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 94596

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

AMOUNT RECEIVED	CHECK NUMBER	

APPROVED BY	DATE

NRC FORM 313 (9 90)

SLEEPSAFE CORPORATION 10-92

PHONE 703-989-5738
2121 ELECTRIC RD., S.W.
ROANOKE, VA 24018

484

July 28 19 94

56-64/514
1456

PAY
TO THE
ORDER OF United states Nuclear Regulatory Commission $ 6,100.00

Six Thousand one hundred and no/100---------- DOLLARS

NationsBank
NationsBank of Virginia, N.A.
Roanoke, VA

FOR Device review/exempt license

Edith N McAweeney

⑈000004 84⑈ ⑆051400646⑆ 1005 9193⑈

APPLICATION FOR DEVICE REVIEW

Submitted by

Sleepsafe Corporation
2121 Electric Road
Roanoke, VA 24018
Scott Markwell, President
(703)-989-5738

7/28/94

TABLE OF CONTENTS

3.1) SUMMARY DATA

3.1.1 Date

The date of the application is July 28, 1994

3.1.2 Applicant

Sleepsafe Corporation
2121 Electric Road
Roanoke, Virginia 24018
Contact: Scott Markwell, President
703-989-5738

Sleepsafe Corporation 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 500S and 200P Series. The model submitted by the drawings 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.

3.1.5 Other Companies Involved

Other companies directly involved 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 an ISO 9000 quality certification or equivalent. Today, we anticipate the manufacturer of our initial production to be:

SCI Systems Inc.
2101 W. Clinton Ave.
P.O. Box 1000
Huntsville, Alabama 35807

SCI is the largest contract manufacturer to the computer industry with 17 plants worldwide.

Our ion chamber supplier will be:

HomeWatch Limited
7/F Shell Industrial Building
12 Lee Chung Street
Chai Wan, Hong Kong

HomeWatch provides a chamber of proven performance over many years. HomeWatch bought the successor company to Wing Wah Chong Investments company and provides the same chamber that has achieved at least one prior N.R.C. licensing (04-21357-01E as example.) Their detectors have passed U.L. 217 and British Standards Institution among others.

HomeWatch purchases its sealed sources already mounted in a source holder from Amersham and NRD.

3.1.6 Radioactive Source Model Designation

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

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

3.1.7 Radionuclides and Maximum Activity

The radionuclide is Americium 241 - 0.9 microcurie.

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

Sleepsafe smoke detectors are designed to save 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 00S 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.

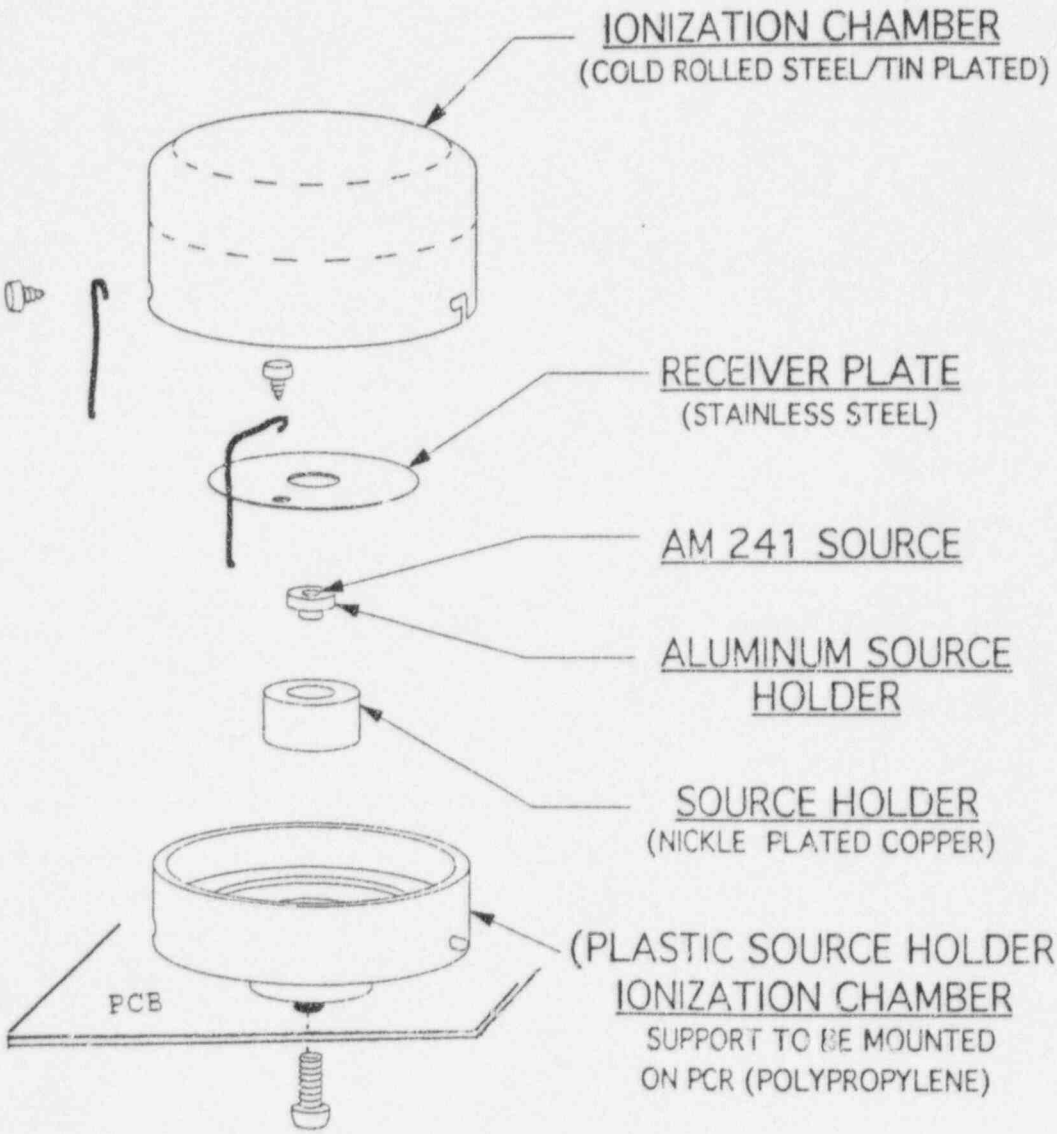
The detector is designed for ceiling or wall installation with screws and anchors. It is not portable and will be installed in a fixed location.

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.

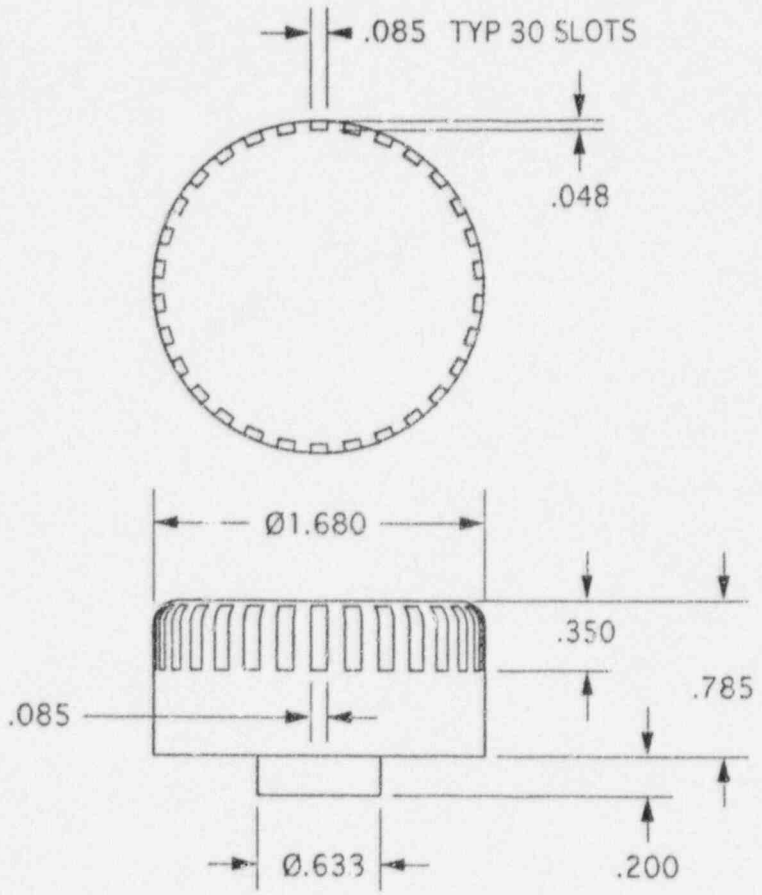
3.2.2 Drawing

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.



CONTAINMENT OF SOUR[illegible]THIN DETECTOR

FIGURE 1



STANDARD HIGH PERFORMANCE CHAMBER

FIGURE 2
Scale = Actual

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. For example, the device will be tested in an environment with temperature extremes between 32 and 120 degrees F with a relative humidity of up to 93 percent. In addition to humidity, they will be corrosion tested with a hydrogen sulfide-air mixture and a carbon dioxide-sulfur dioxide mixture. 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 Model 500SI series 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 in section 3.2.2.

2) Dimension and Materials of the Circuit board:

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

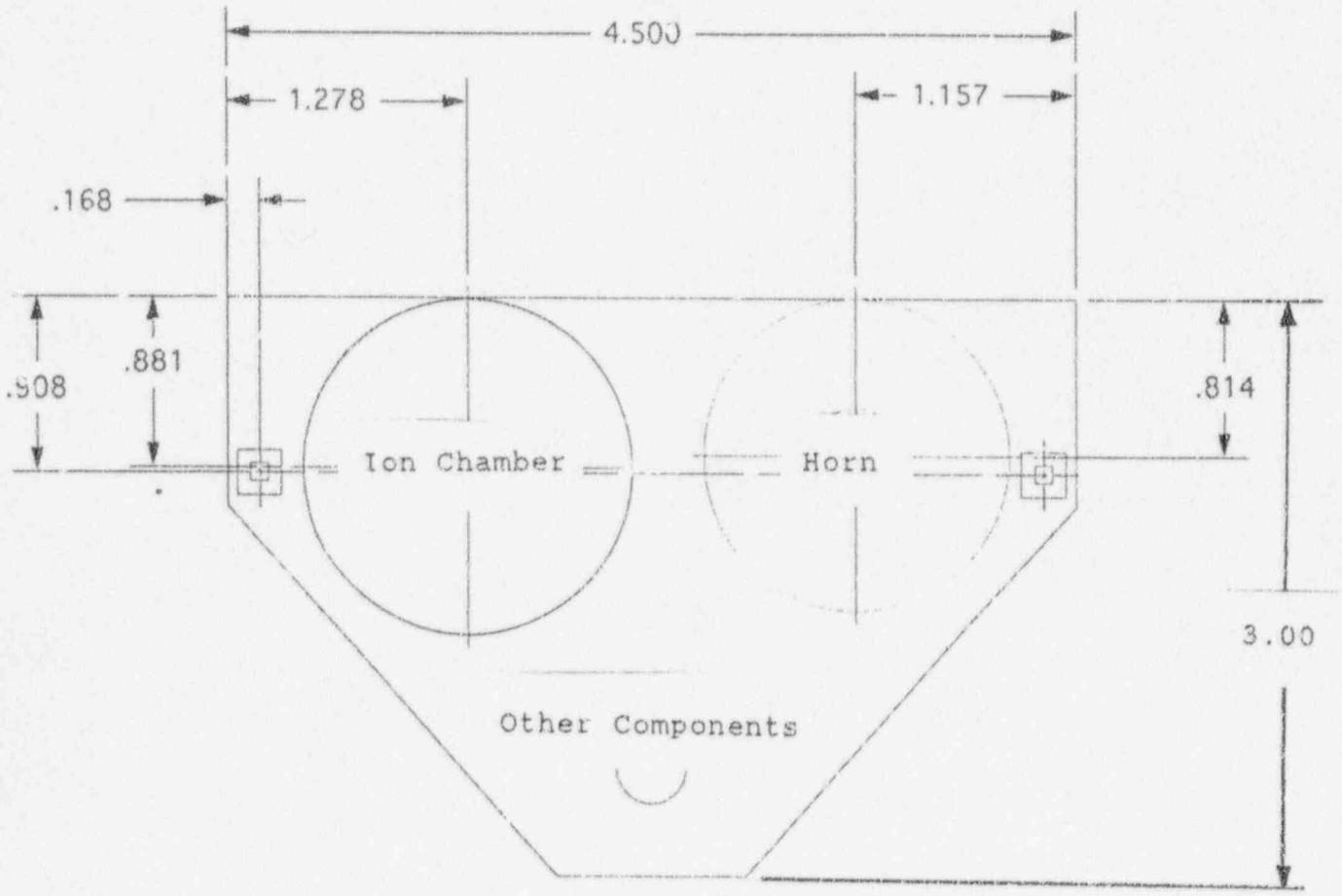


FIGURE 3
Circuit Board REV 1
Scale = Actual

3) Attachment of the chamber to the board:

Please see Figure 1 in section 3.2.2.

