The metal layers now continuously welded are extended in area by means of a power rolling mill to give required active and overall areas.



A - (i) Palladium ~ 0,002 mm
(ii) Gold ~ 0,0002 mm
B - Americium Oxide plus Gold ~ 0,002 mm
C - Gold ~ 0,001 mm
D - 0,20 - 0,25 mm
E - Gold - < 0,001 mm

Date October 26, 1979

Reviewed By Joseph M. Hennessey Jr.

Date October 26, 1979

Concurrence Earl G. Wright

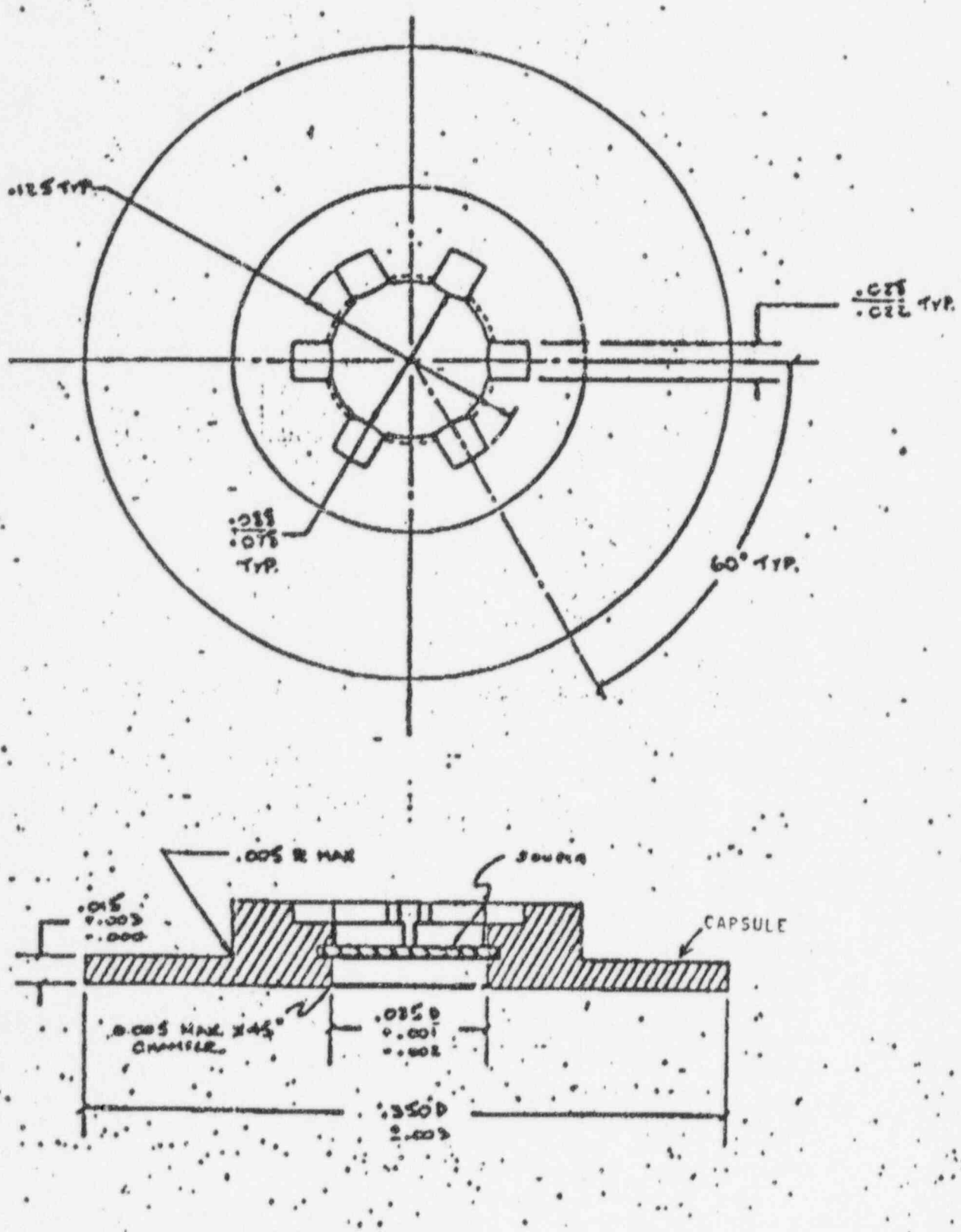
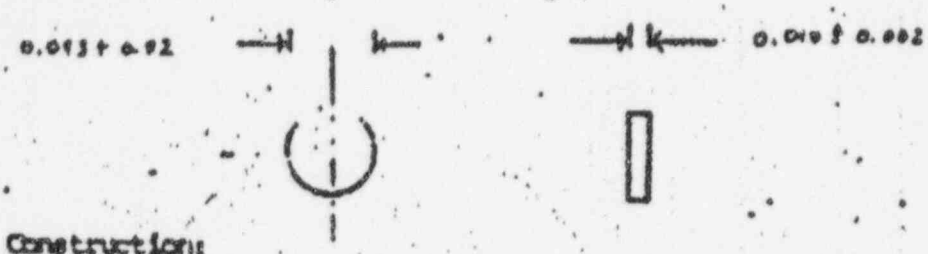


Figure 1a. Americium source mounted in aluminium capsule

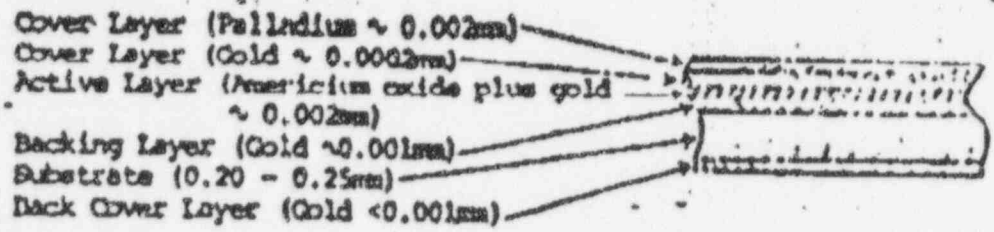
Notes:

(1) Radiation/Source Specifications:

A. Radioisotope: Americium-241
B. Maximum Activity: 1.0 μCi
C. Alpha Energy: 4.2 - 4.8 MeV
D. Source Dimensions:



E. Source Construction:



The radionuclide, as americium oxide, is contained uniformly distributed, and sintered in a matrix of fine gold at temperatures in excess of 800°C. It is further contained between a gold coated substrate of pure fine silver and a front covering of palladium-gold laminate by hot forging. The metal layers, now continuously welded, are extended in area by a power rolling mill to give required active and overall foil areas.

F. Sources are to be wipe tested to 0.005 μCi contamination max.

(2) Source Holder Specifications:

A. Material: H 54-21, 303 Stainless Steel

(3) Source Assembly Specifications:

A. Assemblies are to be wipe tested to 0.005 μCi contamination max. certification required on each lot.

B. Source active face located in down position in assembly drawing.

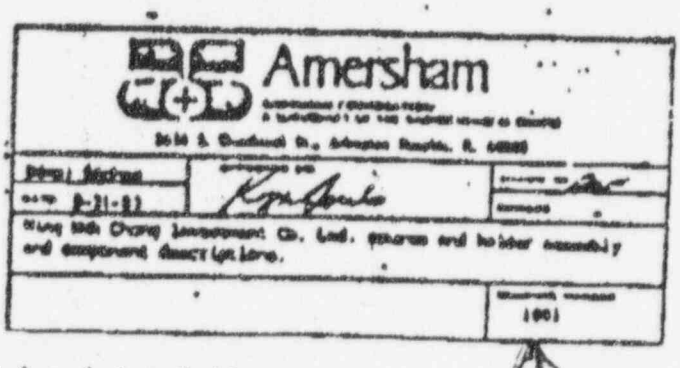


Figure 1 Cross section of Americium foil

1001-7

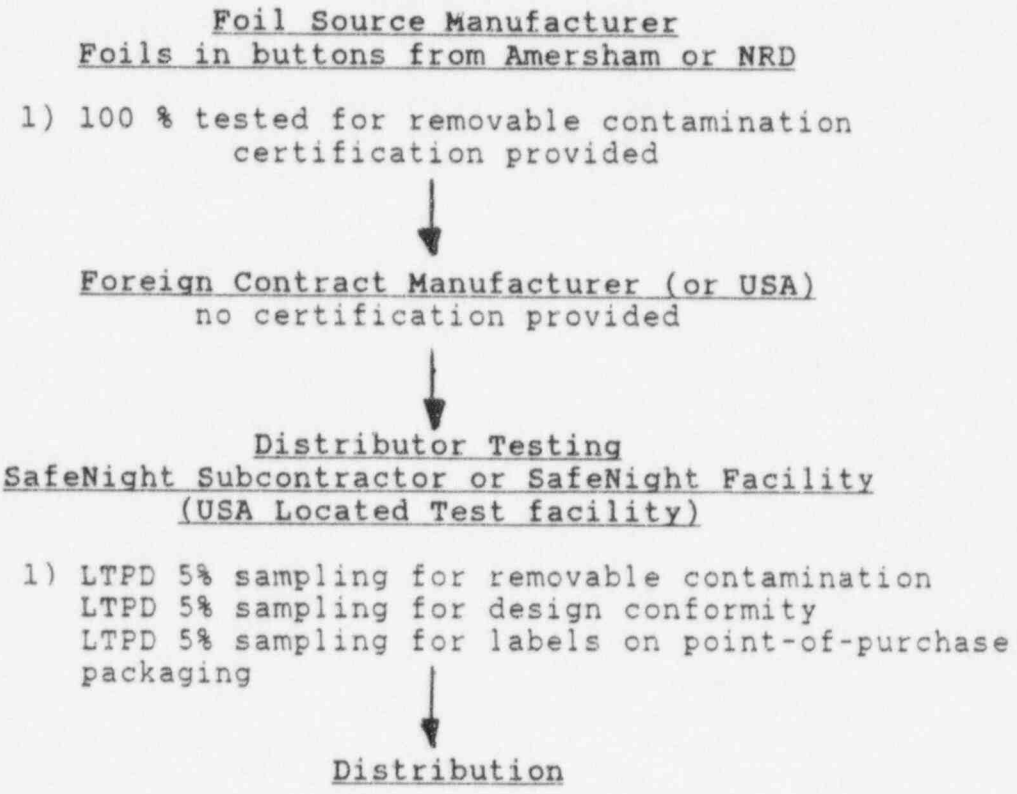
APPENDIX B

QUALITY CONTROL PROGRAM
FOR SAFENIGHT TECHNOLOGY INC.
U.S.NRC SECTION

Basic QC Specifications Flow Chart

SafeNight's Quality Control/ Quality Assurance Flow Chart will occur in one of two ways:

A) Primary checking at USA SafeNight subcontractor or company facility



1. ORGANIZATION

QA Director - President or other officer of SafeNight Technology Inc.
Has the authority, access to work areas, and organizational freedom to identify quality problems, recommend or initiate solutions, verify implementation of solutions, and halt scheduled distribution at any time to ensure that the devices conform to all regulations and specifications. Reviews audits done to insure compliance to QA program.

Name_____

Telephone_____

QA Manager - USA test location manager.
Has the authority, access to work areas, and organizational freedom to identify quality problems, recommend or initiate solutions, verify implementation of solutions, and halt scheduled distribution at any time to ensure that the devices conform to all regulations and specifications.

Name_____

Telephone_____

Location Inspector(s) - USA location inspector. May be the same person as the QA manager. Reports to the QA Manager.
Person or persons responsible for directly inspecting/testing US NRC critical device elements prior to distribution. Responsible to immediately notify the QA Director and QA Manager of any nonconformity.

a) Removable contamination
b) Design conformity
c) Labels on point-of-purchase labels

NRC Contact - the current name, telephone number, and address of the NRC contact.

NRC Contact Name_____

Address_____

_____

_____

Telephone_____

4. DESIGN AND DOCUMENT CONTROL

- SafeNight will insure that all appropriate documents used in the testing and inspection of the device are up to date.

- The USA test location is to maintain only the current NRC approved and licensed drawings. Pending NRC amendments would not be present.

- As soon as a document has been amended and approved by the NRC, SafeNight will insure all old copies of the document are replaced and kept in history files.

- A file will be kept for each different inspection/testing document.

  - approved NRC drawings and specs

  - each equipment instructions

  - each equipment log

  - employee training records

  - QC manual

  - a Verification of Conformance Form

  - nonconforming material report

  - contract manufacturer chamber shipping document

  - other as identified

5. MATERIAL AND SERVICE PROCUREMENT

- SafeNight will keep on file certification that our ion chamber manufacturer gets their source in a button from either Amersham or NRD

6. INVENTORY

Raw Components Inventory

Process

a) the raw component lot is received with shipping documentation
b) documentation is confirmed with a physical count
c) lot is placed in holding segregated from previously tested, inspected, and approved lots
d) the sample is sent to test and inspection

Finished Goods Inventory

Process

a) the manufactured lot is received with shipping documentation
b) documentation is confirmed with a physical count
c) lot is placed in holding segregated from previously tested, inspected, and approved lots
d) a representative sample is taken from lot according to LDPT 5% tables - Figure 6 (P. B32)
e) the sample is set to test and inspection
f) upon 100% successful inspection of sample, lot is moved to an approved lot location

7. PRODUCTION PROCEDURES AND PROCESSES

- Applicant under its distribution license of devices will not perform any electronic repairs to nonconforming devices.

- It is possible that SafeNight or its subcontractor under terms of a possession license would want to replace labels or point-of-purchase packaging if finished products arrive nonconforming.

8. INSPECTION AND TESTING

I. Raw Component Testing

a) prior to contract manufacturing of finished device, a LTPD 5% sample (Figure 6) of each new shipment of ion chambers and/or screws holding chamber to PCB to the contract manufacturer will be sent to the USA Test Location from the contract manufacturer for design/destructive testing. The contract manufacturer will be required to segregate ion chamber/screw shipments until approval from the test location is forthcoming through SafeNight Corporate. Documentation as to the size and handling of the received lot of ion chambers will be required with the sample shipment. A form similar to Form 3 on P. B22 will be used.

b) those chambers will be disassembled and inspected for design conformity
   1)individual parts are of correct dimension per current NRC license drawings (Figures 1,2,3,3A,4 - PP. B26-30)
   2)materials appear consistent with specs (Figure 1)
   3)screw holding chamber to PCB is the right size and length
      a) screw length will be compared to chamber female fitting depth and current PCB production thickness to insure that the screw does not come in contact with source button.
   4)any non-conforming units will be tagged, marked, stamped or segregated from conforming units

c) those chambers will be subject to wipe testing prior to destructive testing

d) destroyed chambers will either be returned to the ion chamber manufacturer or the source and button manufacturer

e) pass or fail notice will be sent to SafeNight Corporate on that shipment lot.
   1) a Verification of Conformance form similar to Form 4 (P. B23) or a Nonconforming Material Form similar to Form 5 (P. B24) will be filled out and placed on file
   2) SafeNight Corporate will notify contract manufacturer of conformance or nonconformance of lot.

II. Finished Goods Testing

a) A random sample drawn from newly received and untested lot arrives in USA test location.

b) 5% LTPD testing and inspection points (the test order may change)

1) design conformity of point-of-purchase packaging - required verbiage per CFR 32.26 5(d) or equivalent
   a) "Contains Radioactive Material Americium 241 0.9 Microcuries"
   b) "U.S. NRC License No. XXX"
   c) "THIS DETECTOR CONTAINS RADIOACTIVE MATERIAL AND HAS BEEN MANUFACTURED IN COMPLIANCE WITH U.S. NRC SAFETY CRITERIA ON 10 CFR 32.27. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS."
2) chamber screw on side of chamber is soldered
3) chamber leads soldered to PCB and IC respectively
4) chamber is snugly secured by the screw on underside of the PCB
5) PCB size thickness is within NRC submitted range - Figure 5 P. B31.
6) PCB is held in place in the plastic housing by 4 or 5 plastic clips
7) plastic housing is within NRC submitted range - dia - 5.0" +/- 2.0"
   thickness - 2.0" +/- 1.0"
8) radiation wipe test the exterior surface of the ion chambers on all 5% sampled units. A maximum of 75 units will be tested per wipe. The trigger level for multiple units using one swipe is 0.005 microcurie.
9) visually inspect all chambers for design conformity
   a) check for proper label on each chamber (required verbiage per CFR 32.26 5(d)) "CONTAINS RADIOACTIVE MATERIAL AMERICIUM 214 0.9 MICROCURIE" and U.S. NRC License No. XXX"
   b) visually compare chamber with drawings of chamber in NRC license
10) assuming 100% conformance of the sample, samples may move on to other non-NRC quality testing or be returned to inventory
   a) a verification of conformance form similar to Form 4 (P. B23) will be filled out and placed on file

9) NONCONFORMING MATERIAL

If defective units are found within the sample, the entire lot will be rejected or inspected for conformance to the quality characteristic(s) in which the sample units were found to be defective. Inspection of the entire lot will be limited to the nonconforming characteristic or characteristics.

Process

a) a report similar to Form 5 (P. B24) will be filled out

b) entire lot will be tested at test location
   1) conforming items are separated from nonconforming ones
      a) nonconforming items are corrected on-site assuming local possession license permits such
         1) a report similar to Form 3 will be filled out
      b) nonconforming items are returned to the contract manufacturer or other contractor for correction or disposal

c) entire lot will be returned to the contractor manufacturer or other contractor
   1) upon its correction and return to the test location, it will be treated as a new lot and resampled, tested, and inspected.