4) 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:

a) diameter of the housing
b) thickness of the housing (separate cover and base)
c) wall thickness (minimum 0.060, typical 0.080)
d) method of attachment of the board to the housing
e) method of closing (hinged cover)

5) Model variations:

As stated the drawings represent the base model 500SI. Other models 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. The maximum sizes for these openings would be caused by the strobe at 1 7/8" dia or the security sensor at approximately 2" by 1-1/2".

3.3.3 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."

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. Other test results can be obtained if necessary.

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) 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. - whose license is this.

3) If requested, drop tests will be conducted as prototypes become available.

4) U.L. testing. Our product will be U.L. tested and approved prior to exempt distribution. That testing likely will not begin before 10/1/94. Should it be necessary, a copy of those results can be provided late in the NRC approval process.

3.3.5 Quality Control

1) Leak testing. The 500S Series detectors ion chambers will be quality tested in accordance with 10 CFR and the "SSSS" position.

2) International Manufacturing Standards. The 500S Series smoke detector will be manufactured meeting ISO 9000 quality standards or equivalent.

3) Underwriters Laboratory Requirements. The 500S Series will be randomly checked for sensitivity per U.L. 217.

4) Procedures manual. A copy of the QC procedures manual will be provided when it is available - late in the U.S. NRC approval process.

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 ..dionuclides 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 (CRNL-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.

(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 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 an 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 dose 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 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 and exposure.

3.3.8 Radiological Safety Instructions

Other owners manual instructions or equivalent ~~that~~ will be included in addition to Section 3.3.3 that may enhance radiological safety:

- Always be careful to avoid unnecessary touching of circuit board components to prevent damage to your detector
- This unit is not consumer serviceable
- This smoke detector is manufactured and distributed under license of the U.S. Nuclear regulatory Commission.

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 500S 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.

The 500S Series detectors ion chambers will be quality tested in accordance with 10 CFR and the "SSSS" position. Our particular ion chamber has been previously licensed in a smoke detector by the U.S. NRC.

And our product will be U.L. tested and approved prior to exempt distribution and manufactured meeting ISO 9000 quality standards.

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 lieu of actual measurements of microrem/hr.

The calculated dose follows:

C= 1X10-6 Curies
N= .36
E= .060

R/hr at 1 foot= 6 CEN.
R/hr @ 1 ft =6(1X10-6)(.36).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

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.

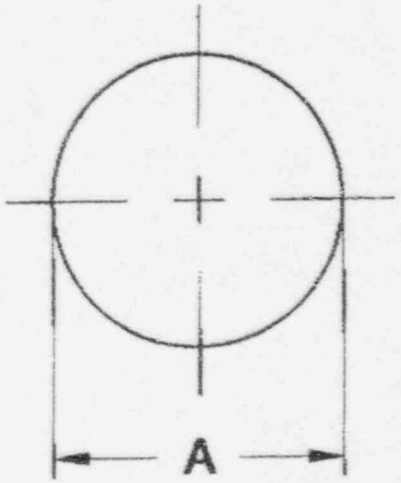
Quality Control Department

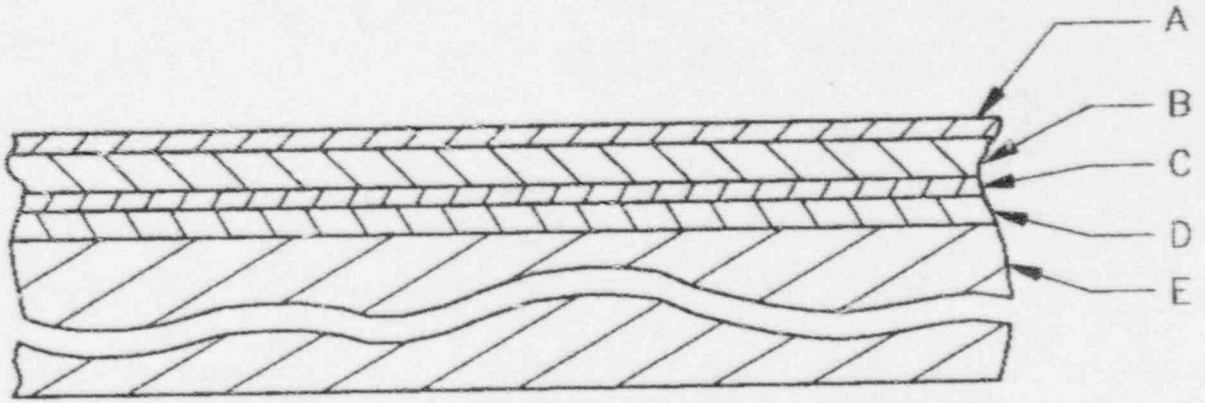
7/21/94
Date

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	DCP





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		

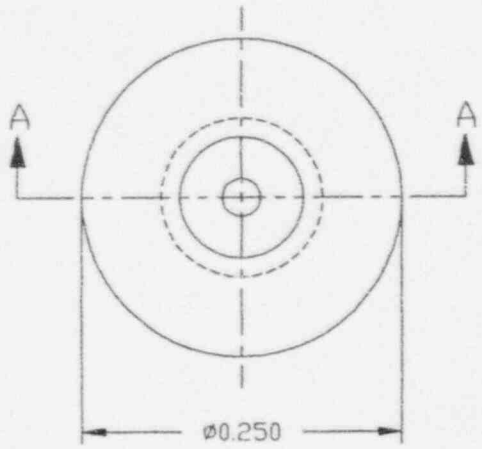
NRD INC.
A SUBSIDIARY OF MARK IV INDUSTRIES, INC.
2637 ALT BOULEVARD GRAND ISLAND, NEW YORK 14072

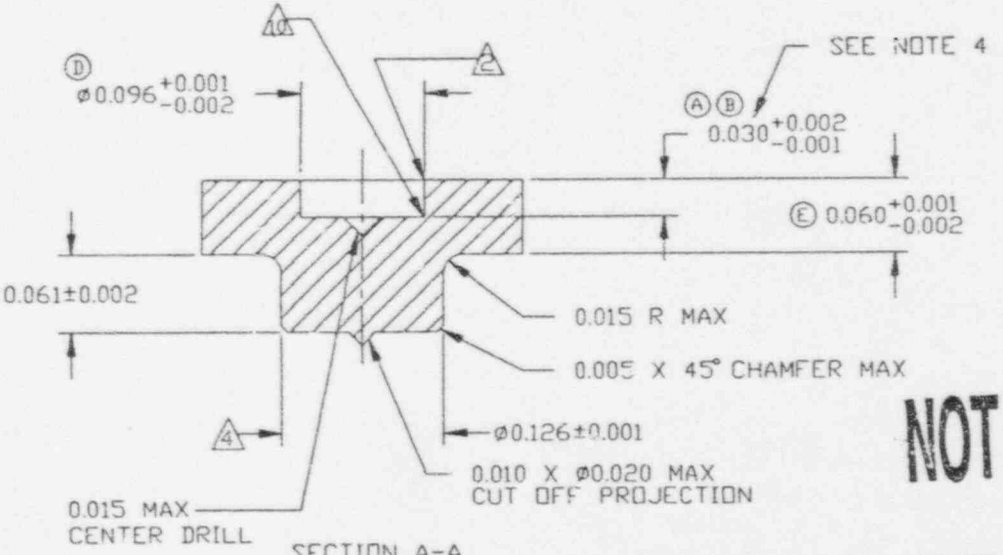
A-001 SINGLE FACE FOIL

MATERIAL & FINISH: Am 241, GOLD, SILVER

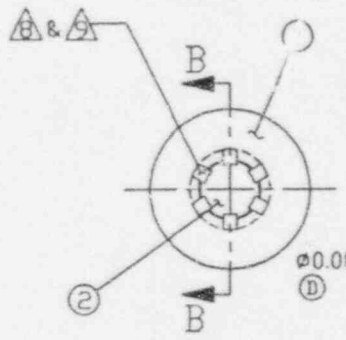
A	DATE	SCALE	DWG NO	REVISION
	13AP79	NA	79A045	3

DATE	SYM	REVISION RECORD	AUTH.	DR	CK.
05JL85	A	ADD NOTE 4	T.C.	JES	
29JA'87	B	CHANGE 0.030 +0.002 -0.003 TO 0.030 +0.002 -0.001		JES	
01DEC88	C	ADD FOIL NOTE		JES	
30AJ/90	4	REDRAWN ON AUTOCAD		CDD	
27NOV90	5	DIM Ø0.096 WAS Ø0.098 Ø0.003 WAS Ø0.003 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 0.060 +0.001 -0.002 WAS 0.060 +0.002 -0.003	TC	CDD	

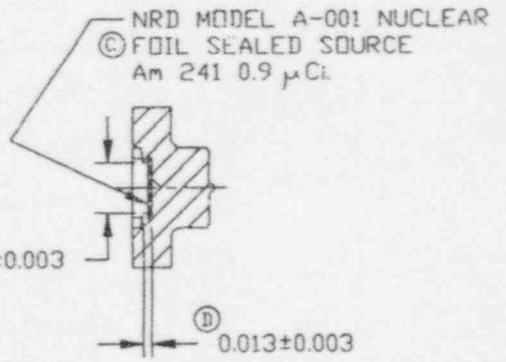




SECTION A-A



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.

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
FRACTIONAL ±	SCALE: 10 : 1
ANGULAR ± 1°	DRAWN BY: JES
	APPROVED BY:
	DATE: 07FE85
	DWG. NUMBER: 85B026
	R: 7

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	DM	CDD	
22NOV91	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	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, and 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.

---

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.

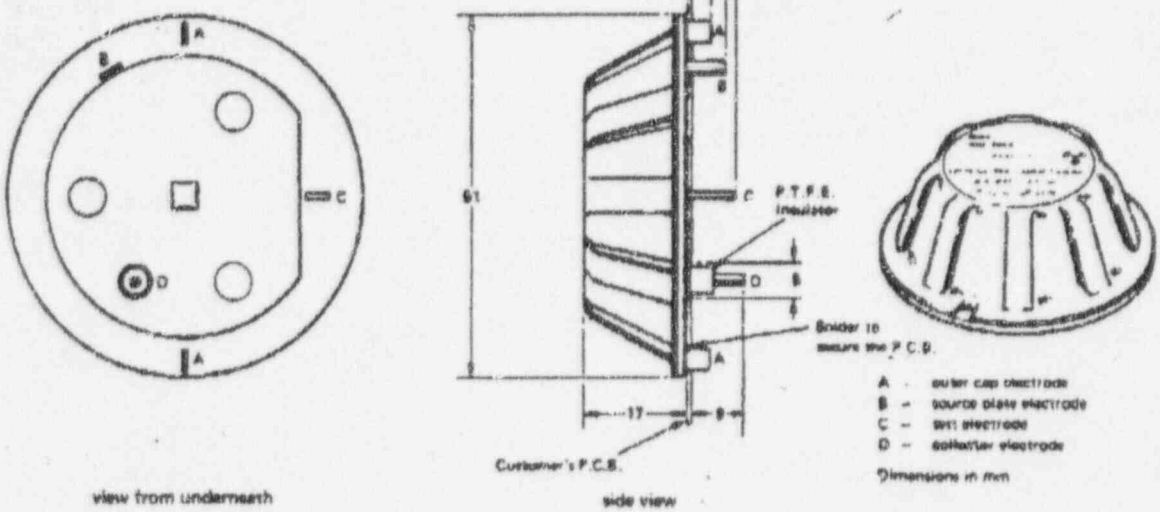
2 Title 49, Code of Federal Regulations, Parts 100 - 199, United States of

Product specification

Smoke Detector Ionization Chamber

Data sheet 11247

DSC.A3



view from underneath

side view

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.

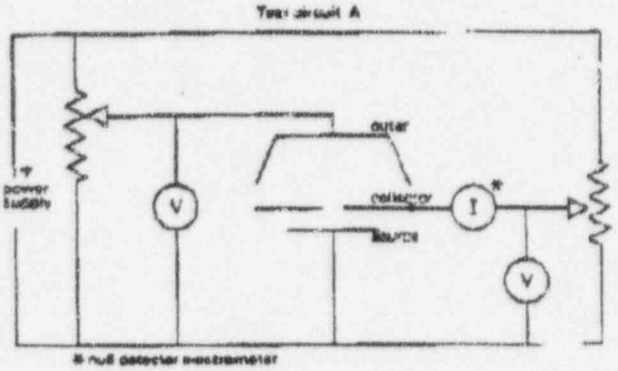
The DSC.A3 incorporates a performance test electrode to permit electrical testing of the chamber during operation, as required by BS 5446. When actuated the electrode disturbs the balance conditions to simulate the presence of smoke.

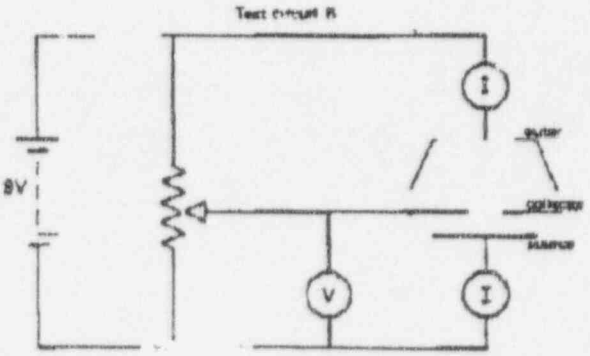
The design is suitable for use with an external integrated circuit containing the electrometer and alarm circuits.