10. PACKAGING AND TRANSPORTATION

Process

a) shipping records will be kept - as to date, shipping destination, lot and lot quantity
b) shipments will be shipped according to current DOT regulations

11. DEVIATIONS AND CUSTOMER COMPLAINTS

- customer complaints may be received a one of several sites

  a) SafeNight customer service location - likely SafeNight corporate headquarters or other contracted service location in relatively close proximity to headquarters
  b) Test or distribution staging sight - will be turned over to the SafeNight customer service location for action
  c) Manufacturing facility - will be turned over to SafeNight customer service location

Customer complaint process

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 will be held in computer database or manual NRC file for periodic trend analysis

A form similar to Form 6 (P. B25) will be used if the complaint is related to SafeNight's NRC license or registration.

NRC Notification Process

a) Is the failure related to the SafeNight license or registration of the product?

   Yes - notify the NRC
   No - no notification is required

12. AUDITS

SafeNight Audit Procedures

A. Frequency
   - audits will be conducted at least yearly

B. Scope
   1) audit scope will include all areas of this document
   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/inspection 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 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 lots?

___ 18) Are they kept separated until after the lot 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 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)

___ l)a verification of conformance form similar to Form 4 filled out and placed on file

Nonconforming Materials

___ 25) Are nonconforming device lots separated from conforming ones?

___ 26) If any nonconforming items are found in a lot, is the entire lot tested or inspected?

___ 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 lot (from the contract manufacturer or other correction location) tested and inspected as a newly arriving 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?

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):___

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

VERIFICATION OF CONFORMANCE

DATE RECEIVED:_____ VOCR#_____

TYPE OF GOODS INSPECTED (check one only):

ION CHAMBERS: ___
Screws : ___

FINISHED SMOKE DETECTORS AND PACKAGING: ___

SUPPLIER: _____

LOT/NUMBER IDENTIFICATION:_____

LOT SIZE QUANTITY: _____

SAMPLE SIZE: _____

This certificate assures that the above goods meet all SafeNight QC NRC licensed specs with zero defects.

Company Name:_____

Inspected By:

_____
Signature Date

Approved By:

_____
Signature Date

_____
Title

Notification sent to SafeNight Corporate(Y/N) ___

Date Sent_____

By (initials)_____

F O R M 4

NONCONFORMING MATERIAL REPORT

DATE RECEIVED:_____ NCMR#_____

TYPE OF GOODS INSPECTED (check one only):
ION CHAMBERS: ___
Screws : ___
FINISHED SMOKE DETECTORS AND PACKAGING: ___
SUPPLIER: _____
LOT/NUMBER IDENTIFICATION:_____

LOT SIZE QUANTITY: _____

SAMPLE SIZE: _____

INSPECTOR NAME:_____

DESCRIPTION OF NONCONFORMANCE:_____
_____
_____
_____

ACTION TAKEN:
A) ENTIRE LOT INSPECTED ___
QUANTITY FAILING _____
REWORK QUANTITY _____
ACTION TAKEN_____

RETURN TO SUPPLIER QUANTITY _____

B) ENTIRE LOT RETURNED TO SUPPLIER ___

REWORK/REINSPECT:

_____
Signature Date

_____
Approval Signature Date

_____
Title

Notification sent to SafeNight Corporate(Y/N) ___

Date Sent_____

By (initials)_____

F O R M 5

NRC CUSTOMER COMPLAINT FORM

DATE: _____
CALL/LETTER RECORDED BY: _____

CUSTOMER NAME: _____

ADDRESS: _____

_____

TELEPHONE: _____

DEVICE MODEL: _____ OTHER ID OF MODEL: _____

PROBLEM: _____

_____

_____

RESPONSE TO CUSTOMER/ACTION TAKEN: _____

_____

_____

CAUSE OF FAILURE _____

_____

LIST OF CUSTOMERS EFFECTED _____

ACTIONS TO BE TAKEN BY EFFECTED CUSTOMERS _____

_____

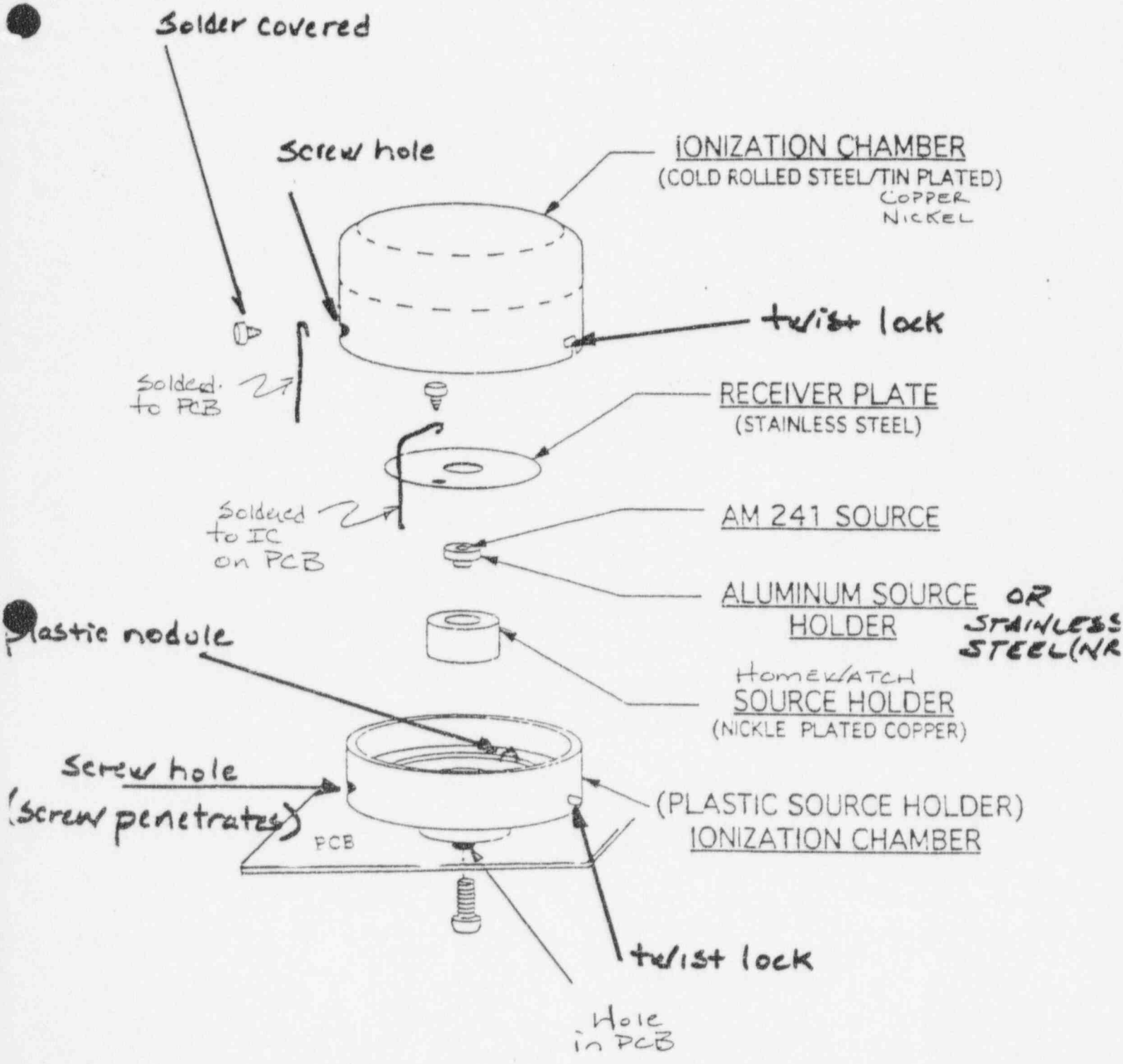
_____

APPROVED BY: _____
CORPORATE OFFICER

NRC NOTIFIED ON: _____
DATE

F O R M 6

FIGURE 1



CONTAINMENT OF SOURCE WITHIN DETECTOR

FIGURE 1

CHAMBER CONSTRUCTION

Pg(5)

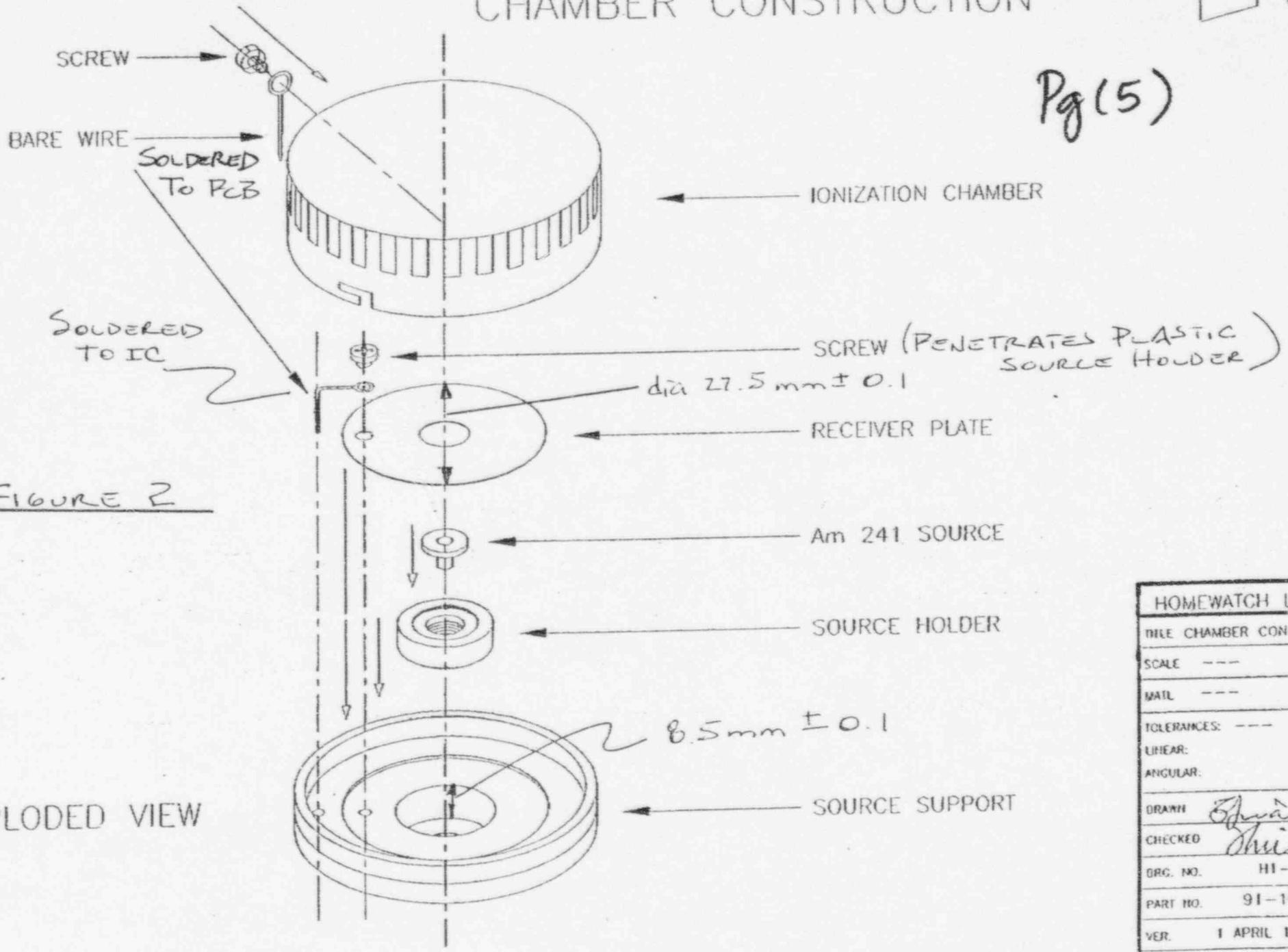


FIGURE 2

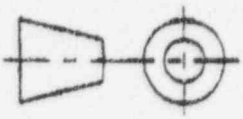
EXPLODED VIEW

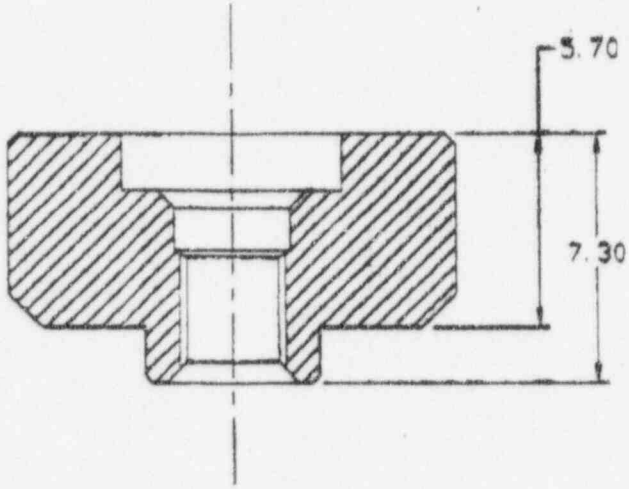
HOMEWATCH LIMITED	
TITLE	CHAMBER CONSTRUCTION
SCALE	---
MASS	---
TOLERANCES: LINEAR: ANGULAR:	---
DRAWN	
CHECKED	
DRG. NO.	H1-100C
PART NO.	91-101001
VER.	1 APRIL 1991 (A)
SHEET	ONE ONLY

NO ALTERATIONS WITHOUT DRAWING OFFICE APPROVAL

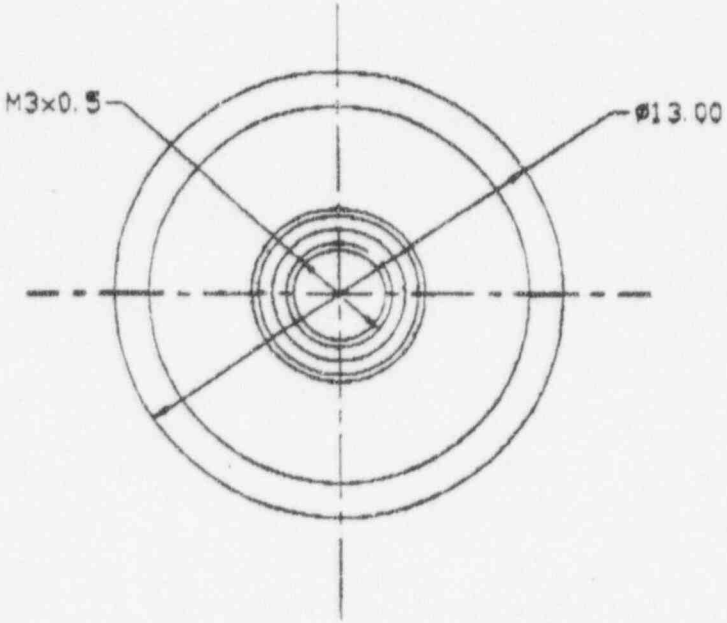
HW

Pg (4)





SECTION AA FRONT



BASE

FIGURE #3

HOMEWATCH LIMITED	
TITLE	NRD SOURCE HOLDER
SCALE	NOT TO SCALE (mm)
MAT.	BRASS plated with Ni
TOLERANCES:	
LINEAR:	±0.2
ANGULAR:	±0.2
DRAWN	
APPROVED	
DWG. NO.	HW-M18
DATE	1 APR 92
VER.	
PART NO.	