*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 1. 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	0·05
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.

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 alpha, 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

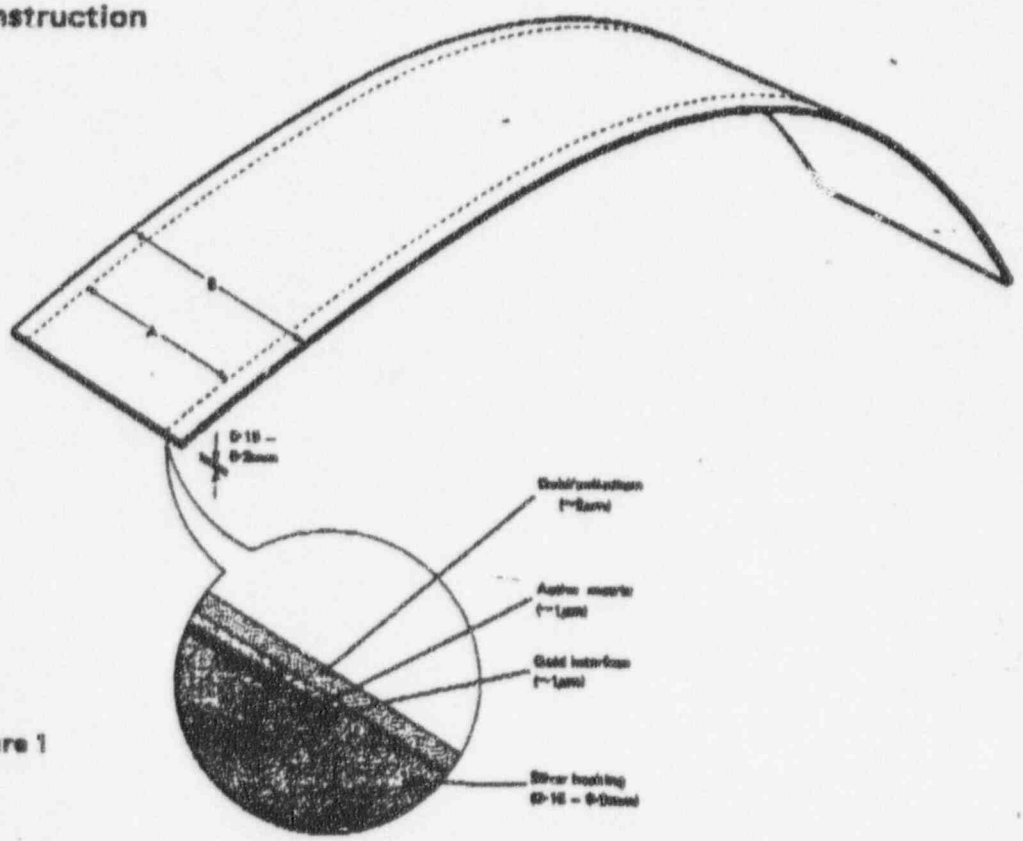


Figure 1

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 (c) 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.

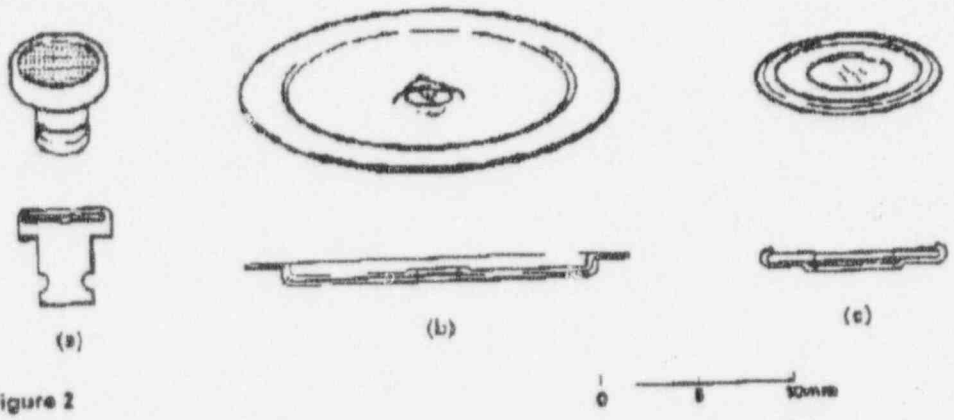


Figure 2

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, 1mCi of activity will give an exposure rate of approximately 1mR/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:	59·5keV (35·3% emitted) Np L X-rays 12–22keV (~40%)
Radiochemical purity:	> 99·2%

Typical spectrum
(americium-241 alpha foil)

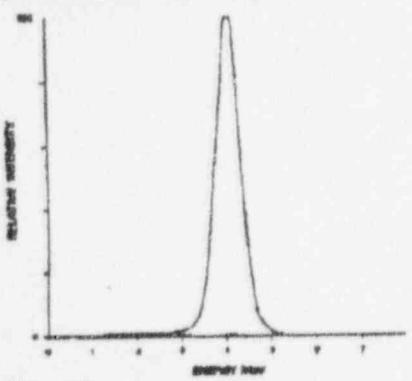


Figure 3

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

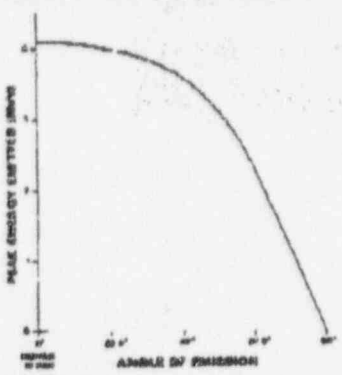


Figure 4

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.

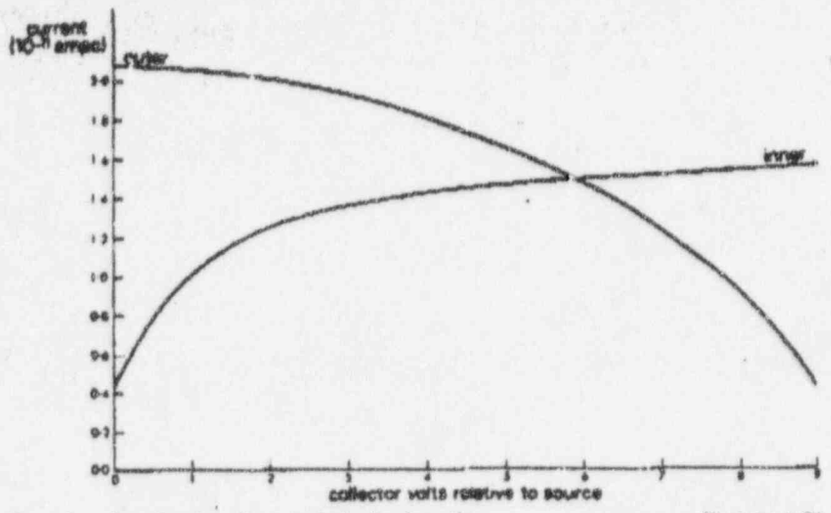


Figure 1 Ion chamber characteristics in clean air (Test circuit B)

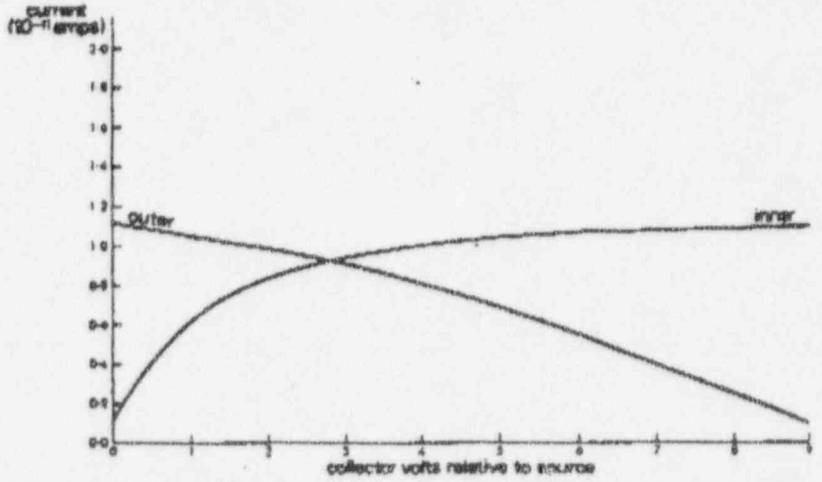


Figure 2 Ion chamber in B.S smoke; obscuration level 4·0% per foot (Test circuit B)

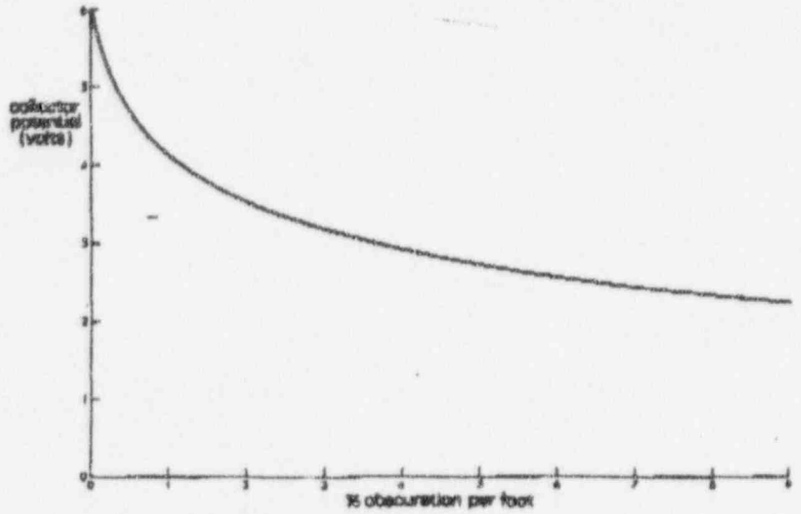


Figure 3 Collector potential change with B.S. smoke.
Whatman no.2 filter paper heated on electric element (Test circuit A)

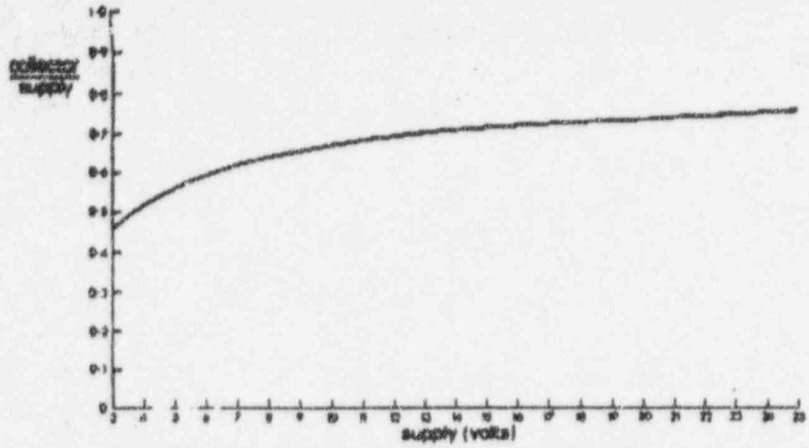


Figure 4 Ratio of collector potential at balance to supply potential (Test circuit A)

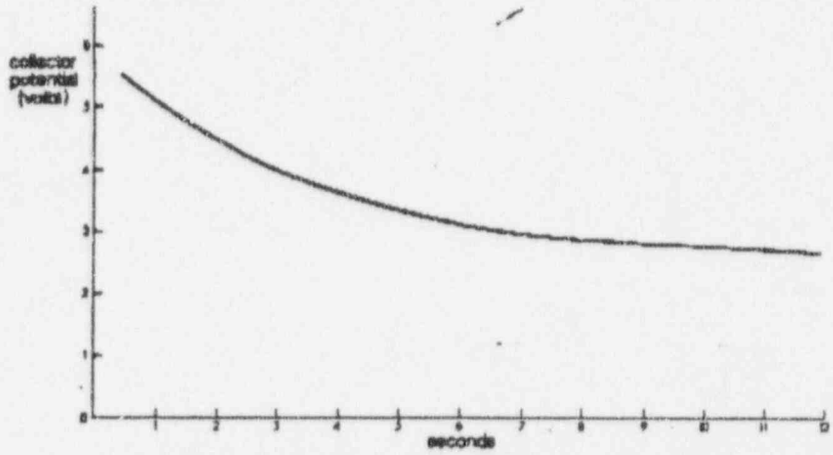


Figure 5 Balance voltage change with time after activation of the test electrode

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 6).

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.