HW

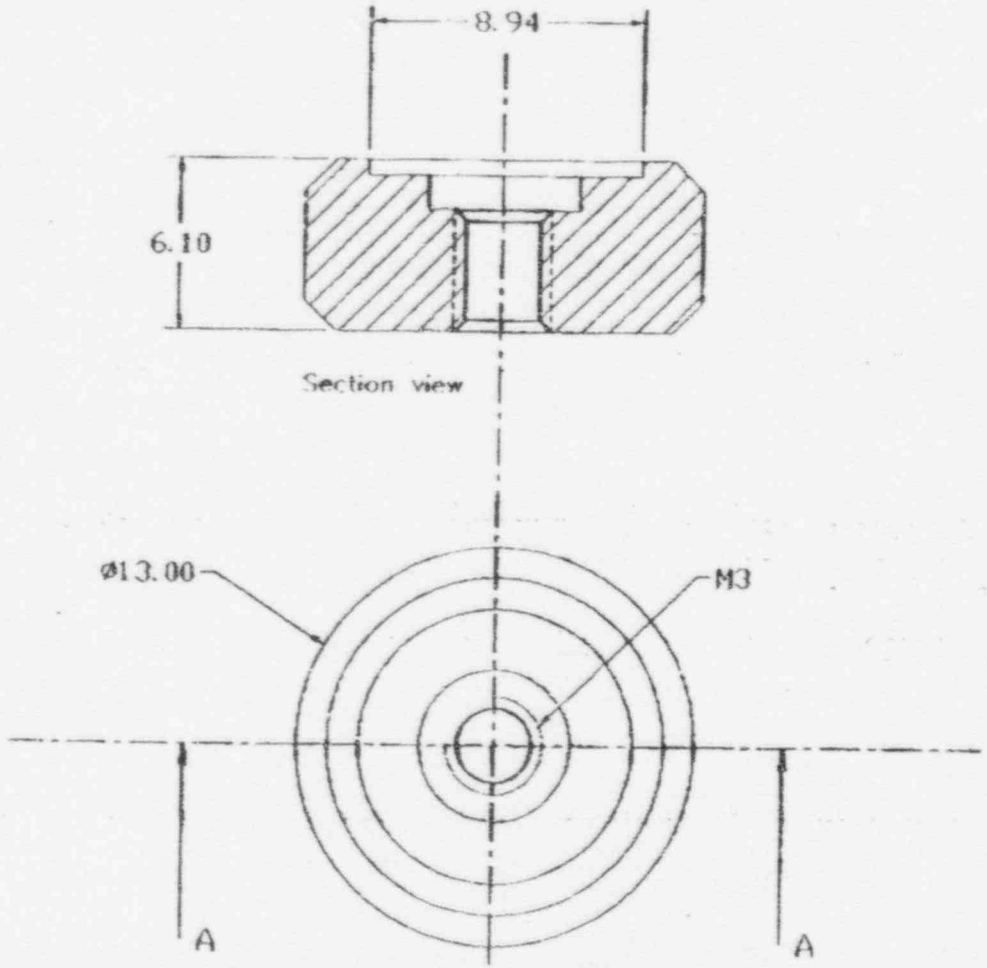


FIGURE 3A

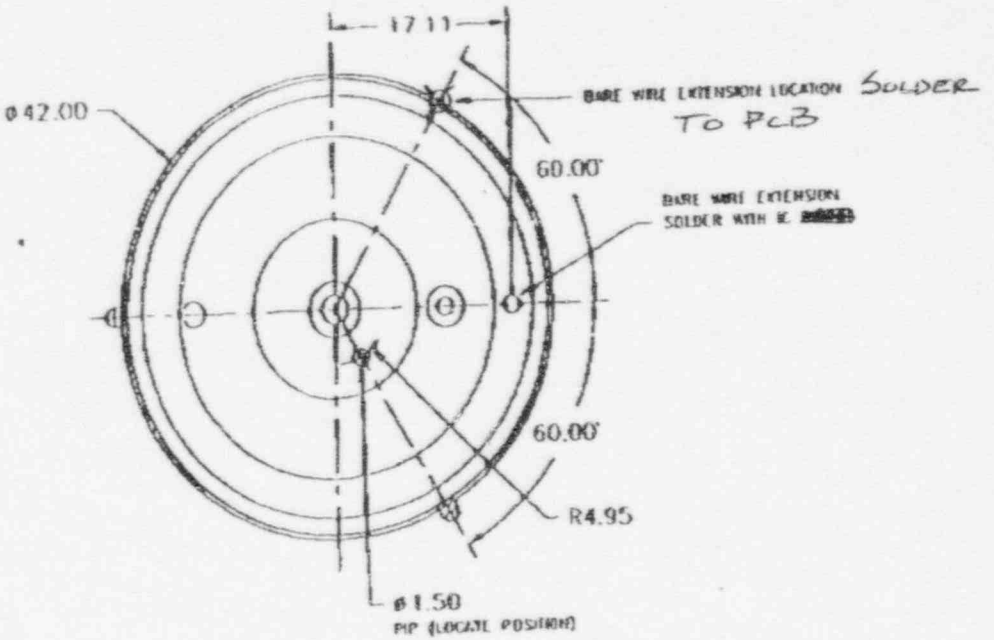
7

B29

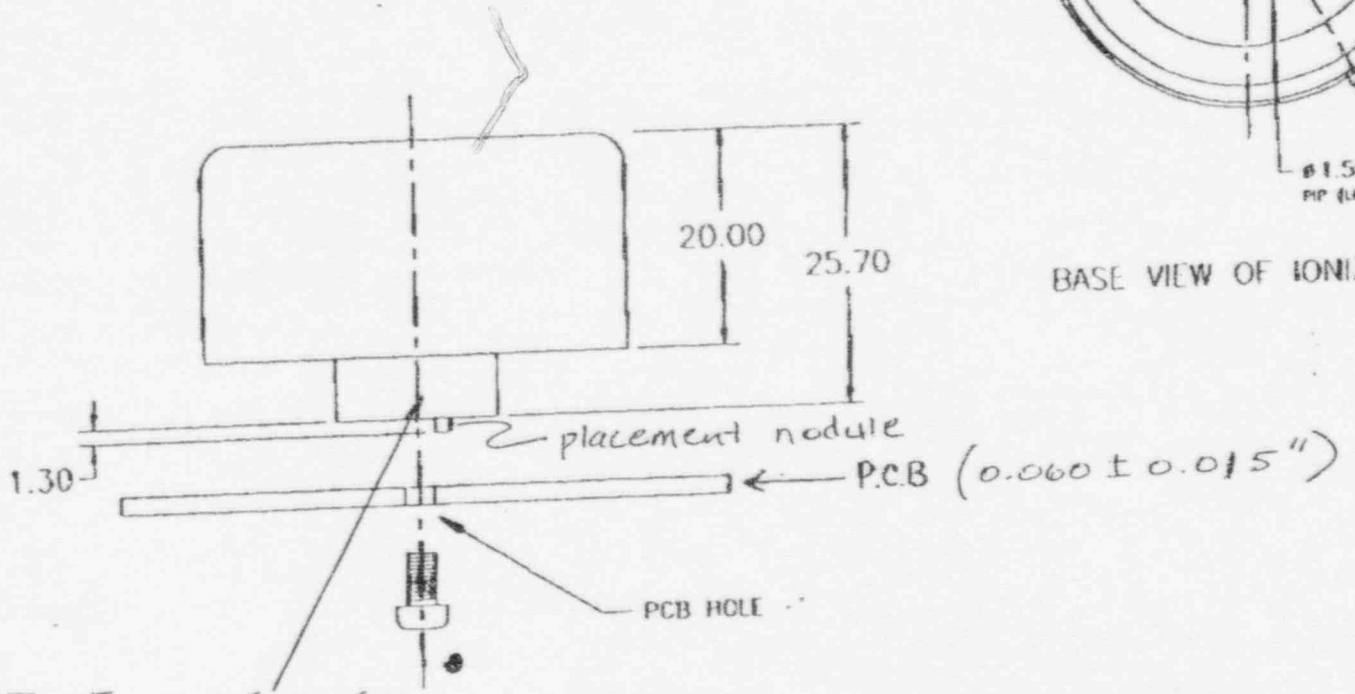
HOMEWATCH LIMITED	
TITLE	Source Holder (Amersham)
SCALE	4 : 1
MAT'L	Brass plated with Nickel
TOLERANCES: LINEAR: ANGULAR:	
DRAWN	Edwin Wong.
APPROVED	
DWG. NO.	HT-008C
DATE	1/4/1991
REVISION	

JCW

FIGURE 4



BASE VIEW OF IONIZATION CHAMBER



B30

HOMEWATCH LIMITED	
TITLE	DIMENSION OF IONISATION CHAMBER
SCALE	1:0.7 (UNIT=mm)
MATL	Unless noted
TOLERANCES:	
LINEAR	
ANGULAR	
DRAWN	
CHECKED	
DRG. NO.	
PART NO.	
REV.	13 NOV 1993
SHEET	ONE ONLY

NO ALTERATIONS WITHOUT DRAWING OFFICE APPROVAL

JCW

28 MAY 09,'94 07:55AM SCI PLANT 1

P.1

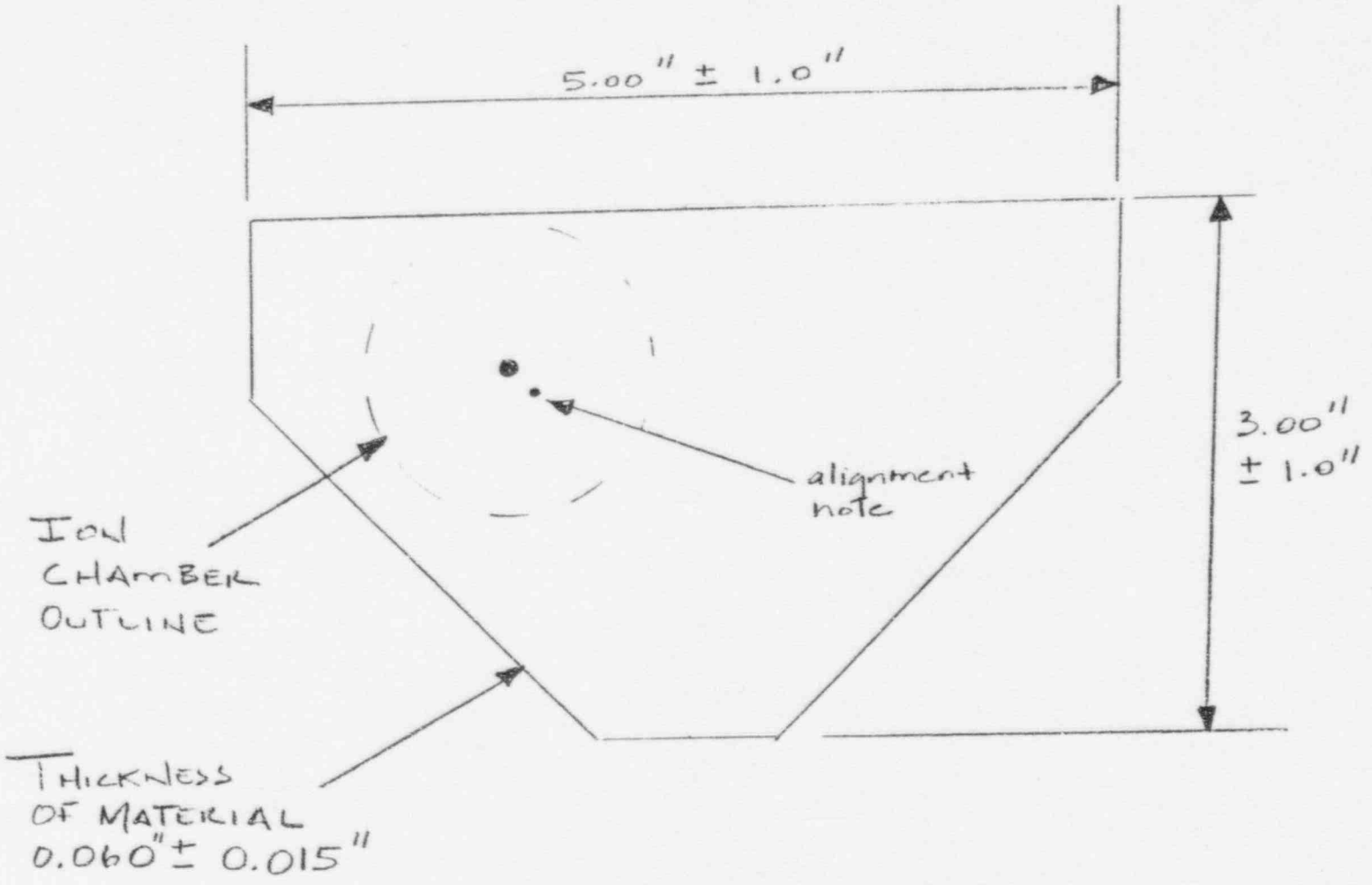


FIGURE 5

PCB LAYOUT
NOT TO SCALE

LTPD = 5 % TABLE

LOT SIZE	N(SAMPLE SIZE)	C(DEFECTS ALLOWED)
1-30	ALL	0
31-50	30	0
51-100	37	0
101-200	40	0
201-300	43	0
301-400	44	0
401-2000	45	0
2001-100,000	75	0

F I G U R E 6

NRC FORM 567
(8-93)

U. S. NUCLEAR REGULATORY COMMISSION

REQUEST FOR A SEALED SOURCE OR DEVICE EVALUATION

INSTRUCTIONS: Send this request AND a copy of all related letters/applications and drawings to: The Sealed Source Safety Section, ATTN: Chief, OWFN Mail Stop 6 H3. Change the License Tracking System milestone to 19 and assign to reviewer code I-5.
NOTE: Retain a copy of this request with the application and background files.

REQUESTER		REGION/LOCATION: ☐ I ☐ II ☐ III ☐ IV ☐ V ☐ HQ ☐ LFDCB
Mitchell		
TELEPHONE NUMBER: 415-6062	DATE: 8-4-94	TYPE OF ACTION REQUESTED (Check as appropriate)
APPLICANT'S NAME: Sheepskin Corporation		☐ SOURCE REVIEW ☐ AMENDMENT OF REGISTRATION SHEET NUMBER(S)
MAIL CONTROL NUMBER(S): 021654		☐ DEVICE REVIEW
LETTER/APPLICATION DATE: 4-8-94	LICENSE NUMBER(S): [illegible]	☐ CUSTOM REVIEW _____

COMMENTS:

FOR SSSS USE ONLY

REVIEWER	MODEL NUMBERS	NUMBER ASSIGNED
DATE RECEIVED	DATE ASSIGNED	DATE TO FEES

TYPE OF ACTION (Indicate the number of each type)

☐ COMMERCIAL DISTRIBUTION (FORMAL) ☐ USE BY A SINGLE APPLICANT (CUSTOM)

SOURCE (9C)	DEVICE (9A)	SOURCE (9D)	DEVICE (9B)
☐ NEW ☐ AMENDMENT	☒ NEW ☐ AMENDMENT	☐ NEW ☐ AMENDMENT	☐ NEW ☐ AMENDMENT

☐ NO SAFETY EVALUATION REQUIRED NO FEES REQUIRED ☐ LICENSING ACTION REQUIRED IF KNOWN ☐ YES ☐ NO

☐ OTHER *(Specify)*

	TOTAL NUMBER OF REVIEW HOURS	NOTES
	NUMBER OF DEFICIENCY LETTERS	
	NUMBER OF DEFICIENCY CALLS	

FOR BILLING PURPOSES ONLY

☐ NAME CHANGE ☐ ADDRESS CHANGE ☐ NEW REGISTRATION -- ADD TO BILLING ☐ PRODUCT INACTIVE -- REMOVE FROM BILLING

FOR FEE USE ONLY

TYPE OF FEE: APP. A + D	FEE CATEGORY: ☒ 9A ☐ 9B ☐ 9C ☐ 9D	
AMOUNT RECEIVED: $3700	CHECK NUMBER: 8484	☐ MATANN UPDATED AS REQUIRED
DATE OF CHECK: 7-28-94	LOG: Aug '94 SSD	☐ MATSYS UPDATED AS REQUIRED
APPROVED BY: LM	DATE RETURNED: 8-5-94	DATE
COMMENTS: (See also Aug I HQS Log)		

NRC FORM 567 (8-93)

ORIGINATORS COPY

030-33624

SLEEPSAFE CORPORATION

"makers of the safe smoke detector"

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

July 28, 1994

Ms. Susan L. Greene
Commercial Use Safety Branch
U.S. NRC - Mailstop T8F5
11555 Rockville Pike
Rockville, MD 20852

Dear Susan:

Enclosed are applications for 1) a device review and 2) an exempt "E" distribution license for our smoke detector product.

Our device will contain the element Americium 241 as a sealed source. The maximum amount that likely would be possessed at any one time would be 100,000 chambers or 1,000 millicuries.

Thank you for your assistance, and I look forward to working with you on this project.

Sincerely,

Scott N. Markwell
President

SNM/ct

Attachments

License Fee Information
on Next Page

021654

030-33624

NRC FORM 313
(9 90)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB NO 3150-0120
EXPIRES 6-30-93

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST 3.75 HRS FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714) U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIALS SAFETY SECTION B
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
NUCEAR MATERIALS SAFETY SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
NUCLEAR MATERIALS SAFETY SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94598

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- [X] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [ ] C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip Code)*

Sleepsafe Corporation
2121 Electric Road
Roanoke, Virginia 24018

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED.

Unknown at this time. A manufacturing agreement has yet to be signed.

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Scott N. Markwell

TELEPHONE NUMBER: 703-989-5738

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY 3h
AMOUNT ENCLOSED $ $6,100.00

13. CERTIFICATION *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE - CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
Scott N Markwell	Scott N. Markwell	President	7/28/94

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS
App	Aug1 HQS	3H	also see SS+D Log Aug '94'

AMOUNT RECEIVED	CHECK NUMBER	
$2400	484	($6100)

APPROVED BY: LM

RECEIVED
AUG 02 1994

DATE

NRC FORM 313 (9 90)

021654

APPLICATION FOR EXEMPT DISTRIBUTION LICENSE

Submitted by
Sleepsafe Corporation
2121 Electric Road
Roanoke, VA 24018
Contact: Scott Markwell
703-989-5738

021654

TABLE OF CONTENTS

U.S. NRC CFR 32.26

12) Results of the prototype testing of the product, including any change in the form of the byproduct material contained in the product, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels and any other changes in safety features

13) The estimated external radiation doses and dose commitments relevant to the safety criteria in 32.27 and the basis for such estimates

14) A determination that the probabilities with respect to the doses referred to in 32.27(c) meet the criteria of that paragraph

15) Quality control procedures to be followed in the fabrication of the production lots of the product and the quality control standards the product will be required to meet

U.S. NRC CFR 32.26

(b) 1) A description of the product and its intended use

The product is a residential smoke detector.

Sleepsafe smoke detectors are designed to safe lives by giving the earliest possible warning of fire to the residential consumer. While most battery-powered smoke detectors are single station only, the Model 500S Series is interconnected with radio signals. When one detector senses smoke, it will signal all others and all will alarm as a multi-station system. Thus, the consumer will get early notification of fire from remote or hard to hear locations such as basements.

The detector is designed for ceiling or wall installation with screws and anchors. It is not portable and will be installed in a fixed location.

The source housing does not move during use.