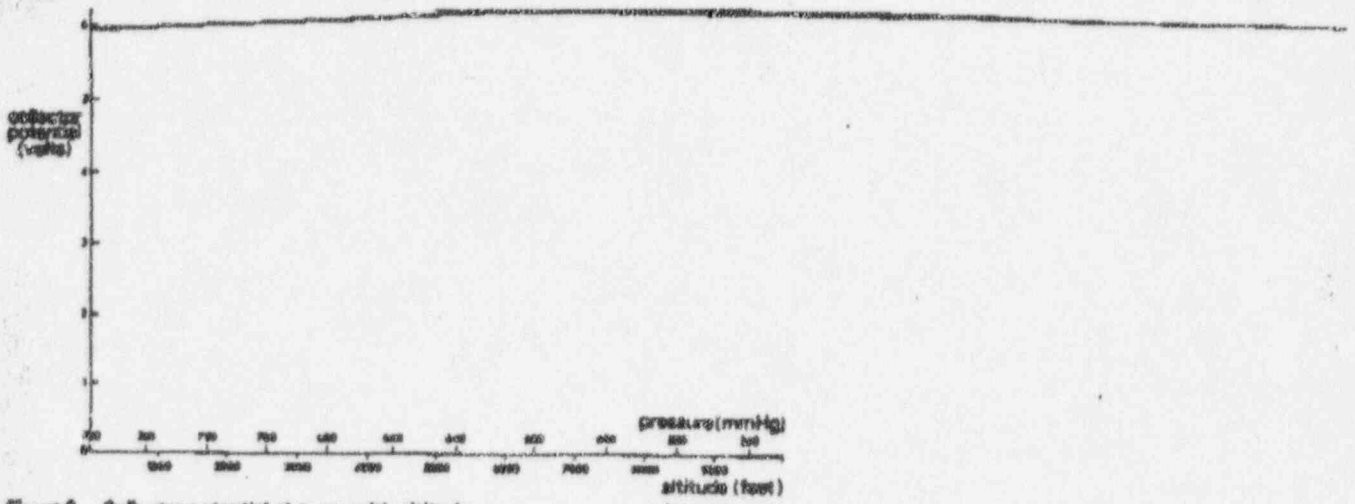


Figure 6 Collector potential change with altitude (Test circuit A)

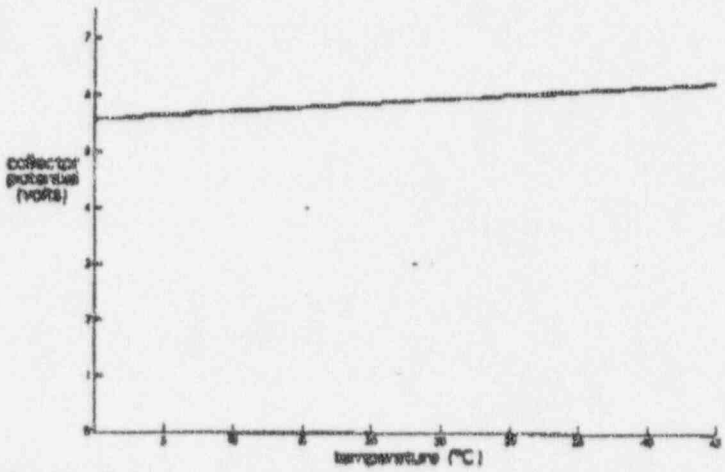


Figure 7 Collector potential change with temperature (Test circuit A)

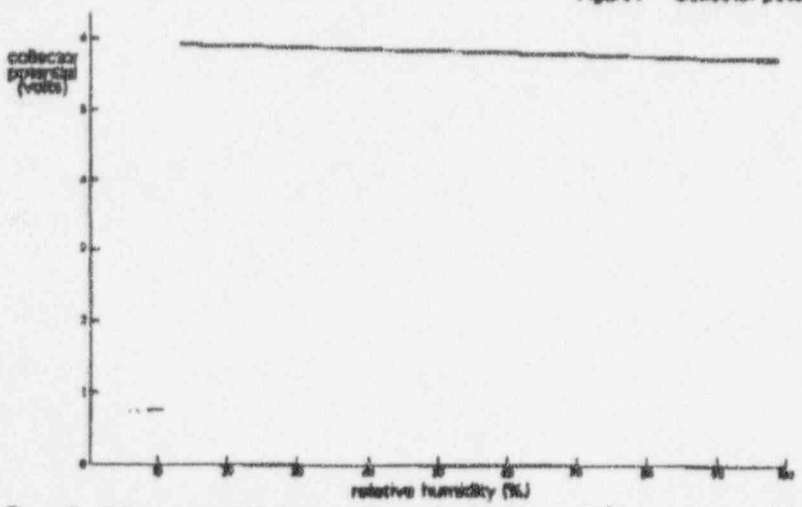
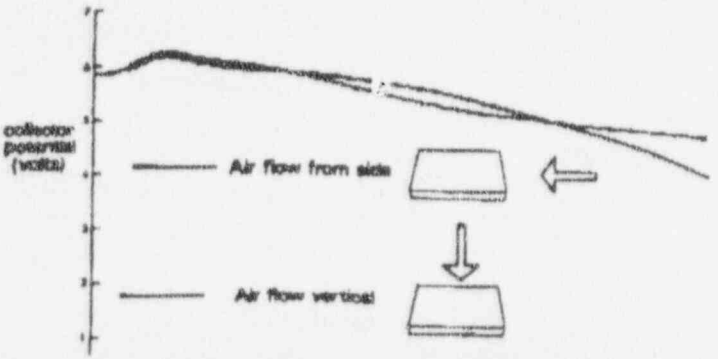
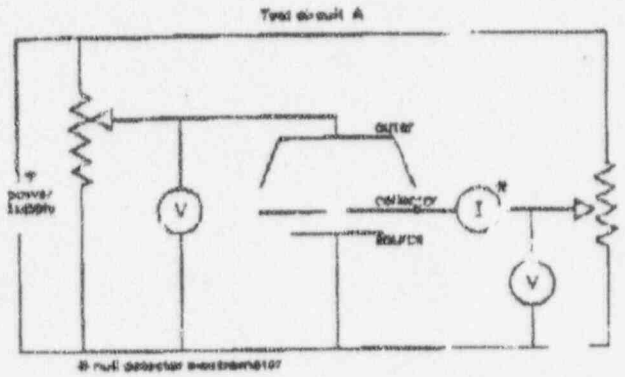


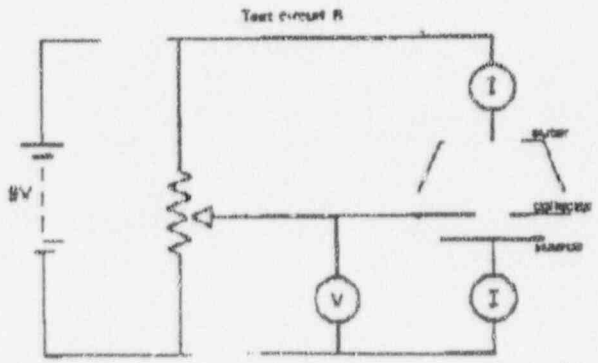
Figure 8 Collector potential change with relative humidity at 35°C (Test circuit A)



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





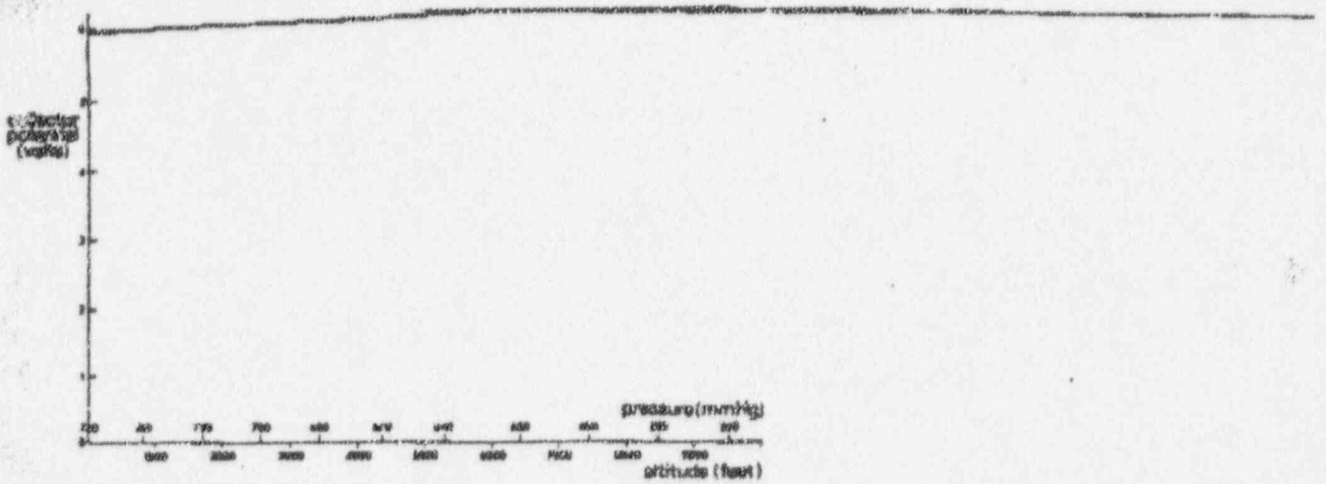


Figure 6 Collector potential change with altitude (Test circuit A)

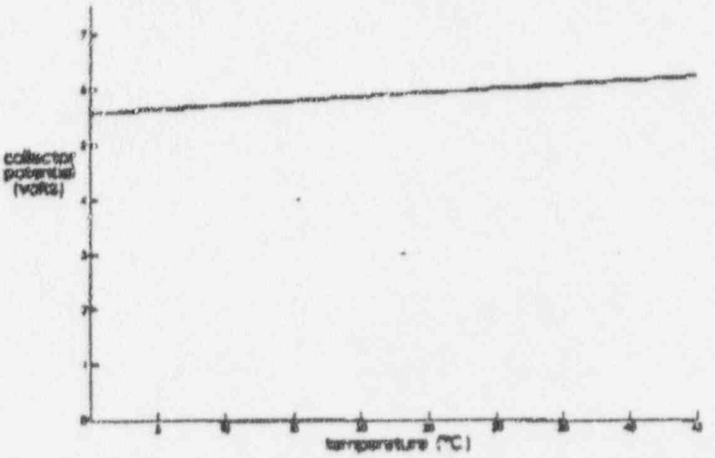


Figure 7 Collector potential change with temperature (Test circuit A)

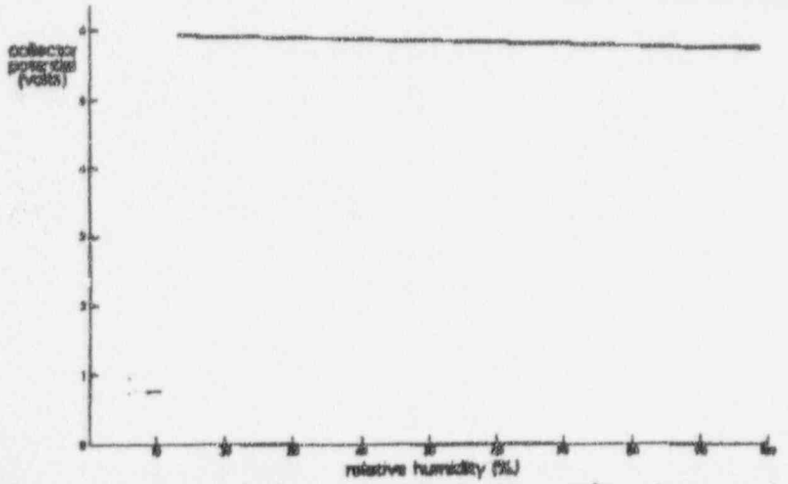
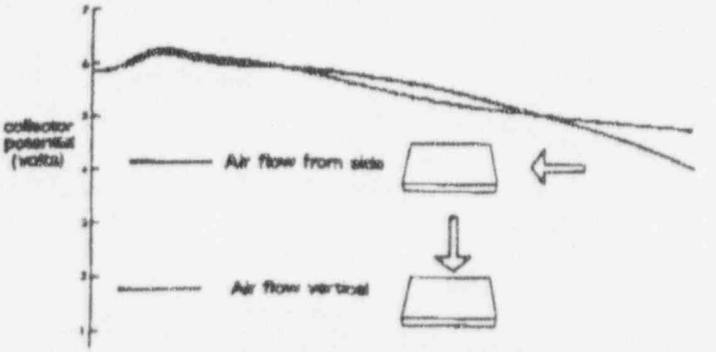
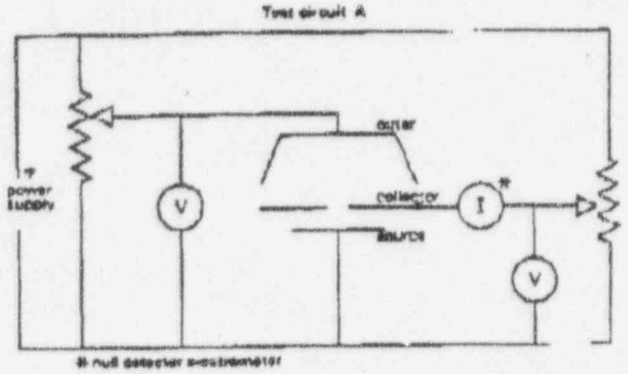


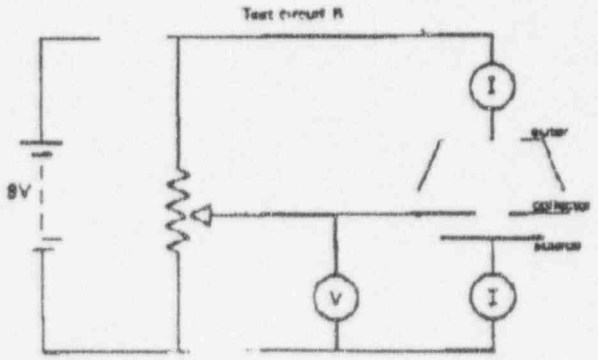
Figure 8 Collector potential change with relative humidity at 35°C (Test circuit A)



1. ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT
"Proposed radiation protection standards for ionization chamber smoke detectors." Nuclear Energy Agency Draft, Paris, OECD, 1978.
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 1. Point-type smoke detectors." London, British Standards Institution, 1977.