The ionization chamber includes a sealed source (Americium 241) and source holder from Amersham or NRD with certification that they have been leak tested in accordance with USNRC leak test requirements. The source holder is crimped into a nickel plated source cup which is recessed into a polypropylene lower chamber and then attached to the printed circuit board by screw. The other part of the ionization chamber consisting of a steel/tin (perforated and insect proof) cover is screwed, soldered, and snapped around and over the source cup for security.

The smoke detector consists of series designated as the Model 500S and 200P Series. The model submitted by the is the base Model 500SI. Other models in the series are identical in construction but may have additional non-radioactive components such as a photoelectric sensor, a strobe, a heat sensor, a security sensor, a carbon monoxide sensor, and additional LED's. These components may cause additional openings in the outer case but will not impact the radiation safety features versus the base model. The 200P series is identical to the 500S series except for the marketing name of the detectors.

The radiation source model designation will be either:

a) Amersham model AMM.1001H source and holder
or
b) NRD model A-001 source in model A-1056 holder

2) The type and quantity of byproduct material

- 0.9 microcurie of Americium-241

3)a) Chemical and physical form

The Americium 241 is itself in a gold matrix and is effectively contained between a palladium-gold alloy and a fine gold interface with a silver backing. The facial palladium-gold alloy is 2 microns in thickness, the gold interface 1 micron in thickness and the silver backing is 0.2 millimeters in thickness. The alpha particles are only emitted from the facial surface. The active area of the gold foil is 3 millimeters in diameter.

3)(b) Changes that might occur during its useful life

The gold alloy form of the Americium 241 makes it fairly inert. In addition, the manner in which it is sealed, as described in item 5 below, isolates the matrix very well from environmental chemical and physical agents. So no changes are expected to occur during its useful lifetime of approximately ten years.

4) Solubility in water and body fluids.

The 241Americium-gold matrix is not very insoluble in water or bodily fluids. In ICRP Publication 30, Part 1, entitled Limits for Intakes of Radionuclides by Workers, the fractional rate at which all ingested compounds of Americium are translocated to body fluids was taken as 5 X 10-4, based on animal studies reporting values <10-4. It also noted that greater gastrointestinal absorption might be expected for complexed forms of Americium and that enhanced absorption has been reported in very young rats. In a case study involving the ingestion of two Americium 241-gold matrix foils that were accidentally swallowed by a worker, less than 1% of the Americium was

lost to body fluids after being exposed within the gastrointestinal tract of the worker for more than 16 days. Further, the activity that was released under these circumstances was so inert that there was negligible (much less than 1.5%) absorption into the blood.

R.G. Niemeyer (ORNL-TM-2684) performed a total of 23 twenty four water leach tests and 15 three-week water leach tests on eight Am 241 foils which had been removed from five-six year old smoke detectors. The sources contained approximately 15 microcuries of Am 241 each and half of the sources were deliberately damaged by drawing a sharp tool along the entire length of the foil before leach tests. The maximum activity leached in these tests was 0.0045 microcuries, which was less than the 0.005 microcuries of leakage allowed by NRC's standard leak test condition for alpha sources. The average leached during the 38 tests was 0.9 nanocuries and 11 of the 38 tests leached less than 0.02 nanocuries.

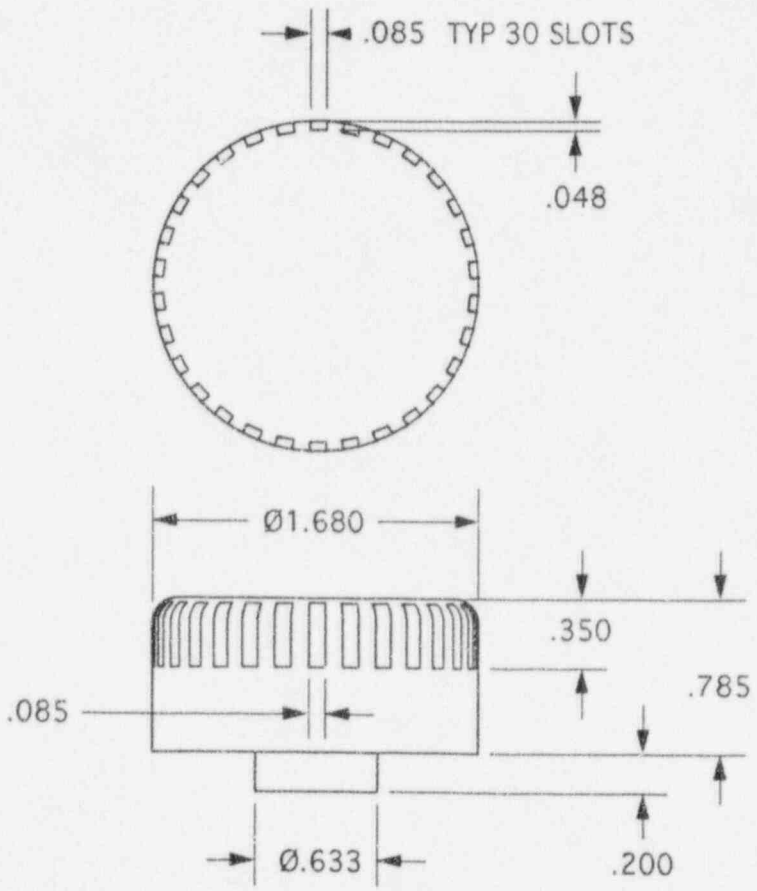
Dale H. Denham, Batelle Pacific Northwest laboratory, (Health Physics 16, 480 (196) stated , with a literature citation to ICRP Report II,"Because most of the compounds of the transplutonium elements are insoluble in biological fluids, ingestion and percutaneous absorption are unlikely to result in significant body burdens. For example, less than 0.01% of the Americium taken into the gut ultimately reaches the critical organ, bone. Hence, at least 500 uCi of insoluble AM 241 must be ingested to produce one bone burden (0.05 uCi)."

Since the AM 241 used in the Model 500S is AMO2 intimately bound in precious metals and is of much lower activity than these tests, leaching of Am 241 into the body from smoke detector sources would be much less than stated by ICRP for insoluble compounds of Americium.

5) Details of construction and design

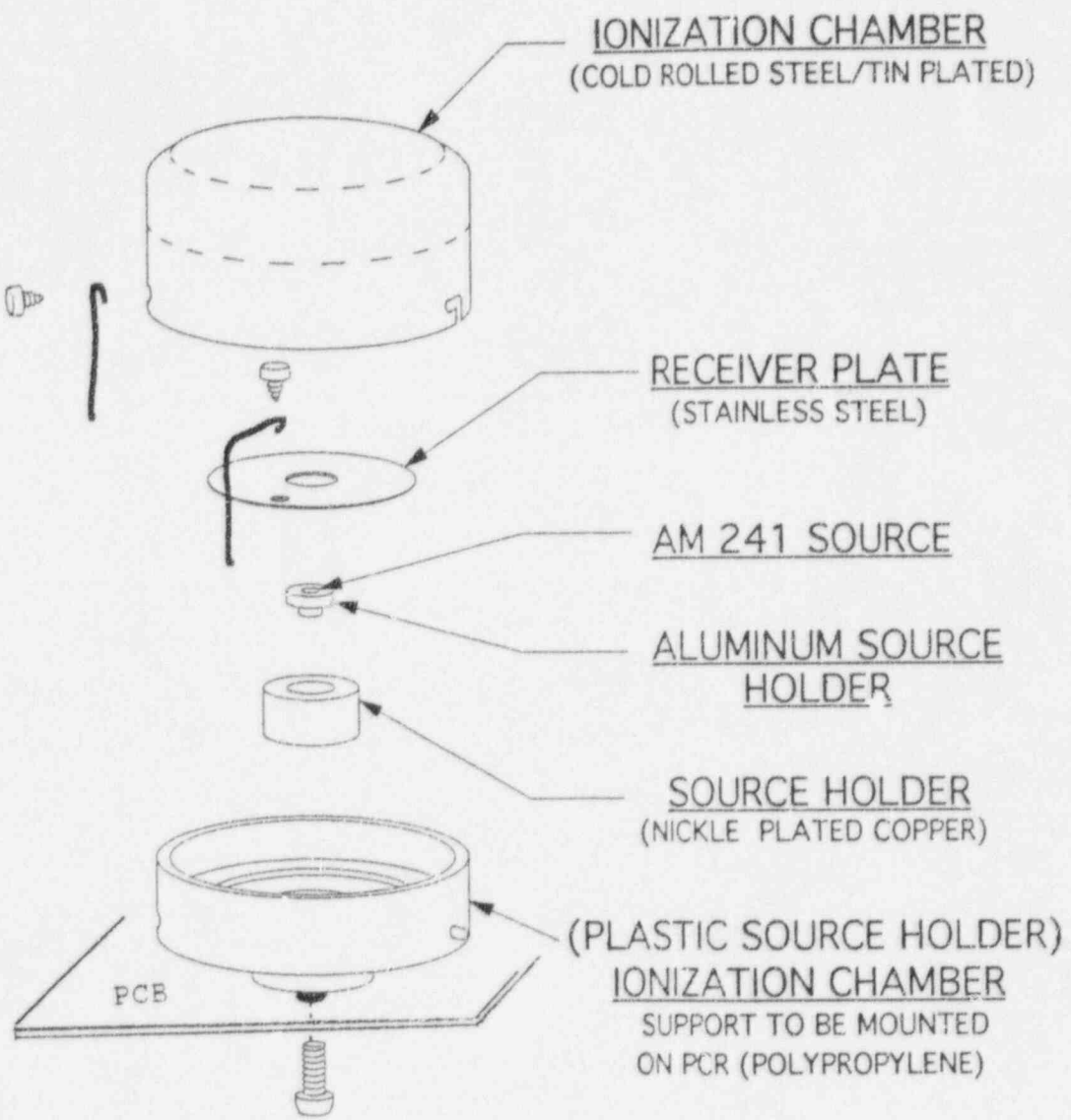
a) Engineering Details of the Chamber and Contents: The ionization chamber includes a sealed source Americium 241 and source holder from Amersham or NRD with certification that they have been leak tested in accordance with USNRC leak test requirements. The source holder is crimped into a nickel plated source cup which is recessed into a polypropylene lower chamber and then attached to the printed circuit board by screw. The other part of the ionization chamber consisting of a steel/tin (perforated and insect proof) cover is screwed, soldered, and snapped around and over the source cup for security.

Drawings of our chamber are detailed in the following Figures 1 & 2. Further detail as to the Amersham and NRD source and source holders are included in Appendix A.



STANDARD HIGH PERFORMANCE CHAMBER

FIGURE 1



CONTAINMENT OF SOURCE WITHIN DETECTOR

FIGURE 2

b) Dimensions and materials of the circuit board:

See Figure 3 below. The circuit board will be of a standard PCB material.

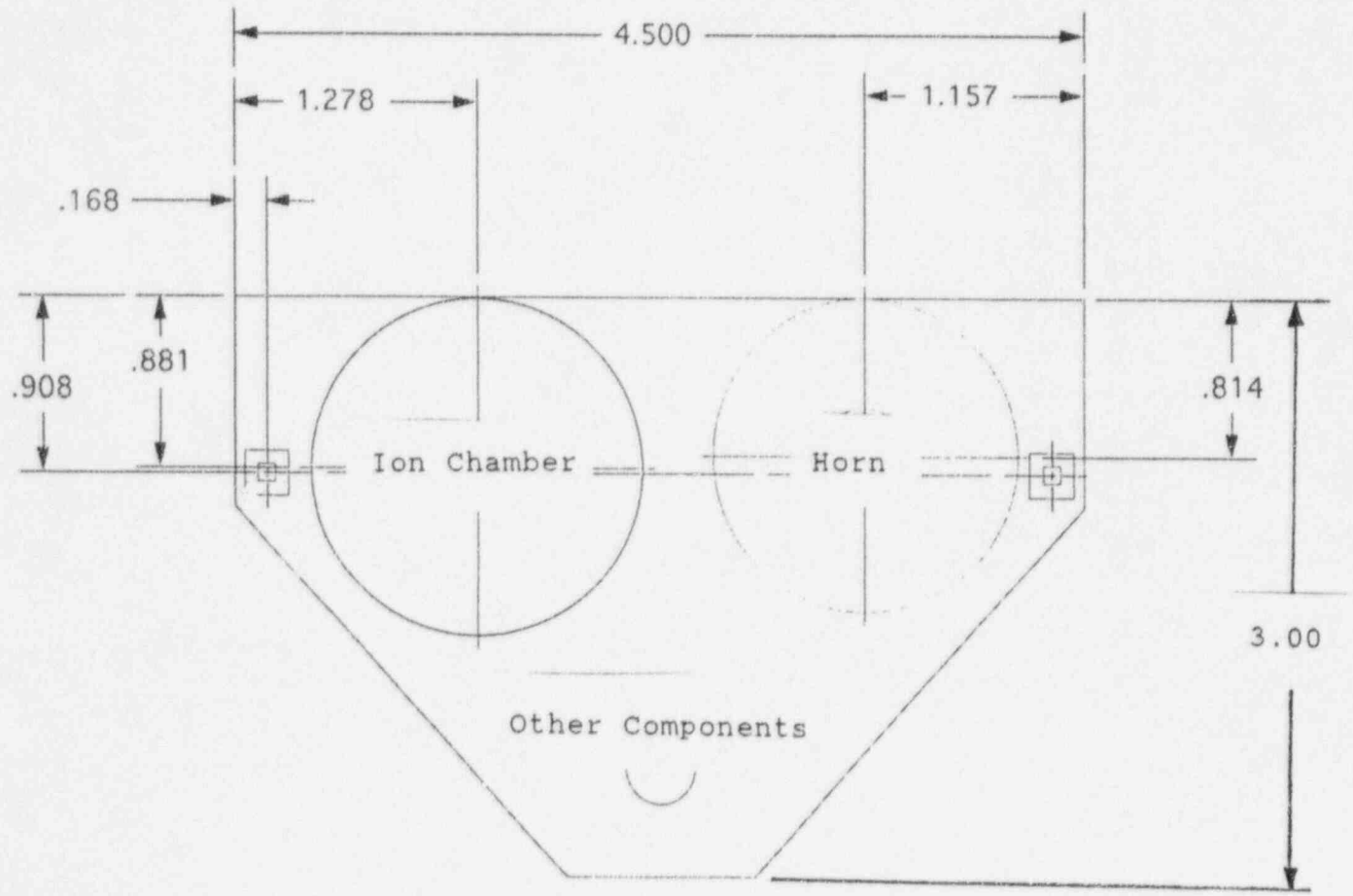


FIGURE 3
Circuit Board

c) Housing:

Materials - the material of the outer housing will be ABS meeting U.L. 94-HB. One exception - the LED lens will be a clear plastic.

Appendix B provides a complete set of housing engineering drawings. Information pertinent as to the requirements of this section have been yellow highlighted and noted with the following letters in blue ink:

1) diameter of the housing
2) thickness of the housing (separate cover and base)
3) wall thickness (minimum 0.060, typical 0.080)
4) method of attachment of the board to the housing
5) method of closing (hinged cover)

d) Labeling:

1) device labeling description

Per the Engineering drawings of Appendix B, the words "CONTAINS RADIOACTIVE MATERIAL AMERICIUM 241 0.9 MICROCURIE" will be etched into the back of the plastic base. The etching will be visible when removed from its mounting. In addition, a durable paper label will be fastened to the back of the plastic base. The label will be visible when the smoke detector is removed from its mounting and will also minimally contain the statement:

"U.S. NRC License No. XXX" or simply the name of the licensee.

2) point of sale packaging marking

The point of sale packaging will contain the following or equivalent:

a) "Contains Radioactive Material Americium 241 0.9 Microcuries"

b) "U.S. NRC License No. XXX" or simply the name of the licensee.

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

6) Maximum external radiation levels

Using radiological data of the Amersham Corporation (confirmed using calculated NRD data sheet), Model DSCA3 ion chamber with AMM.1001H source and holder, the annual dose equivalents at the following distances to the front and back surfaces of the ion chamber are given as follows:

Distance (cm)	OUTER CAP ELECTRODE (Faces to Front)	SOURCE ELECTRODE (Face Rear)
5	0.050 Rem/Yr	0.00090 Rem/Yr
25	0.003 Rem/Yr	0.00004 Rem/Yr

The above measurements were made by Amersham Corporation using thermoluminescent dosimeters (TLDs) of a size less than or equal to 10 square centimeters. These measurements were checked by calculation utilizing a gamma constant of 1.28 microroentgens per microcurie hour for the 59.5 keV gamma. The exposure from the characteristic x-rays were insignificant due to attenuation within the stainless steel housing of the ion chamber and also in the silver backing of the foil.

Due to the greater distance of the surface of our unit from the ion chamber, the doses received from the smoke detectors is expected to be even less than those shown above.

7) Degree of access during normal use

Being a residential smoke alarm, the Model 500S series will be installed according to NFPA 72 and local building codes. Minimally, it will be installed at seven feet high on a wall (or higher on a ceiling) which typically will limit accessibility.

The initial installation of the device will take less than twenty minutes and should be a one-time event. We will recommend weekly testing which will require less than one minute for the system. The device will require a new battery once per year. It is estimated that this will take 2-3 minutes or less per unit. Should the unit go into alarm, the alarm is latching and will have to be reset. Reset will take less than one minute for the system. Of course, alarming whether real or false should be an unusual event. Lastly, we will recommend once per

year vacuuming the outside of the unit, and this should take less than one minute per unit.

Thus given installation location and little maintenance, exposure will be limited.

8) Total quantity of byproduct material expected to be distributed in the product annually

Not more than 1,200,000 smoke detectors are expected to be distributed annually. Each would contain less than 1.0 micocurie for an annual total of 1,200 millicuries.

9) The expected useful life of the product

The expected useful life of the product is 10 years.

10) The proposed methods of labeling

A) device labeling description

Per the Engineering drawings of Appendix B, the words "CONTAINS RADIOACTIVE MATERIAL AMERICIUM 241 0.9 MICROCURIE" will be etched into the back of the plastic base. The etching will be visible when removed from its mounting. In addition, a durable paper label will be fastened to the back of the plastic base. The label will be visible when the smoke detector is removed from its mounting and will also minimally contain the statement:

"U.S. NRC License No. XXX" or simply the name of the licensee.

B) point of sale packaging marking

The point of sale packaging will contain the following or equivalent:

1) "Contains Radioactive Material Americium 241 0.9 Microcuries"

2) "U.S. NRC License No. XXX" or simply the name of the licensee.

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

11) Procedures for prototype testing of the product

1) Amersham and NRD testing. Amersham and NRD sealed sources have been evaluated many times for the U.S. NRC with temperature, pressure, impact, vibration, and puncture tests conducted in accordance with ANSI 524 and ISO 2919 standards.

2) U.L. testing. Our product will be U.L. tested and approved per U.L. 217 prior to exempt distribution.

3) R.G Niemeyer (ORNL-TM-2684) performed elevated temperature tests on foils that had been removed from 5-six year old detectors. Each foil was heated according to a time-temperature curve of Underwriters Laboratory's one hour fire test at 925 degrees. The foils contained 1.7 to 18 u Ci of AM241.

4) If requested, we will provide drop tests after prototypes become available.

12) Results of prototype testing

1) Both Amersham and NRD sealed sources passed all tests and have been found suitable for licensing purposes in the United States. Appendix A details some Amersham and NRD information. Other test results can be obtained if necessary.

2) U.L. testing. Should it be necessary, a copy of those results can be provided late in the NRC approval process.

3) Niemeyer's elevated temperature test showed the average activity loss from the AM 214 was 0.31 %. Most sources showed an average loss of only 0.05%.

4) Drop test results will be added if requested.

Other comments:

Our particular ion chamber has been previously licensed in a smoke detector by the U.S. NRC. ref. U.S. NRC license # 04-21357-01E.

13) The estimated external radiation doses and dose commitments relevant to the safety criteria in 32.27 and the basis for such estimates

(a) Normal Use:
The intake of Americium 241 into the blood system of a user of the unit would be negligible, and the likelihood of such an occurrence would be less than a one in a million chance. The dose commitment result from such a negligible uptake would be much less than 0.005 Rem or 5 Millirem to the whole body, all the blood forming organs, other organ or bodily parts. The information given in Section 4 above would serve as a basis for such a claim.

The external dose equivalent to the head and the lens of the eyes of a seven foot individual (possibly at a distance of a foot from the wall in the vicinity of the smoke detector) with these portions of his/her whole body approximately 25 centimeters from the ion chamber (for a full year, his/her dose equivalent would be 0.003 Rem/year.

This is clearly less than a 0.005 Rem or 5 Millirem whole body dose. Since the limbs of the body, the skin of the entire body, and other organs would be at greater distances from the smoke detector during it use, the dose equivalent to these portions of the body would be less than 5 millirem.

In the above example, it is extremely unlikely that an individual would remain in the vicinity of a smoke detector for such a long time. It is more likely that only 20 minutes are spent in the initial installation and a similar period of maintenance for the other years. So the whole body dose equivalent could be lower than 0.004 percent of the calculated dose equivalent.

If during the twenty minute period of installation or maintenance the individual placed his/her hand on the surface of the smoke detector directly above the ion chamber. At a 5 centimeter distance, the annual dose was measured as 0.05 Rem/year. The surface of the smoke detector is more than 1.5 centimeters away from the ion chamber. The exposures rates at different distances are related in an inversely proportionate relationship to the squares of their distances from the source. Since the top of the ion chamber is more than 1.5 centimeters from the source, the distance from the source is moved from 6.5

centimeters to 3 centimeters. The dose equivalent would then be expected to be 4.7 times the original value of 0.05 Rem/year, resulting in a value of 0.24 Rem/year. So for twenty minutes the total dose equivalent to the hand would be 0.01 Millirem. This is much less than the 75 Millirems allowed to the hand and forearms.

As far as the safety involved in the disposal of a single smoke detector or a number of smoke detectors from consumer use to the natural environment, please refer to the information given in NuReg CR-1775 and CR-1156, "Environmental Assessment of Exposures"

(b) Safety over useful life
In the normal handling and use of the smoke detector during its useful life of ten years, it is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product from wear and abuse. Representative samples of smoke detectors have been subjected to and passed recognized physical, mechanical and chemical tests designed to indicate their ability to withstand adverse environmental conditions. This unit is rugged in construction materials used and in the manner in which it has been bound together as a unit. In addition, it would be isolated on a wall subjected to extreme conditions only in the event of a fire, in which case if it does function, it more than serves its purpose. If the unit does burn up, with the very, very large volume of air and other gases which might be associated with such a burn-up, the large dilution and subsequent decrease in the concentration of any released Americium 241 would probably be insignificant in its effect on the environment.

(c) Worst Case:
In order for dose equivalents to be received that are a factor of one hundred larger than those of 5 millirems listed in column I of the table in Section 32.28, then a failure must occur in both the smoke detector housing and in the ionization chamber. A failure in the ion chamber may mean exposing an individual to the source foil. The radiation exposure would now increase markedly due primarily to the characteristic x-rays which have a combined exposure constant of 14.4 microroentgens per microcurie-hour. In addition, the 26 keV and 33 keV gammas would also present some additional exposure of 0.3 microroentgens/microcurie-hour. The total gamma constant to which an individual would then be exposed would be 16 microroentgens per microcurie-hour. The resulting dose

equivalent levels would be 12.5 times higher. In other words, the .003 Rem/year levels that existed at a distance of 25 centimeters from the outer cap of the ion chamber (26.5 centimeters from the source) would now be 0.0375 Rem or 37.5 millirem. If an individual kept such a sealed source at this distance from their eyes and head for a year, they would receive this dose. The probability of such a failure and occurrence is low - probably less than one in ten thousand. For a hand placed on top of the sealed source for this duration, only a small area slightly larger than a 3 mm diameter would receive a large dose and, if not moved at all during the year, would certainly exceed the 7.5 Rem limit. If the sealed source were to be manipulated in the hand, then the localized maximum intensities would be shared by most of the other portions of the hand so that the average effect is to receive a dose equivalent not nearly as large as a maximum localized dose. Since it is very improbably that the sealed source would be handled continuously for an entire annual period and probably much less so, the expected dose equivalent would be less than the 7.5 Rem limit. The probability of such as occurrence is probably much less than one in ten thousand. In judging the possibilities of receiving an uptake of Americium 241, the chance of such as occurrence is less than a one in a million chance.

In another worst case example, if a sealed source were to be accidentally swallowed by a youngster after successfully prying open the smoke detector and the ion chamber, the source might lodge in his/her throat for a period of time, perhaps two weeks, in which case he/she might receive 50 Rems of dose to this area. If the source were to continue on instead of lodging in the throat, and spend a week in the gastrointestinal tract, chances are that for the source being as inert as it is, that less than 1 percent would get into the bodily fluids and less than 0.1 percent of the latter would get into the blood system. So beginning with less than one microcurie, then only 10 picocuries may expose the whole body blood, but the dose equivalent would be less than 15 Rems.

Further, lets assume a maximum storage at any one location at any time of 25,000 units. Lets also assume a carton contains 24 smoke detectors with a conservatively calculated surface dose of 9.1 uR/hr (hand) and 2.9 uR/hr at 6 inches (body). If a warehouse worker directly handled cartons 10 hours per week, the hand does would be 4.7 mr/yr and body would be 1.5 mr/yr. In actual

practice, such handling would be much more intermittent given the use of fork-lifts etc., and the calculations would be much smaller.

Lastly, there have been a vast number of other scenarios generated showing many different probabilities of hypothetical accidents. A number of these scenarios are in Amersham Corporation's radioactive material license files in your office. Please refer to them as part of our demonstration of creditable accidents beyond the one mentioned in the background to this section.

14. A determination that the probabilities with respect to the doses referred to in Section 32.27(c) meet the criteria of that paragraph.

There have been a vast number of scenarios generated showing many different probabilities of different hypothetical accidents. A number of these scenarios are in Amersham Corporation's radioactive material license files in your office. I would like to be able to refer to them as part of my demonstration of creditable accidents. I would again like also to refer to the actual accidental I described in Section 4 above, which involved 4.22 microcuries of activity and an uptake to the blood of less than 525 picocuries. The item which has not been mentioned is that there is only 0.9 microcuries in each sealed source and leak tests have demonstrated repeated that removable contamination is much less than 0.005 microcuries and in most cases less than the limits of detection of the leak testing procedure.

15. Quality Control Procedures To Be Followed and Required Standards To Be Met During The Fabrication of the Smoke Detectors.

The 500S Series detectors ion chambers will be quality tested in accordance with 10 CFR and the "SSSS" position. And our product will be U.L. tested and approved prior to exempt distribution and manufactured meeting ISO 9000 quality standards. In addition, we will have to meet Underwriters Laboratory manufacturing requirements.

APPENDIX A

NRD INC.
2937 Alt Boulevard North, Grand Island, New York 14072-1292
Telephone: (716) 773-7634
FAX # (716) 773-7744

July 22, 1994

Sleepwell
2121 Electric Road
Roanoke, Va. 24018
Attn: Scott Markwell

Dear Scott,

You asked about external (penetrating radiation) from smoke detectors. This radiation is so low that it can not be measured by simple geiger counters but rather by long exposures (24hrs. or greater) in carefully shielded counting chambers. I believe the calculated dose for 1 microcurie of Am-241 should be accepted in leiu of actual measurements of microrem/hr.

The calculated dose follows:

C= 1X10-6 Curies	R/hr at 1 foot= 6 CEN.
N= .36	R/hr @ 1 ft.=6(1X10-6)(.36).060
E= .060	R/hr @ 1 ft.=.1296X10-6
	.13 ur/hr @ 1 ft.

using inverse square law - dose rate at 2" = 4.68 ur/hr @ 2"

Therefore, the unshielded dose rate from the source separate from the smoke detector is a maximum of 5 microrem/hr. NRD does provide a certificate on leak testing and radioactive content on each shipment.

Sincerely,

Lawrence Keating

Lawrence Keating
Chairman of the Isotope Committee

LK/lm

021654

NRD INC.
2937 Alt Boulevard North, Grand Island, New York 14072-1292
Telephone: (716) 773-7634
FAX # (716) 773-7744

CERTIFICATE OF RADIOACTIVE SOURCE INTEGRITY

Specification: Americium-241 Alpha Foil Model NRD A001
Drawing Number: 85B026
Nuclide & Radiotoxicity Gp.: Americium-241 Group A
Maximum Activity: 0.9 microCuries
Classification Designation: ANSI/ISO C32222
Test Sources: Foil in source holder A-1056

Test	Temperature	Pressure	Impact	Vibration	Puncture
1					
2		Pass <0.05	Pass <0.05	Pass <0.05	Pass <0.05
3	Pass <0.05				
4					
5					
6					

Test carried out in accordance with ANSI-542 International Standard ISO 2919.

Leak Test: Immersion and Wipe

Additional information: Figures in Table denote activity (nCi) measured in liquid after immersion.

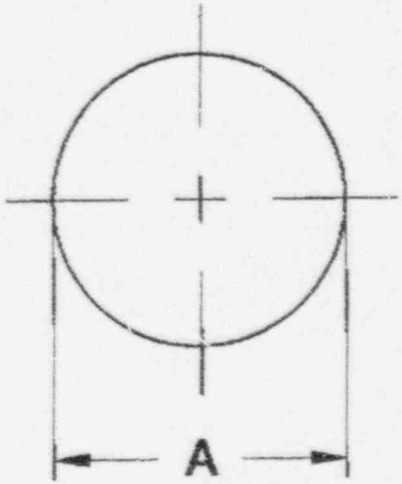
Lawrence Keating
Quality Control Department

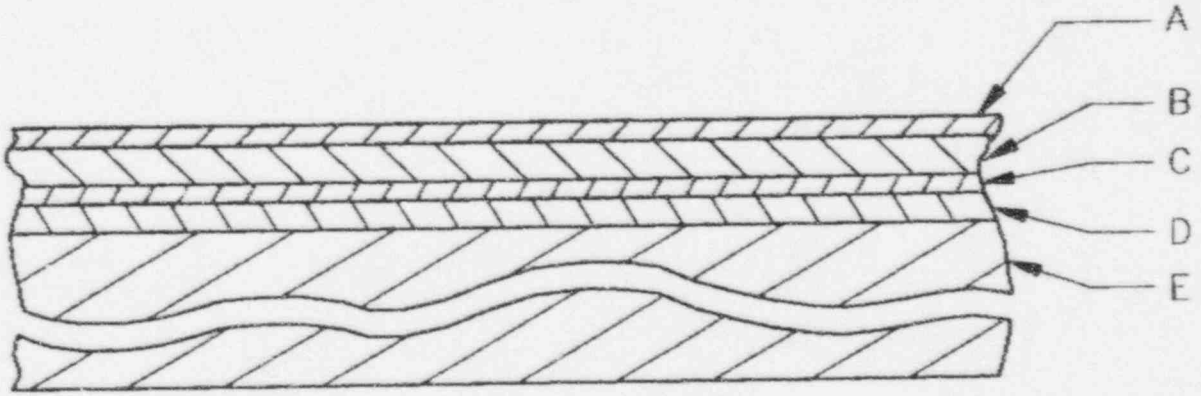
7/21/94
Date

David McGlynn
Source Department

A FOIL DIAMETER	
METRIC ±0.03 mm	DECIMAL ±0.001"
2.3 min	0.092 in.
5.0 mm	0.197 in.
6.0 mm	0.236 in.
16.0 mm	0.629 in.

REVISIONS					
REV.	DATE	DESCRIPTION	AUTH	DR	CK
1	01MR91	REDRAWN ON AUTOCAD		CDD	
2	30JA92	LAYER A CHANGED: YELLOW GOLD WAS GOLD	J.J.	CDD	
3	04MR94	LAYER "B" CHANGED: GOLD OR PALLADIUM WAS GOLD	J.C.	CDD	JCJ





A. YELLOW GOLD PLATE 0.00002"
B. GOLD OR PALLADIUM 0.00004"
C. AMERICIUM 241 AND GOLD 0.00002"
D. GOLD 0.00003"
E. SILVER 0.004" TO 0.007"

UNLESS OTHERWISE SPECIFIED	SIGNATURES	DATE
DIMENSIONS ARE IN INCHES	DRAWN R. BIDELL	
TOLERANCES ON:	CHECKED	
2 PL DECIMALS ±	APPROVED	
3 PL DECIMALS ±	APPROVED	
ANGLES ±	THIRD ANGLE PROJECTION	
FRACTIONS ±		
DO NOT SCALE PRINT		

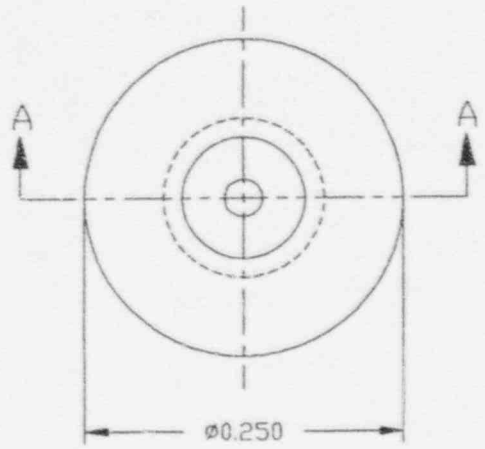
NRD INC.
A SUBSIDIARY OF MARK IV INDUSTRIES, INC.
2937 ALT BOULEVARD GRAND ISLAND, NEW YORK 14072

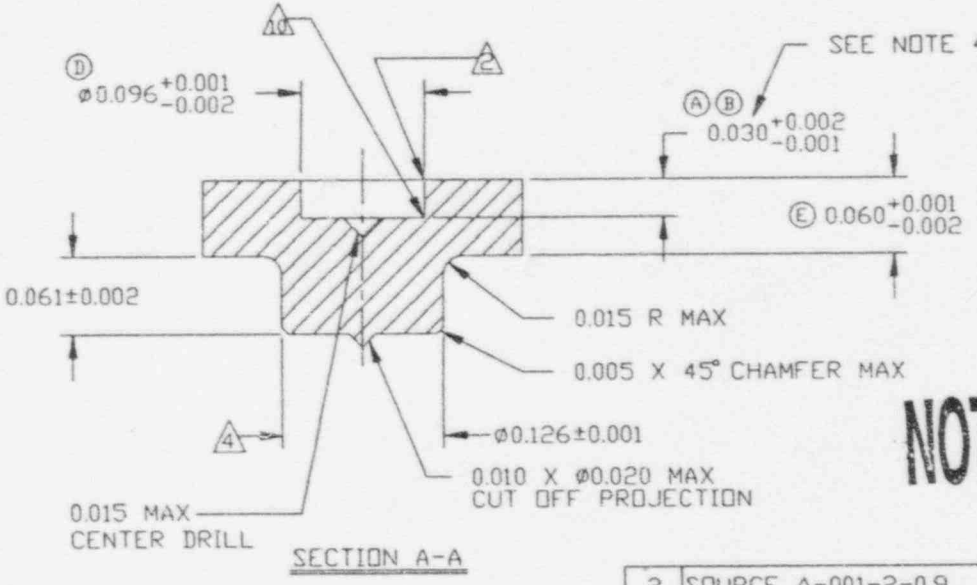
A-001 SINGLE FACE FOIL

MATERIAL & FINISH: Am 241, GOLD, SILVER

A	DATE	SCALE	DWG NO	REVISION
	13AP79	NA	79A045	3

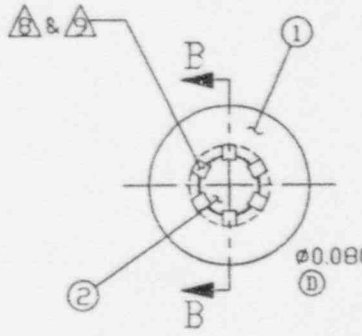
DATE	SYM	REVISION RECORD	AUTH.	DR.	CK.
05JUL85	A	ADD NOTE 4	T.C.	JES	
29APR87	B	CHANGE 0.030 +0.005 -0.003 TO 0.030 +0.002 -0.001		JES	
08DEC89	C	ADD FOIL NOTE		JES	
30AUG90	4	REDRAWN ON AUTOCAD		CDD	
27NOV90	B	DIM Ø0.096 WAS Ø0.090, Ø0.080 WAS Ø0.083, DIM 0.013 WAS 0.015, CHANGED TO A & STAKE ASSY	JES	CDD	
07JA91	6	SPEC 10 CALLOUT ADDED	JM	CDD	
16JA91	E	DIM 0.060 +0.001 -0.002 WAS 0.060 +0.002 -0.002	TC	CDD	



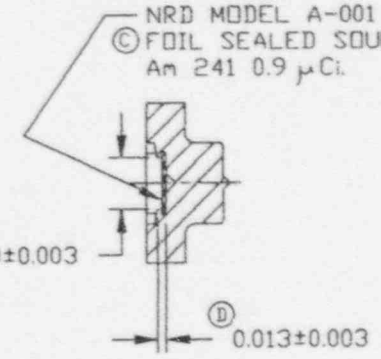


SECTION A-A

NOT TO SCALE



SOURCE AND SOURCE HOLDER IN THE ASSEMBLED STATE.