Circuits used to determine typical characteristics





APPENDIX B

OVERSIZE
DOCUMENT
PAGE(S) PULLED

SEE APERTURE CARD FILES

APERTURE CARD/PAPER COPY AVAILABLE THROUGH NRC FILE CENTER

****

NUMBER OF OVERSIZE PAGES FILMED ON APERTURE CARD(S) 2

****

ACCESSION NUMBERS OF OVERSIZE PAGES:

9701310308-1-2

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

Scott N. Markwell
President

SNM/ct

Attachments

9701310294 XX.

021654

NRC FORM 313
(9 901)
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 94596

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

AMOUNT RECEIVED	CHECK NUMBER

APPROVED BY | DATE

NRC FORM 313 (9 901)

9701310308 90pp

021654

SLEEPSAFE CORPORATION 10-92

PHONE 703-989-5738
2121 ELECTRIC RD., S.W.
ROANOKE, VA 24018

484

68-64/514
1456

July 28 19 94

PAY TO THE ORDER OF United states Nuclear Regulatory Commission $ 6,100.00

Six Thousand one hundred and no/100---------- DOLLARS

NationsBank
NationsBank of Virginia, N.A.
Roanoke, VA

FOR Device review/exempt license

Scott N McNeel

⑈00000484⑈ ⑆051400646⑆ 1005 9193⑈

APPLICATION FOR EXEMPT DISTRIBUTION LICENSE

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

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 cf 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.

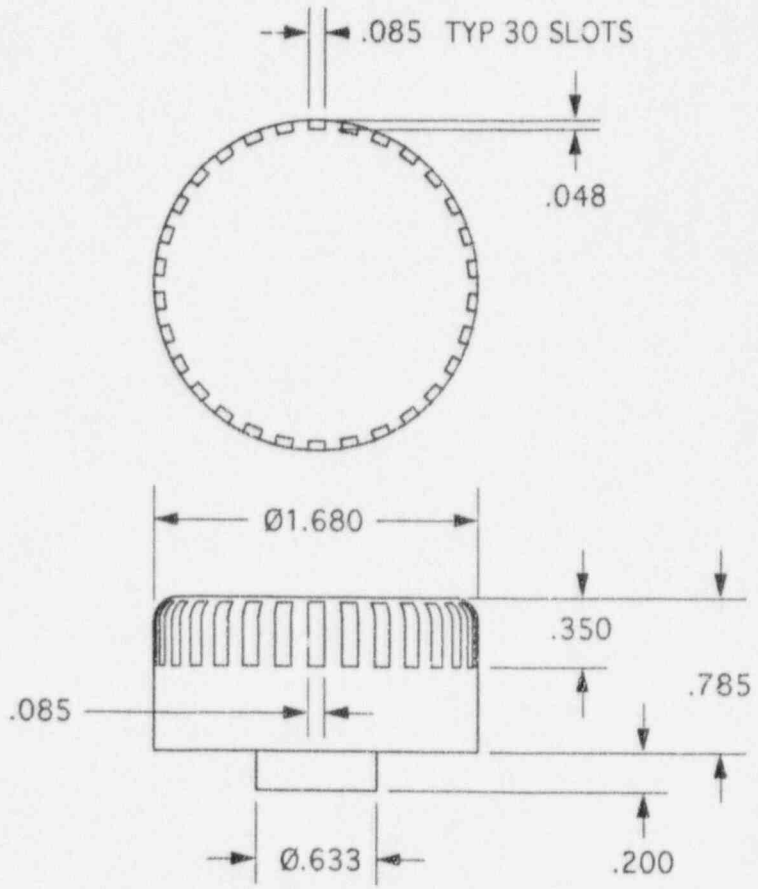
Dale H. Denham, Batelle Pacific Northwest laboratory, (Health Physics 16, 480 (196) stated , with a literature citation to ICRP Report II,"Because most of the compounds of the transplutonium elements are insoluble in biological fluids, ingestion and percutaneous absorption are unlikely to result in significant 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

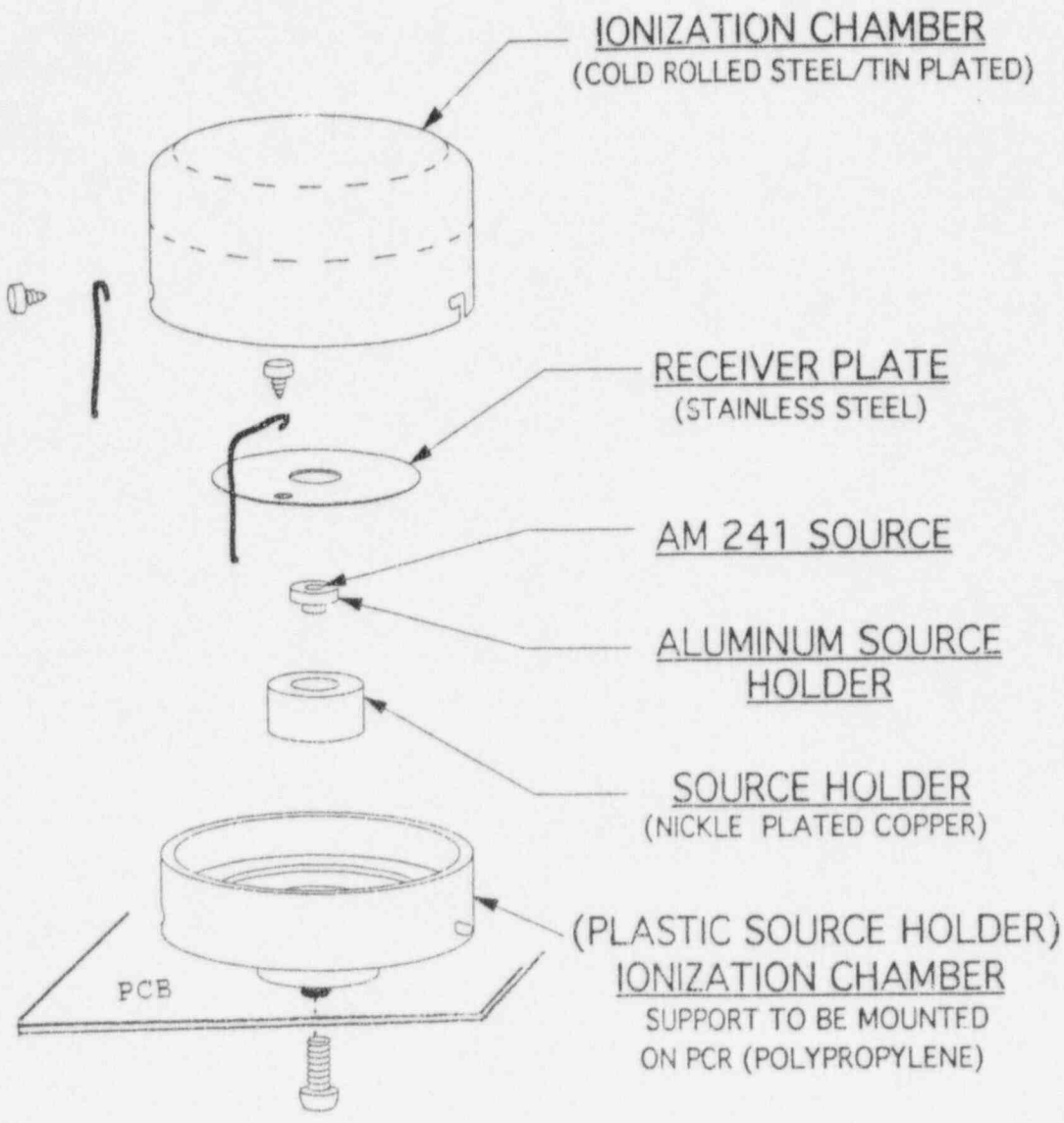
a) Engineering Details of the Chamber and Contents: The ionization chamber includes a sealed source Americium 241 and source holder from Amersham or NRD with certification that they have been leak tested in accordance with USNRC leak test requirements. The source holder is crimped into a nickel plated 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.

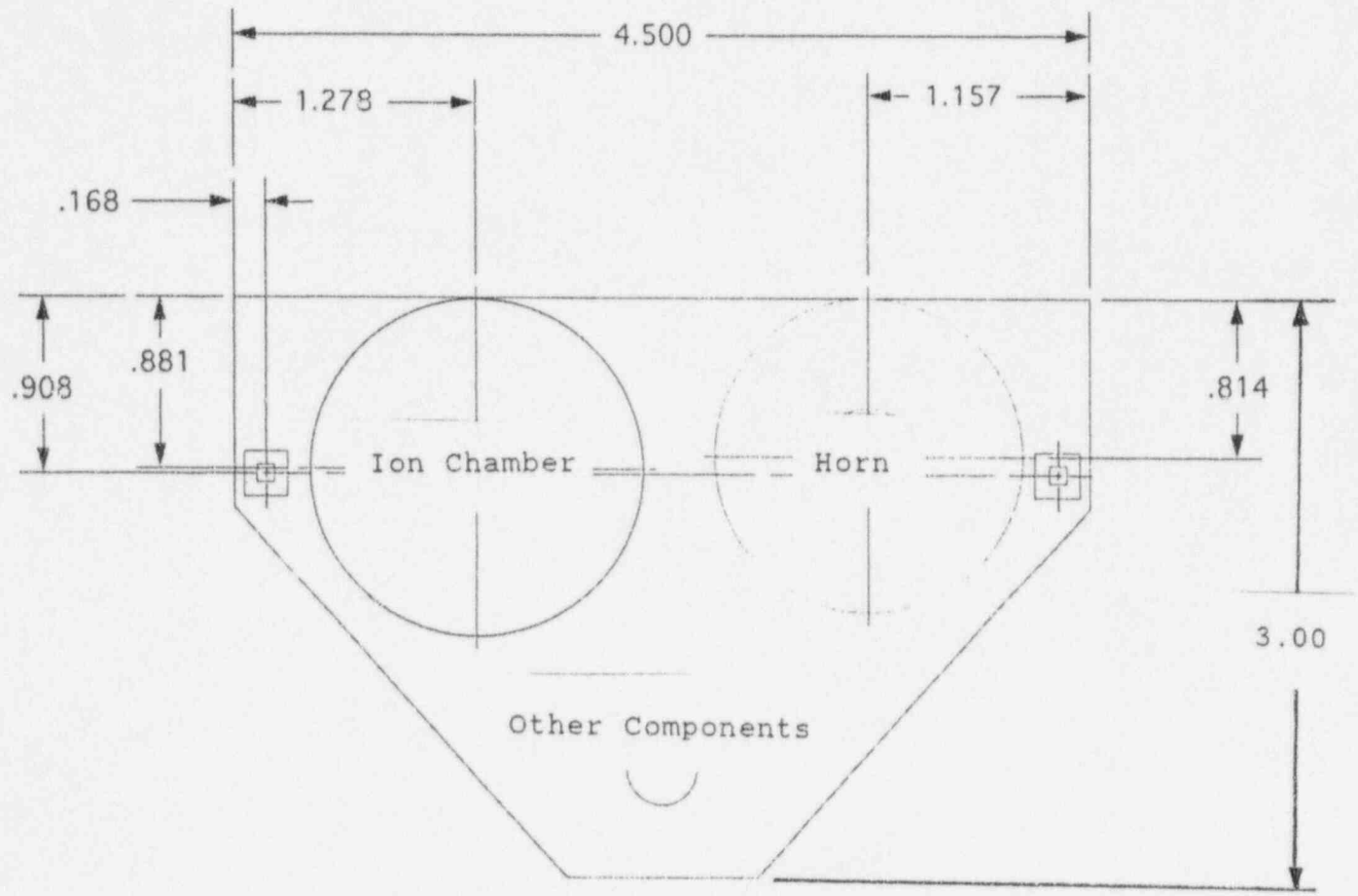


FIGURE 3
Circuit Board

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 iittle 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
N= .36
E= .060

R/hr at 1 foot= 6 CEN.
R/hr @ 1 ft.=6(1X10-6)(.36).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

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.