SECTION B-B
FIVE TIMES SIZE

NOTES:

1. SOURCE HOLDER AND SOURCE HOLDER ASSEMBLY MUST COMPLY WITH NRD SPECIFICATION 2016 DATED 2/8/85.
2. NUMBERED △ REFER TO SPECIFIC NOTES.
3. ALL DIMENSIONS ARE IN INCHES.
Ⓐ 4. EACH SHIPMENT, 0.030 DIMENSION MUST BE HELD TO ±0.001 WITHIN THE +0.002 -0.001 TOLERANCE.

NO.	DESCRIPTION	DWG.	REQ'D	MAT'L
2	SOURCE A-001-2-0.9	79A045	1	COMB.
1	SOURCE HOLDER A-1056	85B026	1	S. STEEL

NRD DIV. MARK IV IND. INC.
2937 ALT BOULEVARD GRAND ISLAND, NEW YORK 14072

TOLERANCES (EXCEPT AS NOTED)	TITLE: SOURCE HOLDER MODEL A-1056		
DECIMAL ± 0.005	MATERIAL & FINISH: SEE NRD SPEC 2016	SCALE: 10 : 1	DRAWN BY: JES
FRACTIONAL ±			APPROVED BY:
ANGULAR ± 1°	DATE: 07FE85	DWG. NUMBER: 85B026	REV:

DATE	SYM	REVISION RECORD	AUTH.	DR.	CK.
29NOV90	1	NOTE 3 & 6 CHANGED: Ø0.096 WAS Ø0.098; Ø0.094 WAS Ø0.096		CDD	
04JA91	2	NOTE 2 CHANGED: 0.001 WAS 0.003	JES	CDD	
07JA91	3	NOTE 10 ADDED	DH	CDD	
22NOV91	4	NOTE 1 CHANGED: B90 WAS B100	JS	CDD	
12DEC91	5	NOTE 1 CHANGED: B100 WAS B90 NOTE 11 ADDED	DH	CDD	
23JN92	6	HARDNESS SPEC REVISED; PAGE 1 OF 2 REMOVED FROM TITLE; NOTE 3 REVISED	T.C.	CDD	JB

GENERAL NOTES FOR STAINLESS STEEL SCREW MACHINE HOLDERS:

1. MATERIAL: 303 STAINLESS STEEL
   FINISHED SOURCE HOLDER HARDNESS: ROCKWELL B100 MAX.
2. COUNTERBORE TO HAVE SHARP CORNERS, 0.001" MAX. COUNTERBORE SURFACE TO BE FLAT AND FREE FROM PROJECTIONS.
3. CONCENTRICITY TO BE WITHIN 0.003" ON ALL DIAMETERS.
4. ROUNDNESS TO BE 0.001" MAX.
5. SURFACE FINISH TO BE NO GREATER THAN 90 MICRO INCHES UNLESS OTHERWISE SPECIFIED. SHARP CORNERS NOT TO EXCEED 0.005" RADIUS.
6. SOURCE HOLDER CAVITY MUST PASS A Ø0.094" PLUG GAUGE CHECK.
7. AFTER MACHINING, PARTS SHOULD BE DEBURRED, PASSIVATED, AND THEN DEGREASED.
8. AFTER ASSEMBLING, CRIMPED TABS SHOULD HOLD FOIL FIRMLY TO THE BOTTOM OF THE FOIL CAVITY. CRIMPED SURFACES SHOULD BE FREE FROM CRACKS OR FLAWS.
9. SOURCE MUST REMAIN FLAT AND FREE OF DISTORTIONS AFTER CRIMPING.
10. CORNERS TO BE SHARP, 0.003" MAX.
11. CUT OFF BURR NOT TO EXCEED 0.003" HIGH X Ø0.015".

FOIL MODEL	A-001
RIVET MODEL	A-1056
ASSEMBLY MODEL	———
ENCAPSULATION CODE	I-405
PROTOTYPE TESTS	11211111
Q.C. TESTS	AGRSVW

NRD INC.
A SUBSIDIARY OF MARK IV INDUSTRIES, INC.
2937 ALT BOULEVARD GRAND ISLAND, NEW YORK 14072

TOLERANCE (EXCEPT AS NOTED)	TITLE: NRD SPECIFICATION 2016		
DECIMAL ±	MATERIAL & FINISH	SCALE	DRAWN BY
FRACTIONAL ±			APPROVED BY J.M.
ANGULAR ±	DATE 08FE85	DWG. NUMBER SPEC FOR 85B026	REVISION 6

U.S. Department
of Transportation

Research and
Special Programs
Administration

400 Seventh Street, S.W.
Washington, D.C. 20590

IAEA CERTIFICATE OF COMPETENT AUTHORITY
FOR SPECIAL FORM NONDISPERSIBLE RADIOACTIVE MATERIALS
CERTIFICATE NUMBER USA/0036/S, REVISION 5

This certifies that the source described has been demonstrated to meet the regulatory requirements for special form radioactive material as prescribed in the regulations of the International Atomic Energy Agency[1] and the United States of America[2] for the transport of radioactive materials.

1. Source Identification - NRD Model A001

2. Source Description - The Special Form material is a laminated metalic foil matrix of silver, gold, and Americium dioxide.as shown on NRD drawing number 92A071 (attached). During transport the material may be in the form of free foils or secured in a variety of holders or mounts.

3. Radioactive Contents - This source consists of Americium-241 as oxide with the activity per foil ranging from less than 0.037 MBq (1 uCi) to 2035 MBq (55 mCi). Activity per unit area does not exceed 0.086 MBq (2.33 uCi) per square millimeter (55.5 MBq (1500 uCi) per square inch).

4. Expiration Date - This certificate expires August 31, 1997.

This certificate is issued in accordance with paragraph 803 of the IAEA Regulations and Section 173.476 of Title 49 of the Code of Federal Regulations, in response to the July 9, 1992 petition by NRD Inc., Grand Island, NY, [redacted] in consideration of other information on file in this Office.

Certified by:

George A. Brown, Chief
Radioactive Materials Branch
Office of Hazardous Materials
Technology

AUG 14 1992
(DATE)

Revision 5 - issued to extend expiration date.

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1 "Safety Series No. 6, Regulations for the Safe Transport of Radioactive Materials, 1973 Revised Edition, as amended," published by the International Atomic Energy Agency (IAEA), Vienna, Austria.

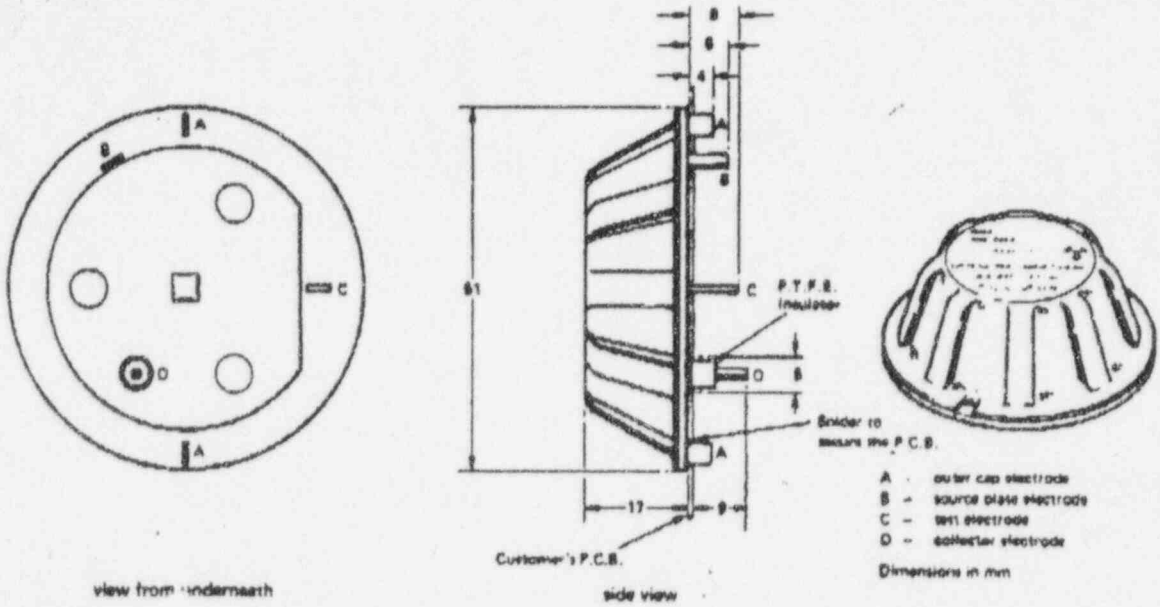
2 Title 49, Code of Federal Regulations, Parts 100 - 199, United States of

Product specification

Smoke Detector Ionization Chamber

Data sheet 11247

DSC.A3



General description

The unit is a dual ionization chamber of advanced design containing a single radioisotope source producing ionization in both chambers. The design was developed using a computer model to optimize performance characteristics. The ionization chamber incorporates a performance test electrode.

Certain aspects of the design, including the test electrode, are the subject of patent applications.

In accordance with OECD recommendations[1] the source activity is less than 1 μCi *(37 kBq)* ^{241}Am. The general construction is designed to meet the requirements of Underwriters Laboratory standard UL 217[2] and British Standard 5446 part 1[3]. For maximum corrosion resistance the electrodes and source holder are made of A.I.S.I. 316 stainless steel, the insulators of polytetrafluoroethylene ('Teflon'*), and the support moulding of polypropylene. The ionizing source is made of a silver and gold composite with a gold/palladium alloy emitting face. Sources of this type are listed as model number AMM.1001 with the US Nuclear Regulatory Commission as suitable for licensing, and are used in the majority of ionization-type smoke detectors.

The units are supplied assembled ready to mount on a suitable printed circuit board using the pre-tinned tags provided. No source adjustment is required.

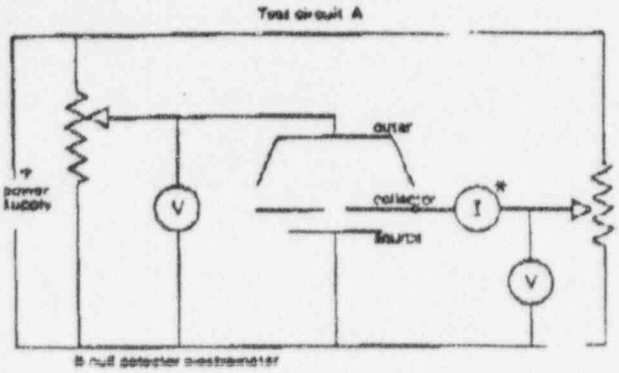
The DSC.A3 incorporates a performance test electrode to permit electrical testing of the chamber during operation, as required by BS 5446. When actuated the electrode disturbs the balance conditions to simulate the presence of smoke.

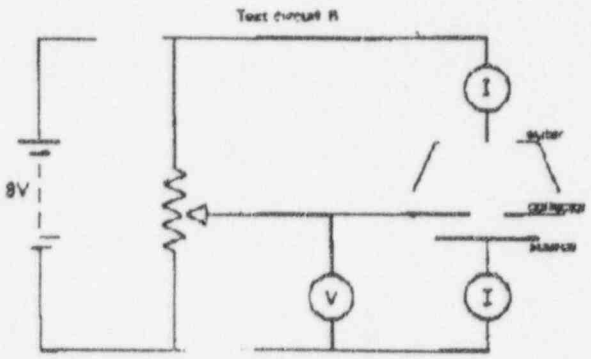
The design is suitable for use with an external integrated circuit containing the electrometer and alarm circuits.

*du Pont trademark

1. ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT
"Proposed radiation protection standards for ionization chamber smoke detectors." Nuclear Energy Agency Draft, Paris: OECD, 1976.
2. UNDERWRITERS LABORATORIES INC
"Standards for safety. Single and multiple station smoke detectors". UL 217, Second edition, New York, UL Inc., First impression, 4th October 1978.
3. BRITISH STANDARDS INSTITUTION
"Specification for components of automatic fire alarm systems for residential premises. Part I. Point-type smoke detectors." London, British Standards Institution, 1977.

Circuits used to determine typical characteristics





Specification (see also Figures for typical characteristics)

Conditions, except where specified, are:

Outer electrode to source electrode potential: 9V
Temperature: 20° ± 3°C
Pressure: atmospheric, near sea level; clean air

	min.	typical	max.	units
Collector electrode balance potential	5·0	–	6·0	V
Change in collector balance potential with smoke				
(a) 0·2% obscuration/ft*	–	0·7	–	V
(b) 4·0% obscuration/ft*	–	3·0	–	V
Insulator leakage	–	–	0·5	pA
Capacity (collector to outer + source electrodes)	–	6	–	pF
^{241}Am source activity	–	0·5	0·7	µCi
		(18·5	*25·9*	*kBq)*
Change in collector balance potential when the test electrode potential is changed from outer potential to source potential	–	3·5	–	V

*These are the obscuration limits specified by UL 217[2]

Radiological data

Users of these units in all countries should ensure that they comply with all relevant regulations on the control of radioactive materials.

The following information is given for guidance.

External radiation dose rate calculations based on thermoluminescent dosimetry (TLD)

direction	distance (cm)	approximate absorbed dose (rad/year)
Normal to surface of outer cap electrode	5	0·06
Normal to surface of outer cap electrode	25	0·003
Normal to source electrode	5	0·0009
Normal to source electrode	25	0·00004

These data will enable users to comply with the U.S. Code of Federal Regulations [10 CFR.32.26.(6).]

Principle of operation

The collector electrode is charged by any imbalance in the ionization currents flowing in the inner and outer chambers, until these currents come into balance (see Figure 1). In the absence of smoke or combustion products the collector electrode remains at this balance potential except for excursions due to statistical fluctuations in the ionization currents. When smoke enters the chambers the ionization currents are affected, that in the outer chamber more so than that in the inner chamber. The collector electrode is then charged to a new balance potential (see Figures 2 and 3). This change in potential can be used to trigger an alarm circuit.

The test electrode is designed to simulate a smoke obscuration typically of 4%/ft. The variation of the balance voltage with time after activation of the test electrode is shown in Figure 5.

Buckinghamshire HP7 9LL

Product specification

Americium-241 alpha foil and sources

Data sheet 11262

Americium-241 alpha particle emitting foil, made by Amersham International, is a versatile material which combines high integrity of containment with relatively high emission efficiency. It can be formed or cut into various shapes to suit a wide variety of applications.

In most cases, and particularly for use in ionization chamber smoke detectors, it is preferably mounted in specially designed holders to provide sealed sources.

Because americium-241 emits only alphas, low energy X- and gamma radiation with no beta radiation, it has a significant advantage over radium-226 which it is tending to replace in the majority of applications.

Construction

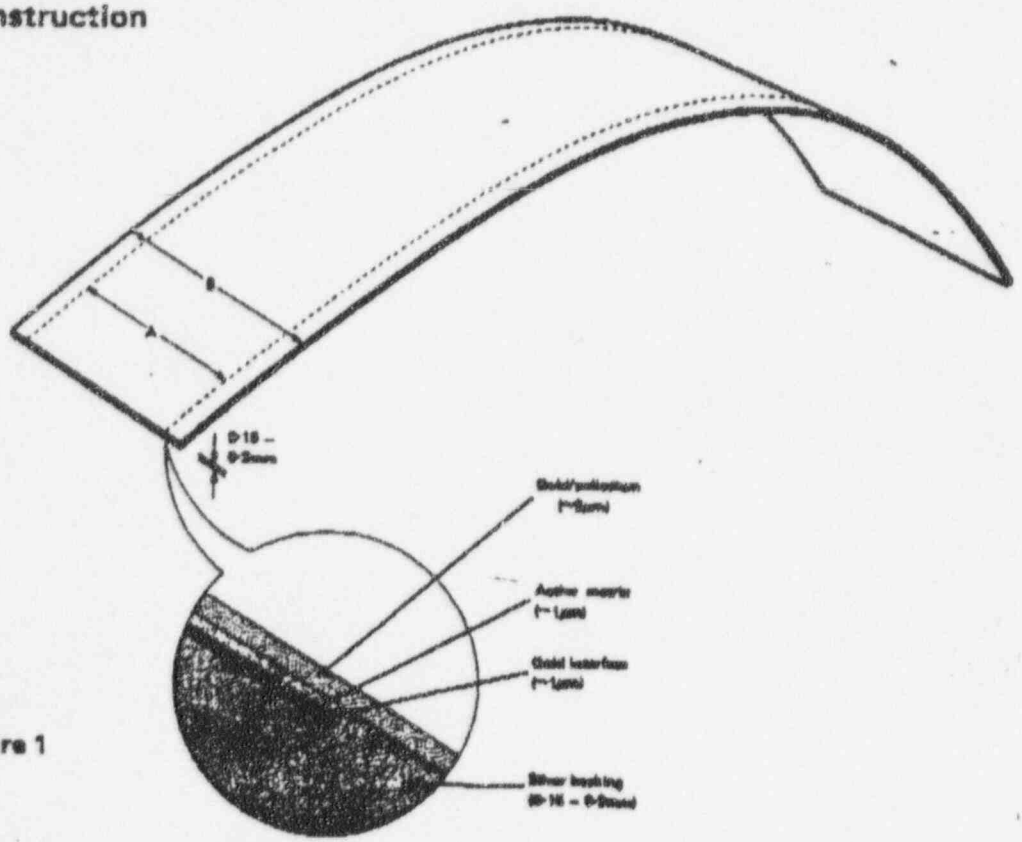


Figure 1

Foil

The radioactive material, in a gold matrix, is effectively contained between a palladium-gold alloy, palladium-gold laminate or pure fine gold face and a silver backing (see Figure 1). The front face is thick enough to retain completely the americium-241, but thin enough to allow efficient emission of the α-radiation. In some cases the silver backing is sandwiched between a second layer of americium-241/gold matrix and palladium/gold face to give double-sided foil, emitting from both faces.

The manufacturing process begins with the production of a small billet consisting of an intimate mixture of americium oxide and pure gold. The billet is first sintered and then hot forged in a silver case with a gold-palladium alloy face. Repeated rolling of this composite, under carefully controlled conditions, produces a continuously welded metal strip of the required dimensions with the active layer confined between inactive borders and protected by a thin face of gold, palladium-gold alloy or palladium-gold laminate.

Dimensions and activity loading can be varied between quite wide limits; the types of foil routinely produced are listed below:

linear activity µCi/cm	MBq/cm	activity on active area µCi/cm²	MBq/cm²	active width A mm	total width B mm	code
10	0·37	8	0·296	12·5	20	AMM.7
30	1·11	100	3·70	3	20	AMM.1
40	1·48	32	1·18	12·5	20	AMM.4
125	4·63	100	3·70	12·5	20	AMM.8
160	5·92	128	4·74	12·5	20	AMM.2
240	8·88	192	7·10	12·5	20	AMM.3

Widths A and B refer to the dimensions shown in Figure 1

Foils are normally supplied in lengths of 25 or 100cm. Foils of other dimensions and active loadings can be produced to customers' specifications. The maximum loading is normally 200µCi/cm² (7·4MBq/cm²).

Foil pieces
Amersham International has developed techniques and equipment which enable cutting operations to be performed cleanly, reproducibly and safely. It is recommended that this operation, together with mounting to give sealed sources free from leakage and removable surface contamination, be carried out in our laboratories

Sealed sources
For the majority of applications, and particularly for use in smoke detectors, sealed sources are prepared by mounting a disc of foil (usually about 5mm diameter) in a metal holder in such a way as to retain the disc and protect the edge of the foil

This method of manufacture produces sources which will pass statutory leak tests, and which meet the requirements of most regulatory authorities. A wide variety of such sources is in regular production and some typical examples are shown in Figure 2. Different methods of retaining the foil are used. In the first example (a) the foil is held in place by the crimped edge of the holder. In the other sources the foil is sandwiched between metal plates which are held together by spot welding (example (b)) or the rolled-over edge of the holder (c). The foil used in these two sources emits from both faces.

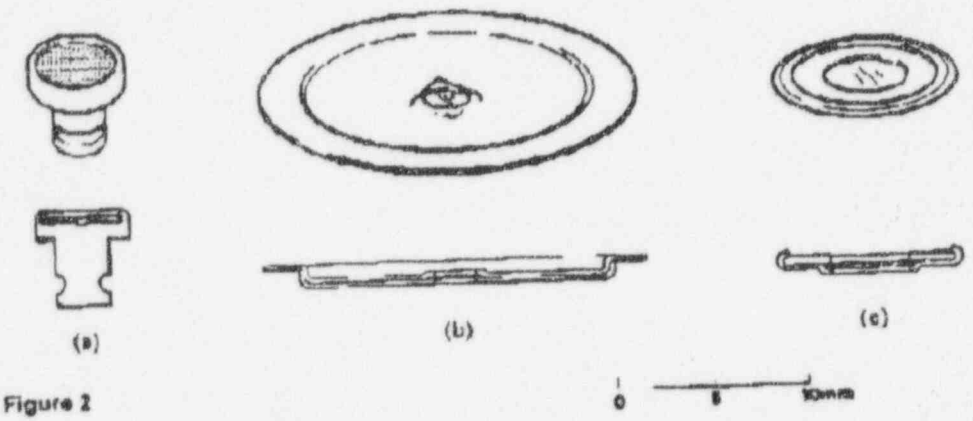


Figure 2

Other designs of holder can be provided to meet users' special requirements. Amersham International offers a service of assisting customers with the design of source holders. Consultations at an early stage to agree specification will normally cover the following aspects.

Source holder: shape
method of attachment to support
dimensions and tolerances
material of construction and finish

Source output: radioactive content and tolerance
required ion current and tolerance
required alpha energy spectrum

In addition, information will be required on measurement specification and procedures, quality control and integrity requirements, quantities, delivery schedule, and details of probable working environment

Quality Control

Surface contamination

Foil: The alpha-emitting face of each length of foil (excluding cut edges) is wiped with a swab of cotton wool moistened with ethanol or water; the activity removed is measured by a scintillation technique. Acceptance limit 0·005μCi (*185Bq*). This test conforms to British Standard Specification 5288.

Sources: For mounted sources, a similar test is carried out on a batch basis to ensure that any loose contamination arising from cutting or other manufacturing operations is less than 0·005μCi (*185Bq*) per batch.

Foil pieces: The tests used to check for surface contamination will depend on the size, shape and quantity of pieces. They may be varied to suit the user's requirements. Further details will be provided on request.

Activity measurements

Foil: The active content of the foil is determined by carefully defining an area of the active zone, shielding it from the surrounding activity, and measuring the total gamma and X-ray emission using a thin NaI crystal detector. The americium-241 content per unit area can be calculated from these measurements. The deviation from the stated nominal value is usually less than ±15% per square centimetre. The face thickness is checked by critically examining the alpha energy spectrum from measurements with a silicon surface barrier detector. The uniformity of distribution of the active content, and the position of the active/inactive boundaries are both checked by using autoradiography techniques.

Sources: The specification for sealed sources and cut pieces is normally agreed between Amersham International and the customer. The specification should include acceptable tolerances on all the measurements requested. Normally the two measurements required are active content and ion current, the latter being measured on an air ionization chamber, which may be supplied by the customer.

Integrity

Representative samples of the different types of foil, and various ionization chamber smoke detector assemblies have been subjected to internationally recognised physical, mechanical and chemical tests designed to indicate their ability to withstand adverse environmental conditions. The results of the tests are available on request.

Tests for "Special Form" radioactive material

Americium-241 alpha foils manufactured by Amersham International have passed the tests for Special Form radioactive material as specified in 'Regulations for the safe transport of radioactive materials 1973' *.

Sealed source model numbers listed by USNRC

Americium-241 alpha foils manufactured by Amersham International have been evaluated by the United States Nuclear Regulatory Commission and found suitable for licensing purposes in the United States.

The sealed source model numbers are:

AMM.1001 — unmounted foil piece
AMM.1001D — foil piece with alpha particles emitting from both sides
AMM.1001H — foil piece mounted in holder

ISO classification

The International Organization for Standardization (ISO) has proposed a system of classification of sealed radioactive sources based on safety requirements for typical uses (see ISO.2919). Prototype sources are subjected to the following tests: temperature, external pressure, impact, vibration, puncture.

Each test can be applied in several degrees of severity and test results are expressed as a five figure code to indicate the severity of the tests. The code is preceded by a letter related to certain activity limits dependent upon the toxicity, solubility and reactivity of the active components of the source.

The ISO recommended rating for ionization chamber smoke detector sources is C32222. However, a typical rating for americium-241 foil sources manufactured by Amersham International is C44334, and ratings as high as C64564 have been achieved by using optimum design conditions.

Other tests

Many other tests designed to simulate severe industrial environments have been performed on samples of alpha foil. These tests have included exposure to sulphur dioxide gas, to salt spray, and to ozone, immersion in body fluids, abrasion by sand particles, etc. Full details of these tests can be supplied on request.

*Regulations for the safe transport of radioactive materials, 1973 revised edition. Vienna, International Atomic Energy Agency, 1973

Safety precautions

The Ionising Radiations (Sealed Sources) Regulations, 1969, require that alpha foil should not be handled with the bare fingers. Foil, foil pieces and mounted sources should be handled using forceps or protective gloves. Other mechanical handling systems may be used, but in all operations care must be taken to prevent damage to the front face of the foil.

Processing unmounted foil pieces and foil subdivisions may require additional safety precautions. Users should contact Amersham International or the competent national authority for advice on particular operations.

The low energy photon emission should not require shielding at the low activities normally associated with these foils. For example, 1 mCi of activity will give an exposure rate of approximately 1 mR/hour at 10cm.

Further safety advice is available for users who may be using large quantities of ^{241}Am foil, such as in the production of smoke detectors.

Recommended working life

The recommended working life of a source is that period recommended by Amersham International within which the source should be replaced. The period given has been assessed on the basis of such factors as toxicity of nuclide, total initial activity, source construction, half-life of nuclide, typical application environments, operational experience, test performance data, etc.

Prepared and mounted americium 241 foil pieces as supplied by Amersham International have a recommended working life of 10 years when used in dry, non-corrosive atmospheres. For use in other environmental conditions, advice should be obtained from Amersham International.

A recommended working life cannot be given for any foil which is to be processed further by the customer. However, Amersham International is willing to advise and cooperate with the customer in assessing the recommended working life of the finished product, providing full details of the manufacturing procedure, design and application of the source are known.

Nuclear data for americium-241

Half life:	433 years
Alpha energies (emitted from foil):	~4·6MeV (typical spectrum, see figure 3) The spatial distribution of the alpha energies is shown in figure 4.
Photon energies:	59·6keV (35·3% emitted) Np L X-rays 12–22keV (~40%)
Radiochemical purity:	> 99·2%

Typical spectrum
(americium-241 alpha foil)

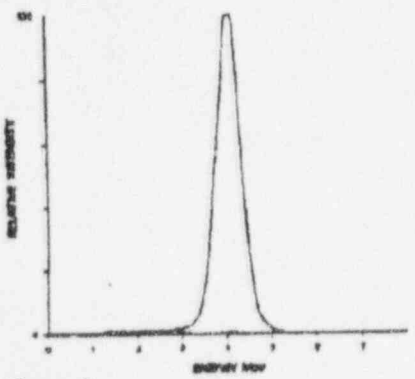


Figure 3

Spatial distribution of α-particle energy for foil with 3µm face

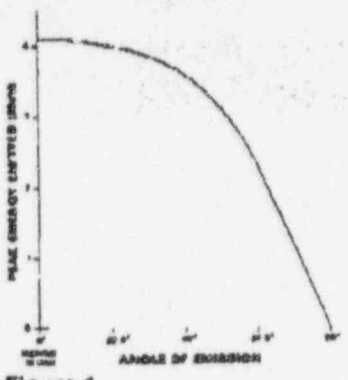


Figure 4

Spectra measured at Amersham International using a Si surface barrier detector.
(α-energies degraded due to transmission through gold alloy face of foil).

Related products

Alpha foils of a similar construction but containing radium-226 are also available. Details can be supplied on request.

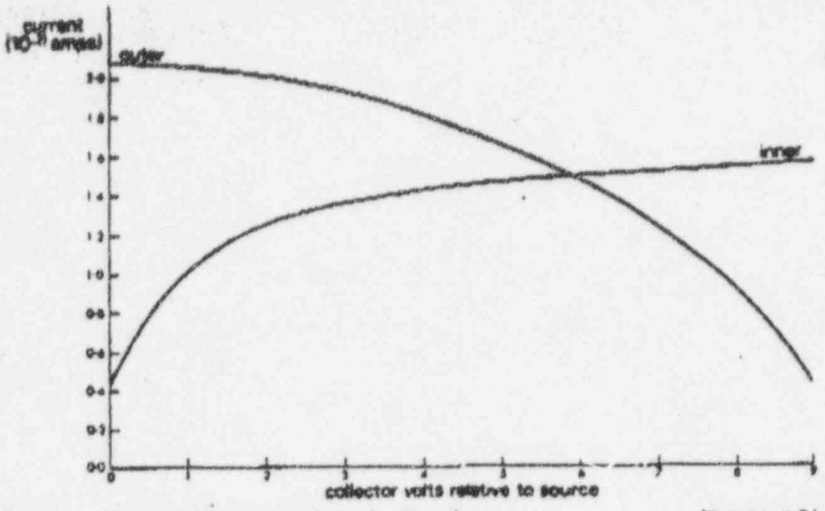


Figure 1 Ion chamber characteristics in clean air (Test circuit B)

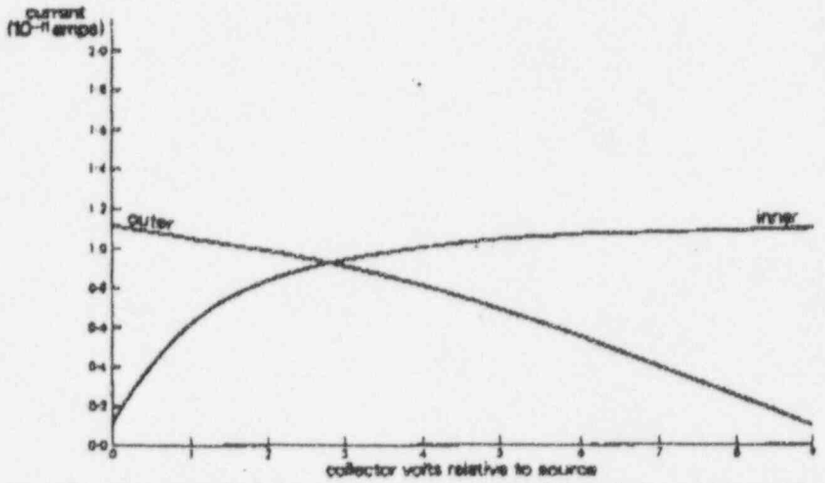


Figure 2 Ion chamber in B.S. smoke; obscuration level 4·0% per foot (Test circuit B)

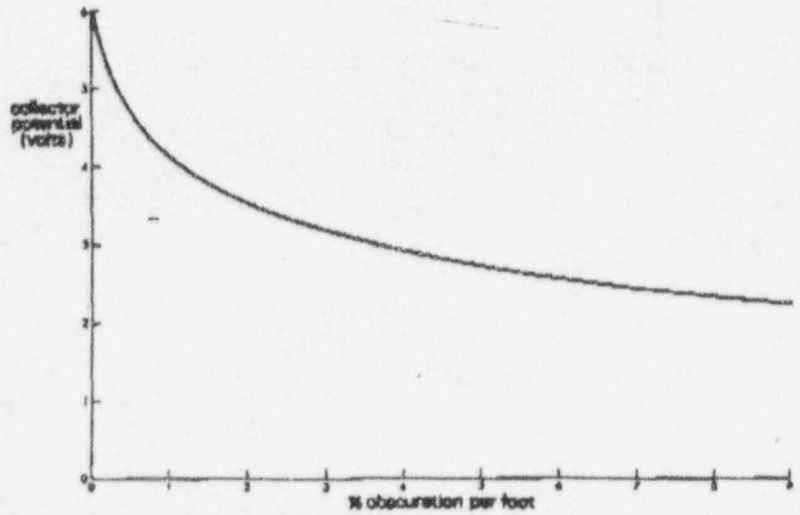


Figure 3 Collector potential change with B.S. smoke.
Whatman no.2 filter paper heated on electric element (Test circuit A)