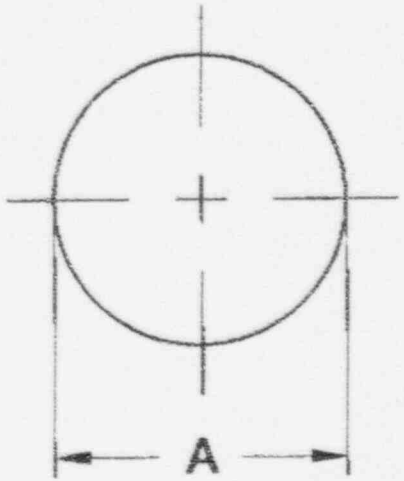
Lawrence Keating
Quality Control Department

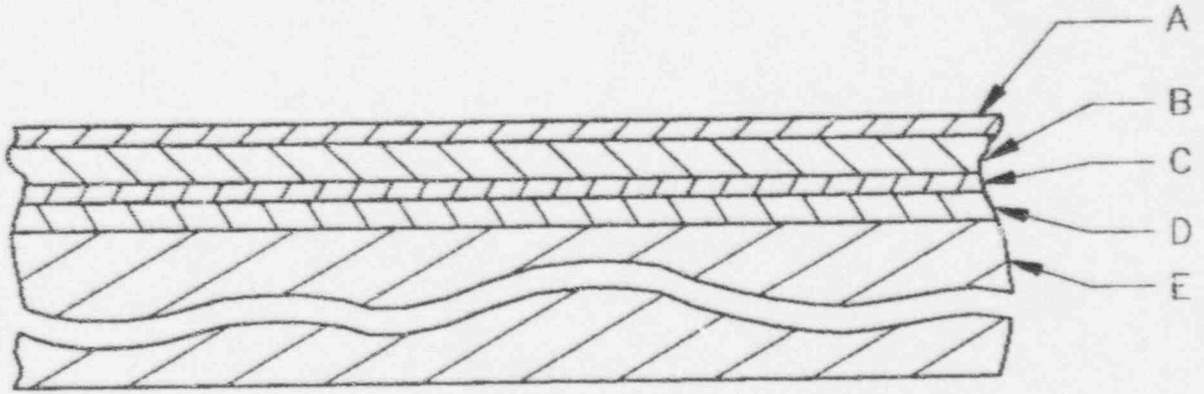
7/21/94
Date

David M. Hall
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	JCP





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"

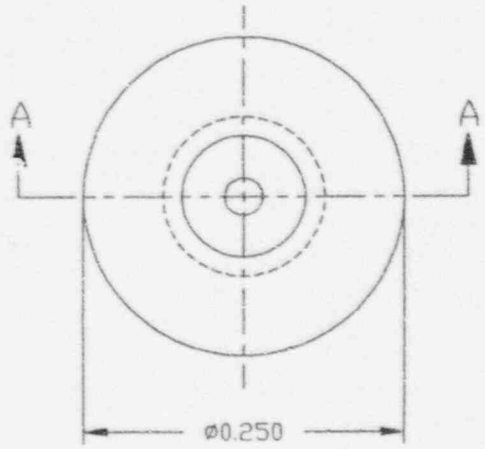
UNLESS OTHERWISE SPECIFIED	SIGNATURES	DATE
DIMENSIONS ARE IN INCHES	DRAWN R. BIDELL	
TOLERANCES ON:	CHECKED	
2 PL DECIMALS ±	APPROVED	
3 PL DECIMALS ±	APPROVED	
ANGLES ±	THIRD ANGLE PROJECTION	
FRACTIONS ±		
DO NOT SCALE PRINT		

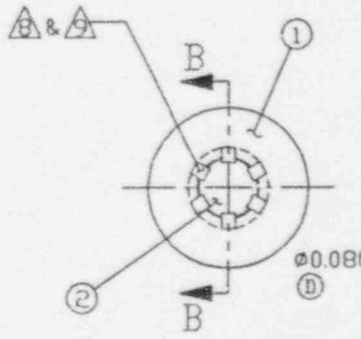
NRD INC.
A SUBSIDIARY OF MARK IV INDUSTRIES, INC.
2937 ALT BOULEVARD GRAND ISLAND, NEW YORK 14072

A-001 SINGLE FACE FOIL

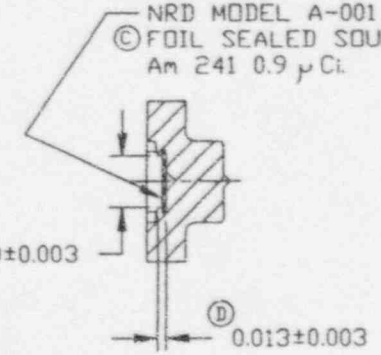
MATERIAL & FINISH				
Am 241, GOLD, SILVER				
A	DATE 13AP79	SCALE NA	DWG NO 79A045	REVISION 3

DATE	SYM	REVISION RECORD	AUTH.	DR.	CK.
05.8.85	A	ADD NOTE 4	T.C.	JES	
29APR87	B	CHANGE 0.030 +0.005 -0.005 TO 0.030 +0.002 -0.001		JES	
01DEC88	C	ADD FOIL NOTE		JES	
28AUG90	4	REDRAWN ON AUTOCAD		CDD	
27NOV90	B	DIM ⌀0.096 WAS ⌀0.090, ⌀0.080 WAS ⌀0.083, 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 0.060 -0.001 -0.002 WAS 0.060 +0.002 -0.003	TC	CDD	

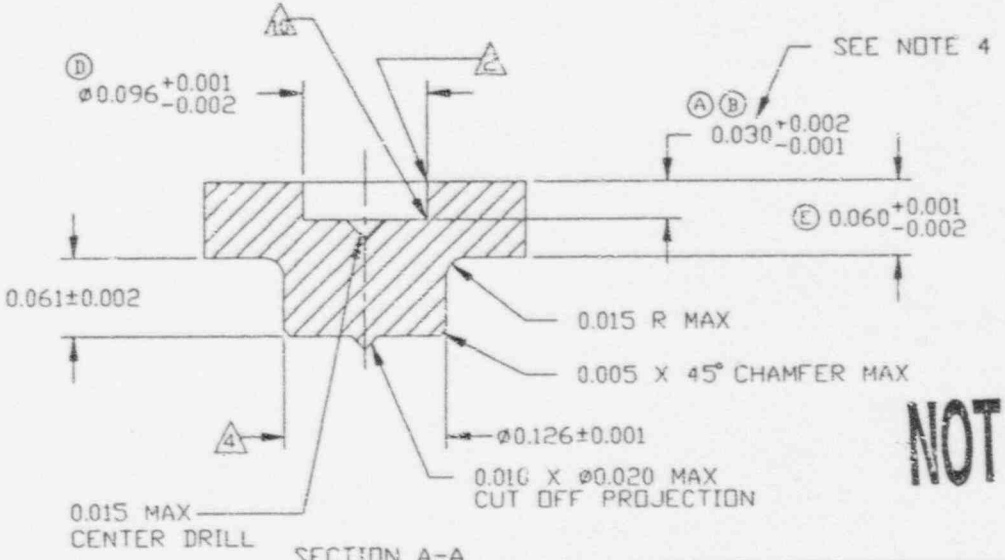




SOURCE AND SOURCE HOLDER IN THE ASSEMBLED STATE.



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)
DECIMAL ± 0.005
FRACTIONAL ±
ANGULAR ± 1°

TITLE: SOURCE HOLDER MODEL A-1056
MATERIAL & FINISH: SEE NRD SPEC 2016
SCALE: 10 : 1
DRAWN BY: JES
APPROVED BY:
DATE: 07FEB85
DWG. NUMBER: 85B026
SHEET: 1

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 15 ADDED	DH	CDD	
22NOV91	4	NOTE 1 CHANGED; B90 WAS B100	JS	CDD	
18DEC91	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	DA

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)
DECIMAL ±
FRACTIONAL ±
ANGULAR ±

TITLE: NRD SPECIFICATION 2016
MATERIAL & FINISH
SCALE
DRAWN BY
APPROVED BY J.M.
DATE 08FE85
DWG. NUMBER SPEC FOR 85B026 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, and 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.

---

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.

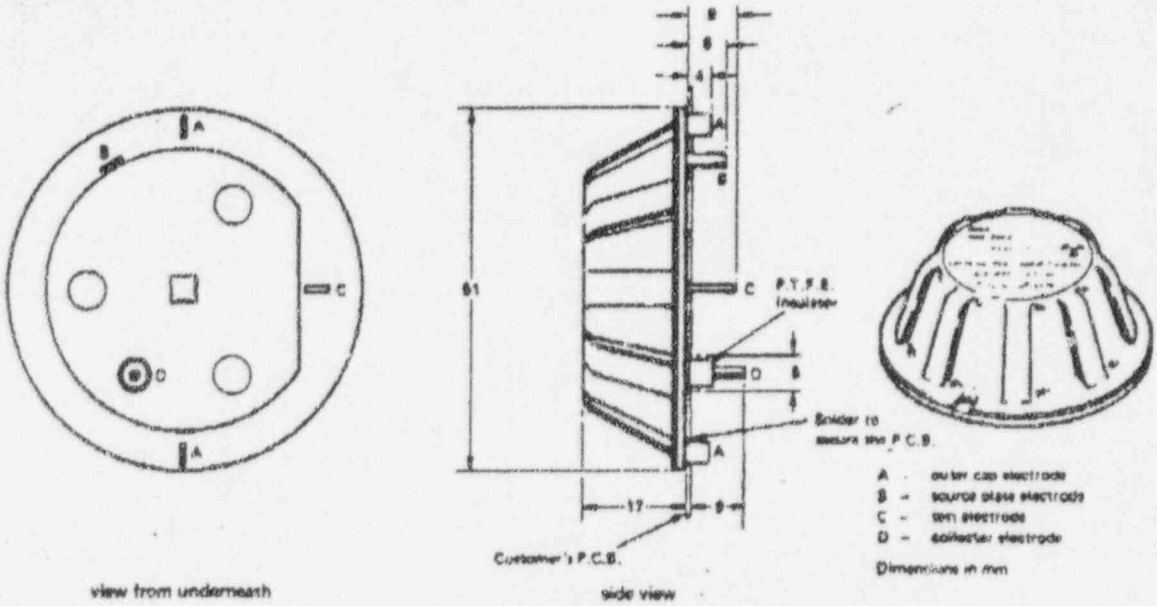
2 Title 49, Code of Federal Regulations, Parts 100 - 199, United States of

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.

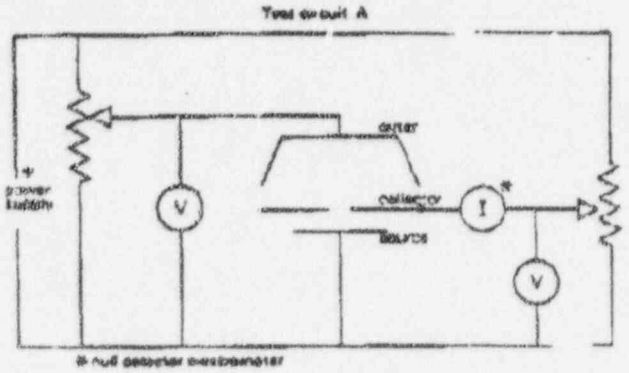
The DSC.A3 incorporates a performance test electrode to permit electrical testing of the chamber during operation, as required by BS 5446. When actuated the electrode disturbs the balance conditions to simulate the presence of smoke.

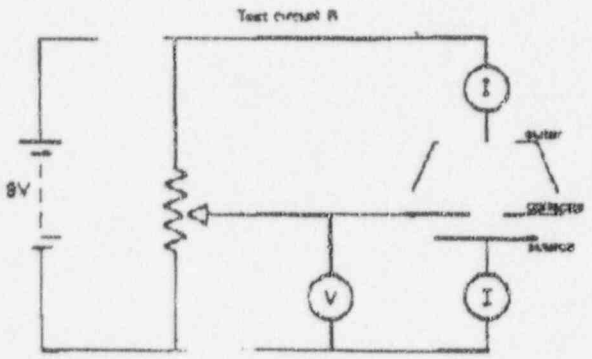
The design is suitable for use with an external integrated circuit containing the electrometer and alarm circuits.