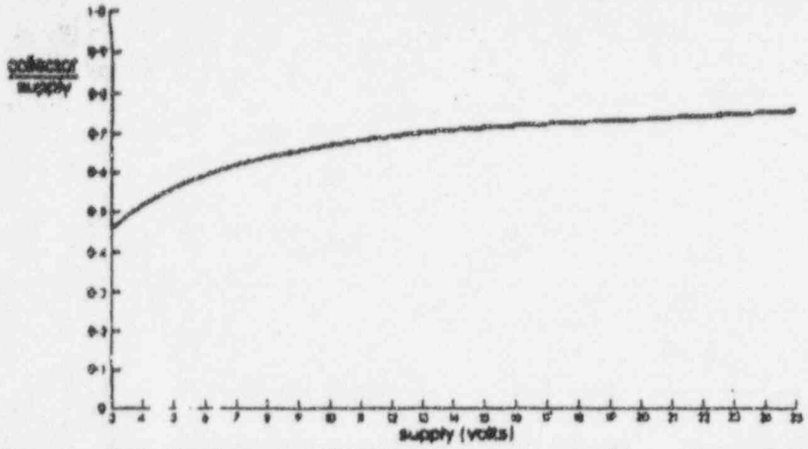


Figure 4 Ratio of collector potential at balance to supply potential (Test circuit A)

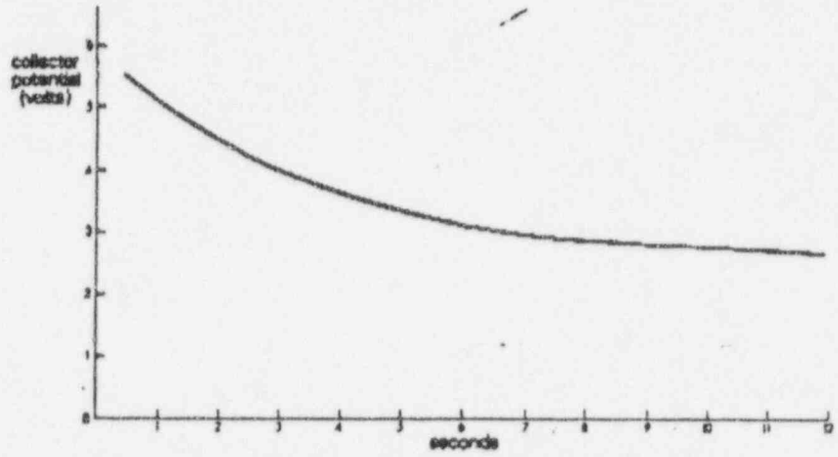


Figure 5 Balance voltage change with time after activation of the test electrode

Precautions and recommendations

The chamber ionization currents are small (order of 10pA) so the utmost care should be taken to preserve the insulation of the collector electrode and any detection device connected to it. In particular, care should be taken to avoid contaminating the insulators with soldering flux. The insulators should not be handled. The lead connecting the collector electrode to the detector circuit should preferably be short and clear of the circuit board and other components. To improve corrosion resistance the associated circuit should be enclosed in a sealed container and the chamber terminals sealed with a suitable sealant where they enter the container. Care should be taken to avoid sealant on the sides of the insulator of the collector electrode terminal. Chambers intended for installation at high altitudes may require adjustment of the tripping level of the detector circuit for optimum sensitivity (see Figure 8).

The balance voltage is relatively unaffected by variations, within reasonable limits, in temperature, humidity and wind velocity (see Figures 7, 8 and 9). For applications involving use in a wider range of temperatures than those shown, the detector circuit should incorporate some temperature compensation.

The chamber collector electrode is shielded by the outer cover from external electric fields. Suitable shielding should be provided for the associated circuits, especially because of the necessarily high impedance of the circuit connected to the chamber collector electrode.

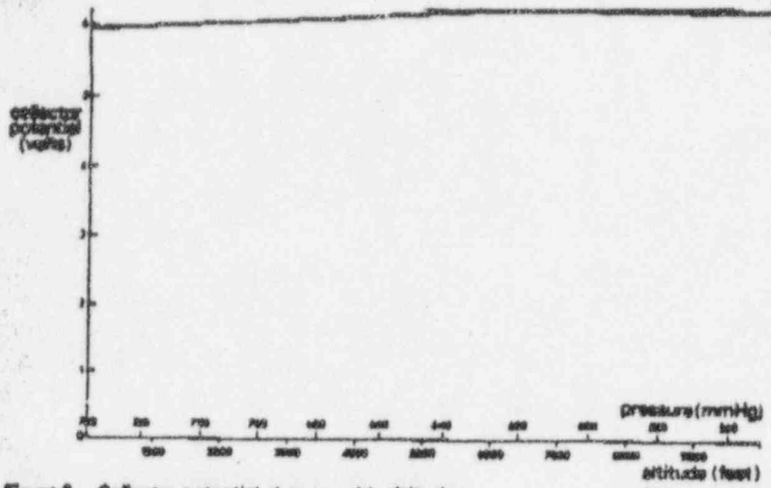


Figure 6 Collector potential change with altitude (Test circuit A)

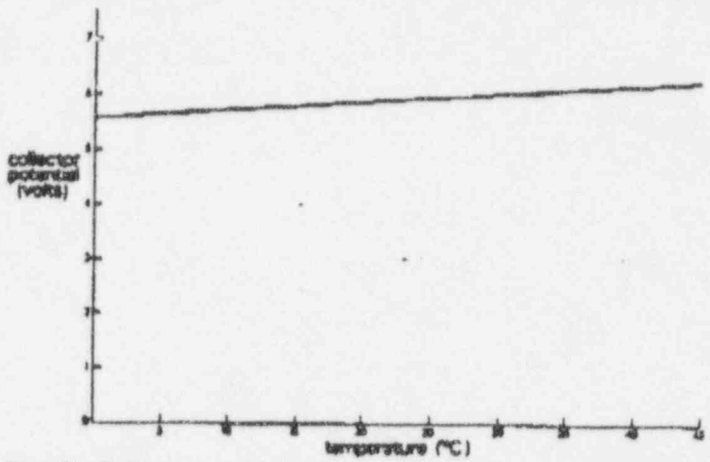


Figure 7 Collector potential change with temperature (Test circuit A)

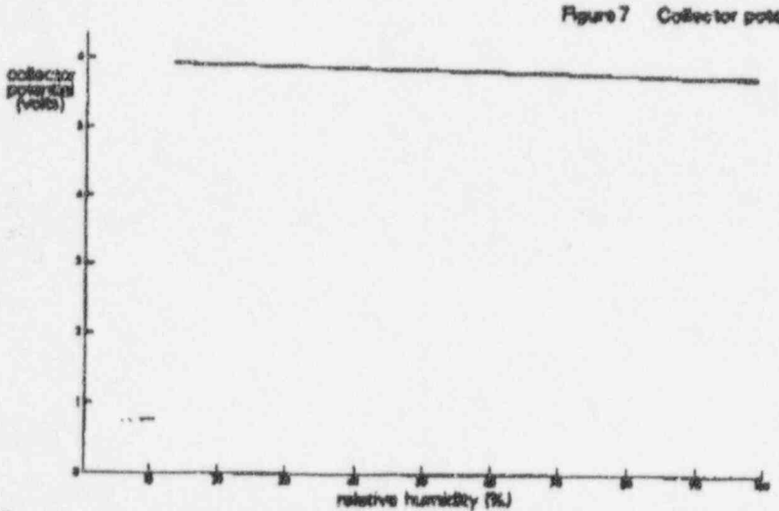
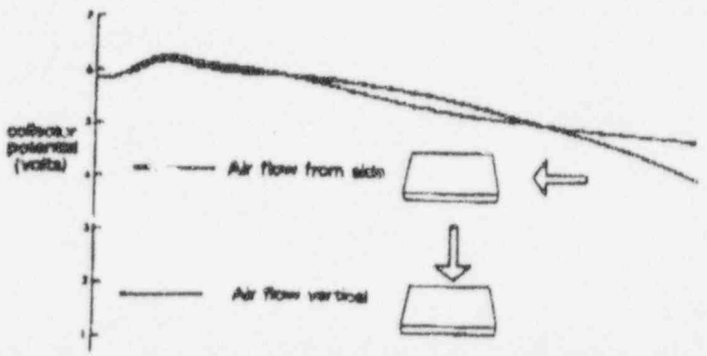
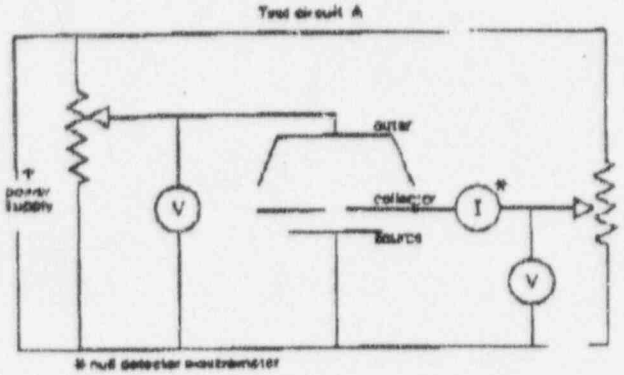


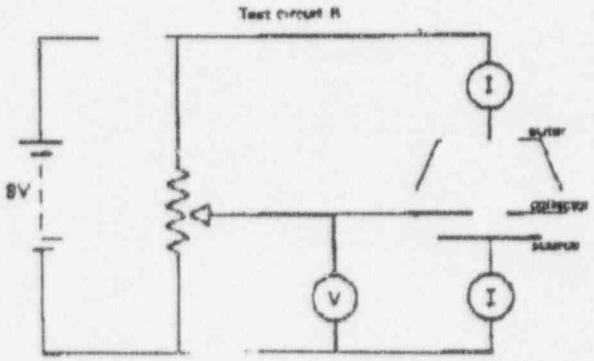
Figure 8 Collector potential change with relative humidity at 25°C (Test circuit A)



1. ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT
"Proposed radiation protection standards for ionization chamber smoke detectors." Nuclear Energy Agency Draft, Paris, OECD, 1976.
2. UNDERWRITERS LABORATORIES INC
"Standards for safety. Single and multiple station smoke detectors". UL 217, Second edition, New York, UL Inc., First impression, 4th October 1978.
3. BRITISH STANDARDS INSTITUTION
"Specification for components of automatic fire alarm systems for residential premises. Part I. Point-type smoke detectors." London, British Standards Institution, 1977.

Circuits used to determine typical characteristics





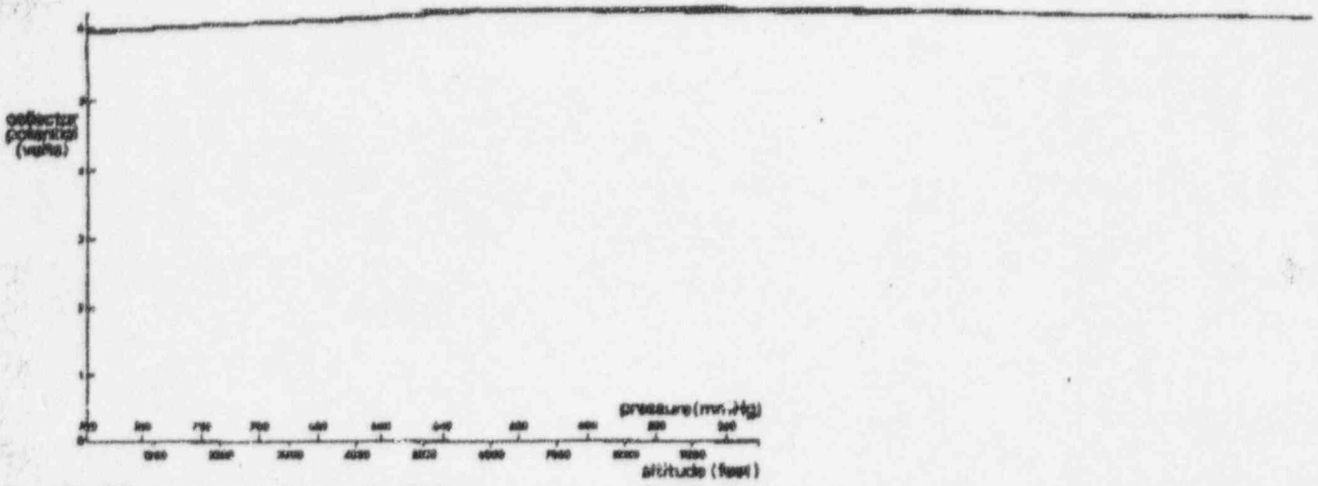


Figure 6 Collector potential change with altitude (Test circuit A)

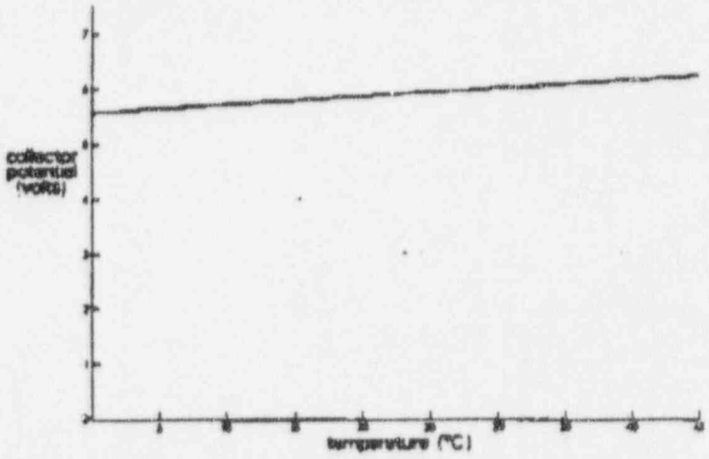


Figure 7 Collector potential change with temperature (Test circuit A)

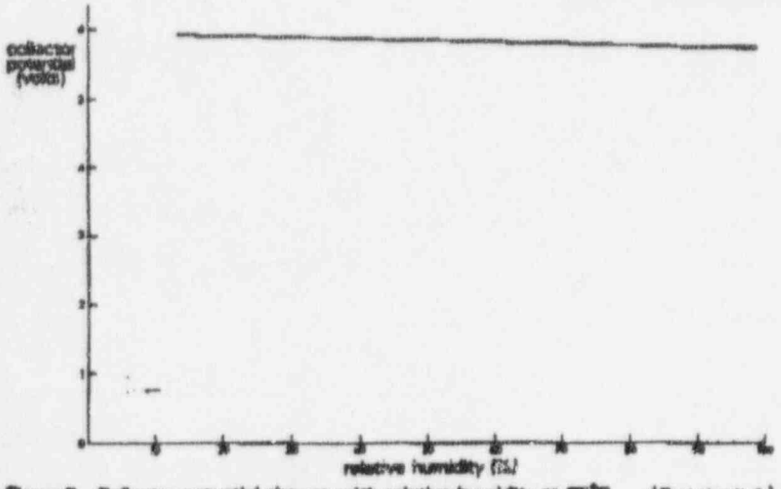
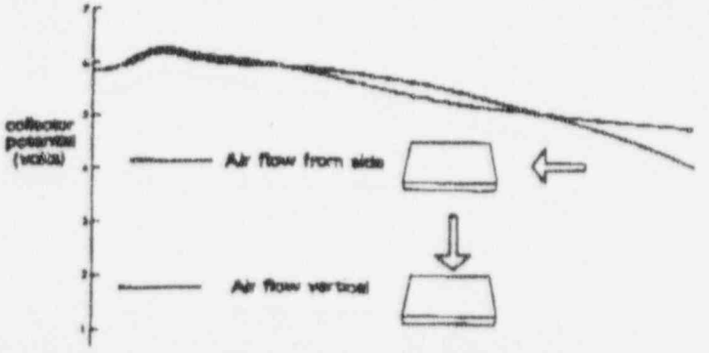


Figure 8 Collector potential change with relative humidity at 25°C (Test circuit A)



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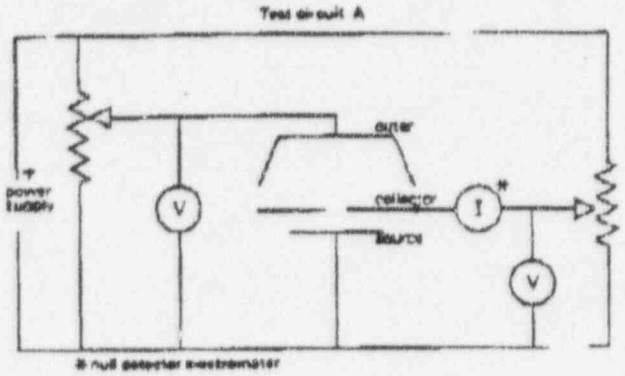

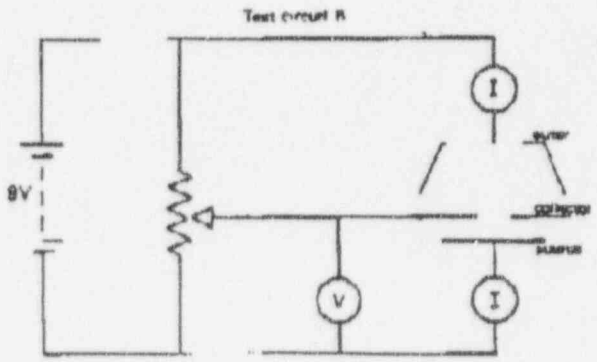

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