*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: 8V
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	0·05
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 alpha, 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

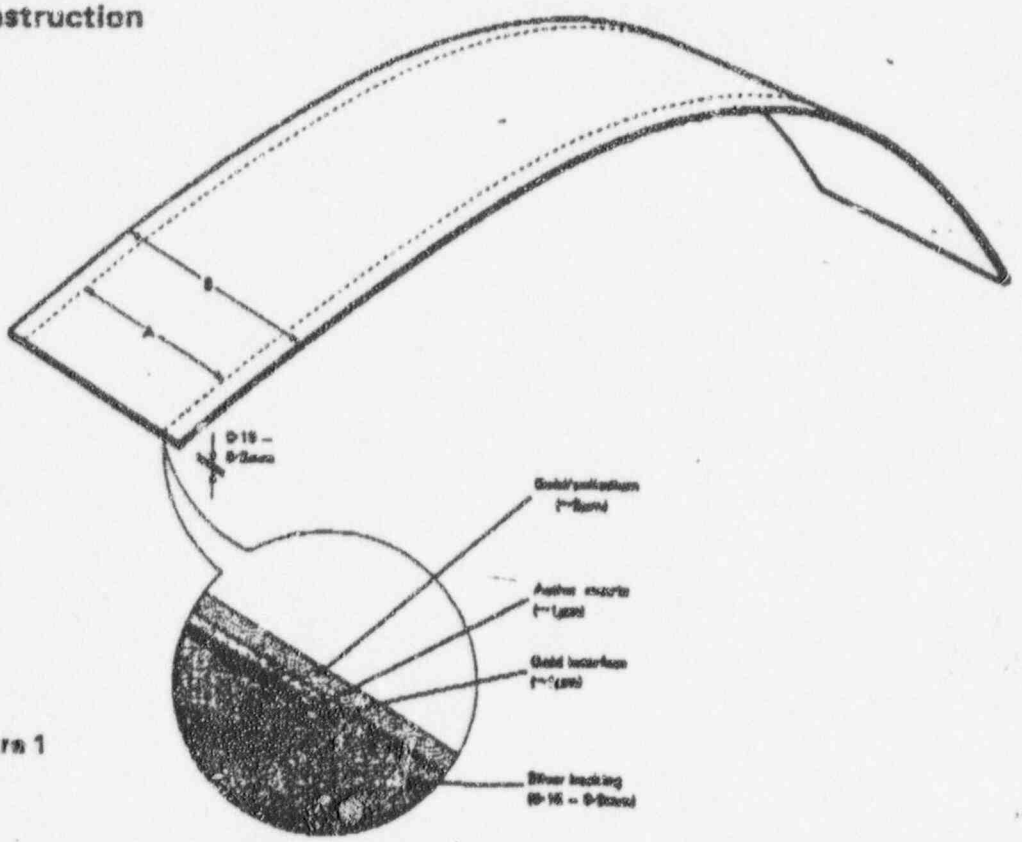


Figure 1

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	12·6	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	12·6	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 (c) 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.

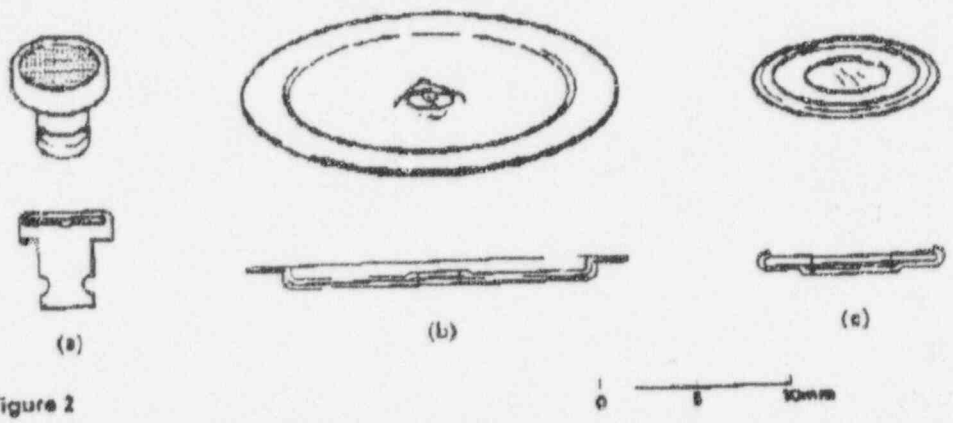


Figure 2

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:	59·5keV (35·3% emitted) Np L X-rays 12–22keV (~40%)
Radiochemical purity:	> 99·2%

Typical spectrum
(americium-241 alpha foil)

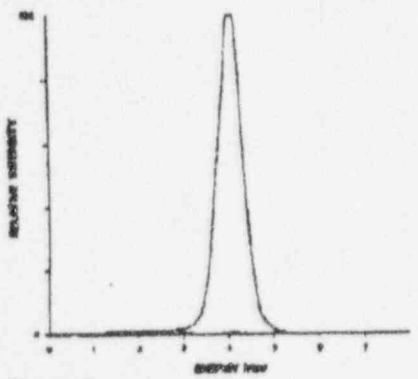


Figure 3

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

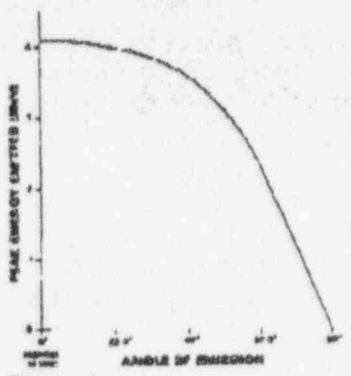


Figure 4

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.

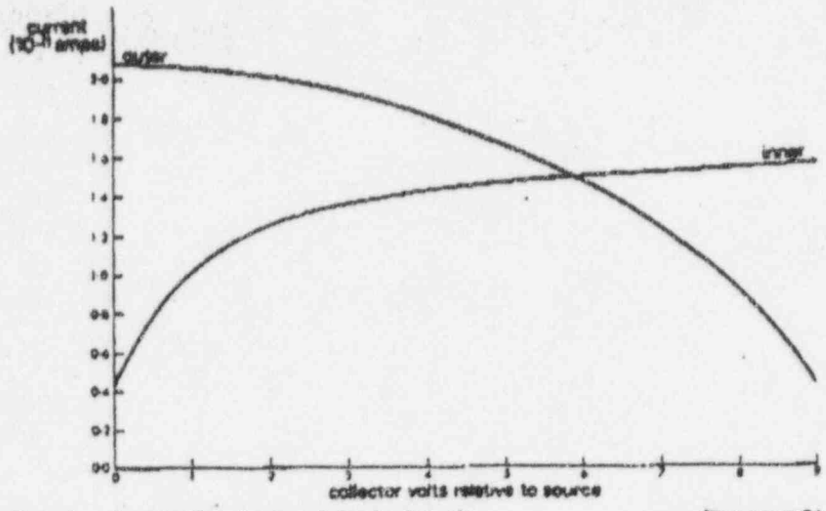


Figure 1 Ion chamber characteristics in clean air (Test circuit B)

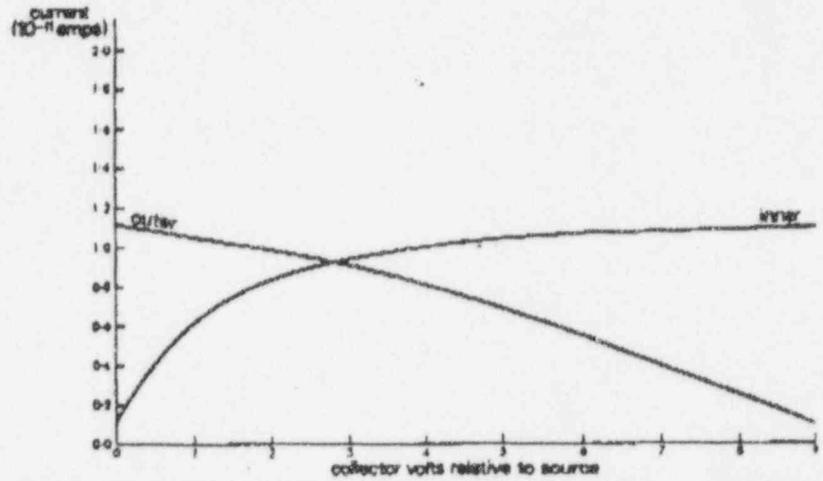


Figure 2 Ion chamber in B.S. smoke; obscuration level 4·0% per foot (Test circuit B)

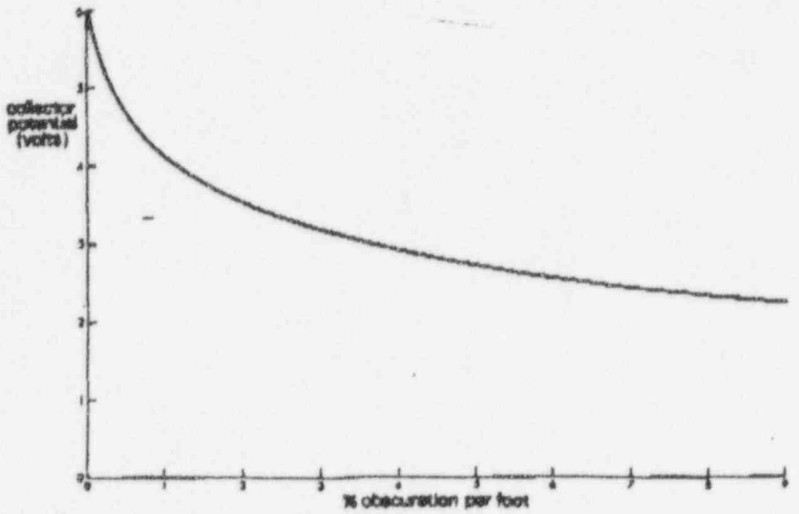


Figure 3 Collector potential change with B.S. smoke.
Whatman no.2 filter paper heated on electric element (Test circuit A)

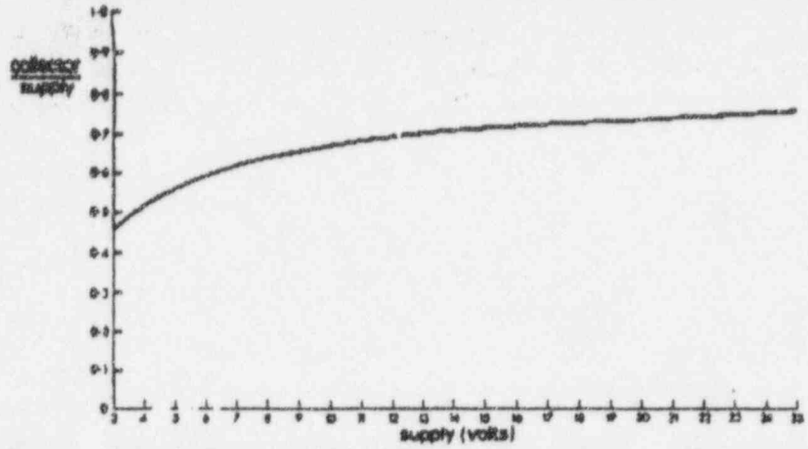


Figure 4 Ratio of collector potential at balance to supply potential (Test circuit A)

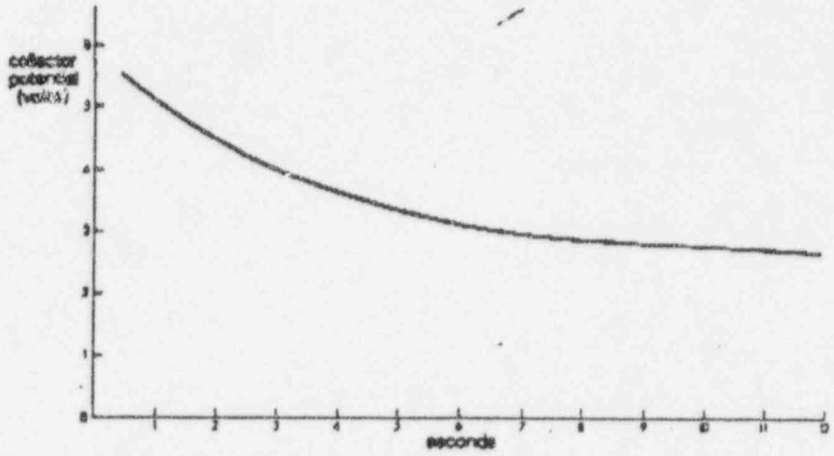


Figure 5 Balance voltage change with time after activation of the test electrode

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 6).

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.

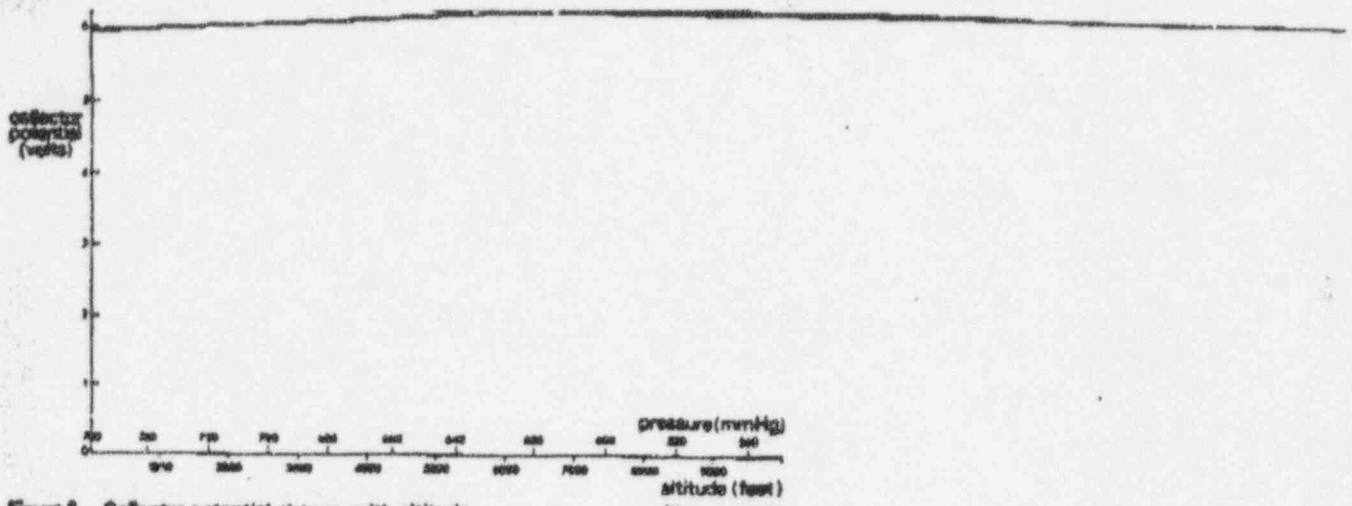


Figure 6 Collector potential change with altitude (Test circuit A)

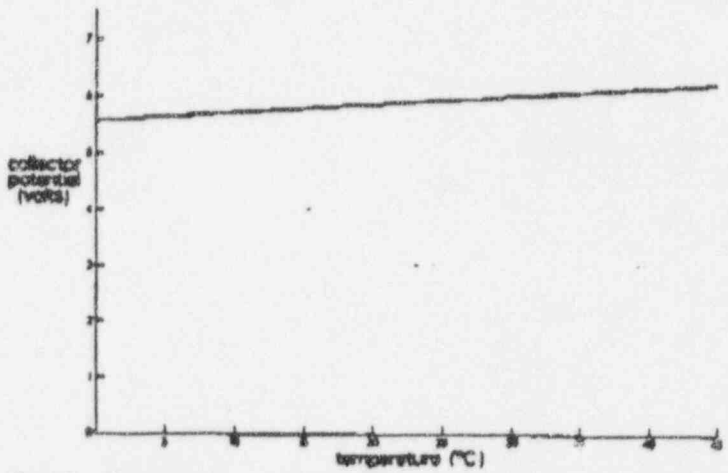


Figure 7 Collector potential change with temperature (Test circuit A)

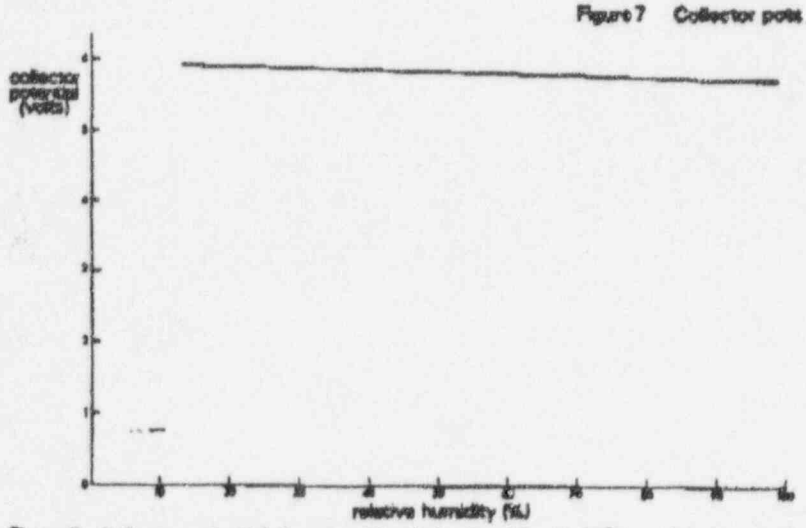
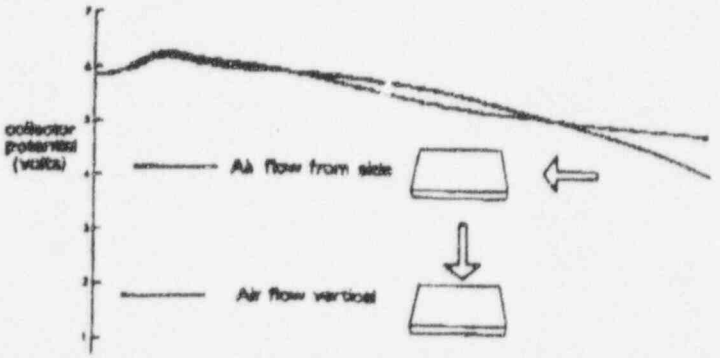
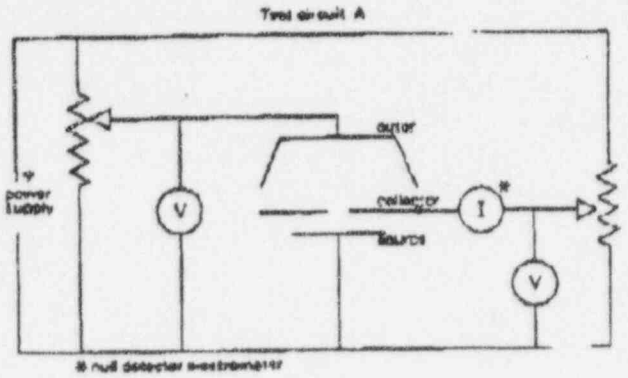


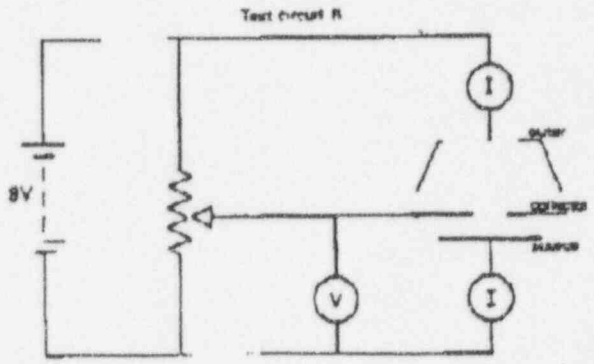
Figure 8 Collector potential change with relative humidity at 28°C (Test circuit A)



1. ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT
"Proposed radiation protection standards for ionization chamber smoke detectors." Nuclear Energy Agency Draft, Paris, OECD, 1978.
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





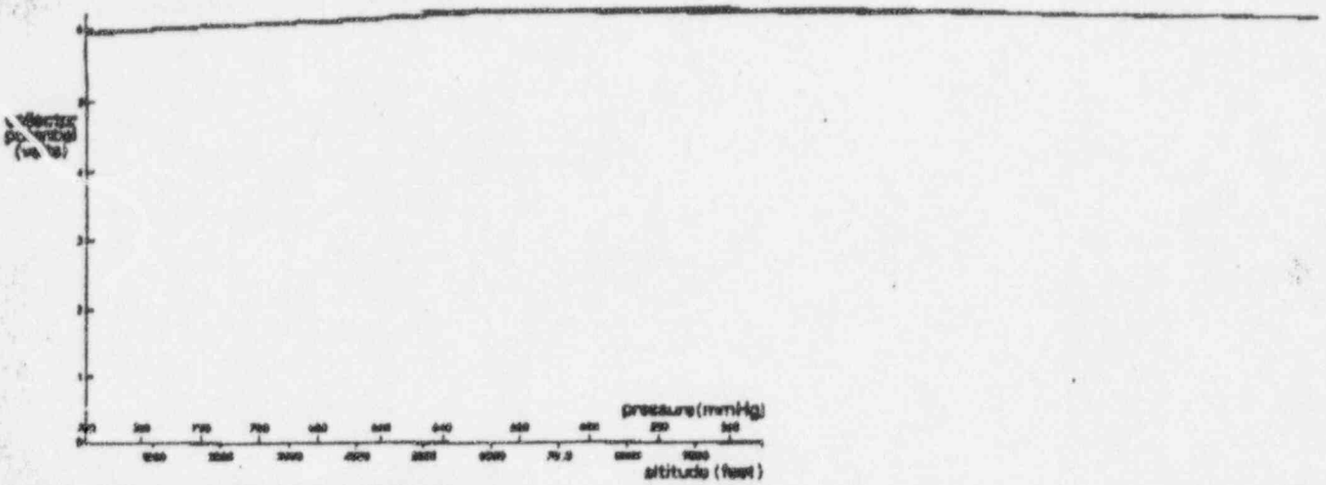


Figure 6 Collector potential change with altitude (Test circuit A)

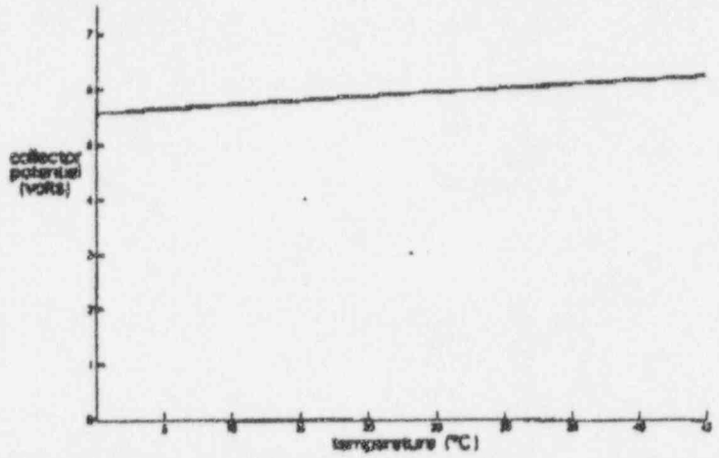


Figure 7 Collector potential change with temperature (Test circuit A)

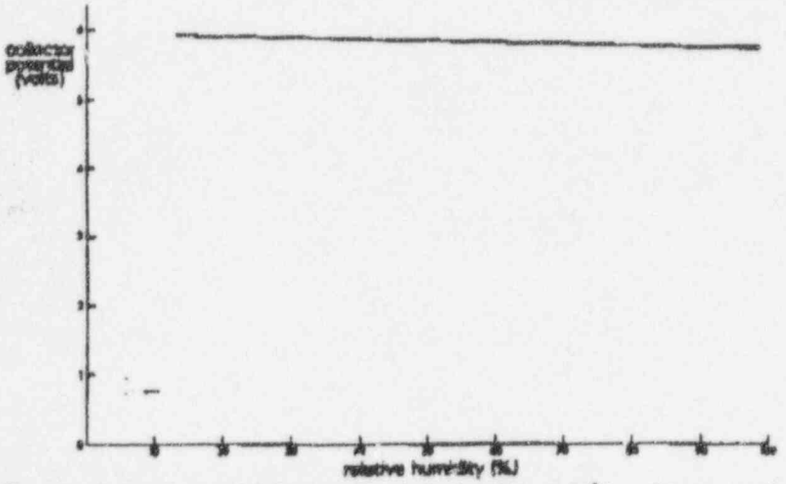
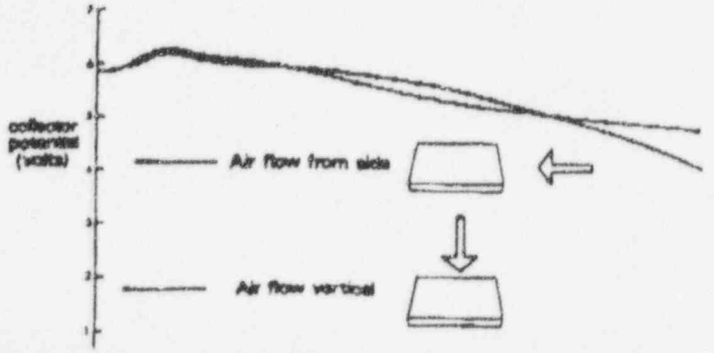
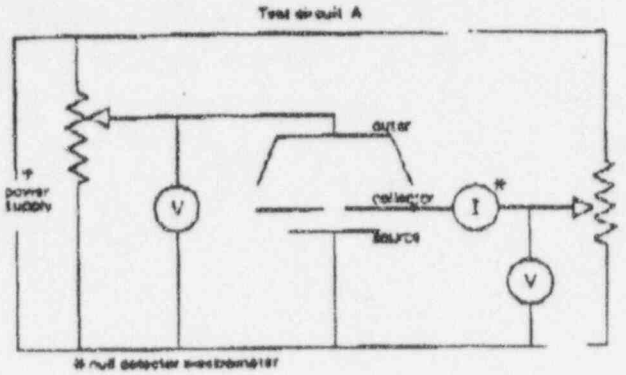


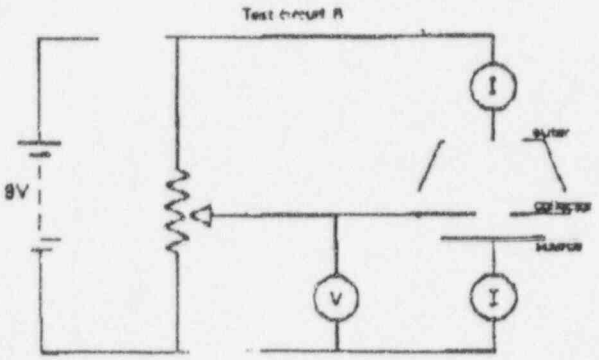
Figure 8 Collector potential change with relative humidity at 25°C (Test circuit A)



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





APPENDIX B

OVERSIZE
DOCUMENT
PAGE(S) PULLED

SEE APERTURE CARD FILES

APERTURE CARD/PAPER COPY AVAILABLE THROUGH NRC FILE CENTER

****

NUMBER OF OVERSIZE PAGES FILMED ON APERTURE CARD(S) _____

****

ACCESSION NUMBERS OF OVERSIZE PAGES:

9701310308-1-2 Dupe