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# FAX


## Hochiki America Corporate Planning

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**DATE:** September 19, . 996 **CC:** LL- HA

**TO:** Chris Brown- USI RC **Pages:** 7

**FROM:** Gyo Shinozaki

**RE:** Response to phone conversation

The following pages are Hochiki America's responses to the phone conversation we had on September 17th. The first section titled "Revision to Application" contains italicized statements. These are either additions or revisions to the Quality Control section of our June 7th application (pag 5 through 7). The second section titled " Clarification of Issues" refers to the tamperproof outer cove for the AIE type detector and the equivalent of CPM to curies.

If there are any additional questions please do not hesitate to ask me.

## 1) REVISION TO APPLICATION:

## Quality Control

The following procedures are followed both at Hochiki Corporation as well as Hochiki America Corporation. (Data will be made available through Hochiki America Corporation's Quality Control Department):

**Receipt of Foils**

Incoming inspections are performed when containers of radioactive material are received. The outside of the shipping container is smear tested and the results recorded. The inside of the inner container is smear tested and the results recorded. If any contamination is detected, the foils are isolated and returned to the manufacturer for disposal. If there is no contamination detected the foils are placed in the safe and the information recorded. Before the foils are dispersed to the assembly area the inside of the container is smear tested and the results recorded and initialed. If any contamination is detected the foils are isolated and returned to the manufacturer of the foils for disposal. These tests are conducted by using a cotton tip swab wetted with alcohol. Wipes are inserted into the chamber of the Radiation Monitoring Device and counted. The results are recorded on the appropriate forms. The background of the Radiation Monitoring Device will be determined by counting with the chamber empty and the results recorded in the appropriate space on the applicable form. Any wipe showing greater than 10 cpm above background will be recounted to verify results. If results continue to show more than 10 cpm above background, item(s) will be cleaned until no activity is detectable.

There are two survey meters that can be used to make these tests. Each will be calibrated by the manufacturer against known radioactive materials including americium annually. The testers are incorporated into Hochiki's equipment calibration program.

*The following is how Hochiki America insures radioactive foil integrity:*

***Foil Integrity from Manufacturer ( applies to AIE type)***

*Certificates of Conformance are submitted by either vendor ( NRD or Amersham) with each shipment received . These certificates insure that our vendor have checked 100% of the material for removable contamination. The certificate also insures that a minimum of LTPD 5% are checked for design conformity.*

*The following is how Hochiki America insures chamber design conformity:*

***Raw Materials ( applies to AIE type)***

*Incoming inspections are done on all raw materials. Materials that make up the ionization chamber assembly are checked for dimensional conformity to controlled drawings for the individual parts. By checking for design conformity at the raw materials level design conformity of the ionization chamber can be assured. All results are recorded on appropriate forms. Enclosures A4, A7, A10, A11, B5, B7, B9, B11and B16 indicate the minimal areas that are measured for dimensional conformity to specification.*

***Assembled Ionization Chambers ( applies to AIE type)***

*A minimum random sample of 45 PCs. of daily production of ionization chambers will be wiped and recorded. This quantity represents LTPD 5% of daily production. 100% 0f assembled chambers are also visually inspected for design conformity.*

**FINISHED GOODS PRIOR TO SHIPMENT *( applies to AIE type)***

All (100%) of the daily quantity of units ready for final packaging will be wiped, counted, recorded and initialed. The following are the procedures routinely performed:

1. Indicate on the form provided the lot number, date, serial numbers and the sample size of the lot checked.

2. Background of the Radiation Monitoring Device currently being used will be determined by counting with the chamber empty and the results recorded on the appropriate form.

3. A cotton tip swab, wetted with alcohol, will be used to wipe the detectors. The area wiped will not exceed 100 cm per wipe.

4. Wipes will be taken through the slots in the outer enclosure until the swab touches the bug screen.

5. A maximum total of 100 detectors are to be wiped before the swab is placed in the meter and the findings recorded and initialed.

6. Any wipes showing a reading greater than 10 cpm above background will be recounted to verify results. If the wipe shows more than 10 cpm above background, the detectors will be re-wiped and the data recorded. If the detectors show the presence of contamination, they will be checked and cleaned until no activity is detectable, or the contaminated detector(s) will be disposed of by a NRC approved procedure.

***Point of Sale Package Conformity ( applies to AIE type)***

*A random sample of a minimum of LTPD 5% will be visually checked for conformity to Hochiki America's packaging and labeling specifications.*

***Actions Taken when Non Conforming Materials Are Found ( applies to AIE type)***

*Any physical non conformity or contamination detected will result in an investigation until the cause is found. The conclusions of this investigation will in most every case be one of the following:*

*1) Rejection of the entire daily production*
*2) Wipe test of 100% of the days production and disposal of contaminated units only.*
*3) Re-measure the sample and re-evaluate.*
*4) In cases of physical non conformity, disposal of non conforming units.*

*All investigations will follow Hochiki America Quality Procedure 7.33 which requires proper documentation of all conclusions.*

Contaminated units will be properly disposed of according to applicable regulatory procedures.

**Product Manufactured at Hochiki Corporation and Received By Hochiki America** ***( applies to AIC type and AIE type manufactured at Hochiki Corporation)***

1) Incoming inspections will be performed using LTPD 5% Sampling for removable contamination. The table below will be used to determine sample size. The Radiation Monitor Device and Wipe Test method described abcve will be used.

| Lot Size | Sample Size |
|---|---|
| 1- 400 | 44 |
| 401- 2000 | 45 |
| 2001 - 100,000 | 75 |

2) Results will be recorded on appropriate forms and filed by the Hochiki America Quality Control Department.
3) A visual inspection of a random sample of the units will be done using the table above to insure proper design conformance. Units can not be disassembled to inspect the chamber because this may affect product settings.
4) *All product manufactured at Hochiki Corporation and received at Hochiki America will be accompanied by a Conformance to Radiation Safety Statement. This statement will act as proof that Hochiki Corporation performed all radiation safety tests.*

***Actions Taken when Non Conforming Materials Are Found ( applies to AIC type and AIE type manufactured at Hochiki Corporation)***

*Any physical non conformity or contamination detected will result in an investigation until the cause is found. The conclusions of this investigation will in most every case be one of the following:*

*1) Rejection of the entire lot and disposal by Hochiki America.*
*2) Wipe test of 100% of the received lot and disposal of contaminated units only.*
*3) Re-measure the sample and re-evaluate.*
*4) In cases of physical non conformity, disposal of non conforming units.*

***Hochiki America Incoming Inspection Sampling Plans***

Hochiki America uses ANSI/ASQC Z1.4- 1993 "Sampling Procedures and Tables for Inspection" to calculate our sampling plans at incoming inspection. We are currently using General Inspection Level II with an AQL of 1.0% for most materials.

## 2) CLARIFICATION OF ISSUES

### AIE Type Outer Cover Tamperproof Mechanism

The AIE type detector Outer Cover ( see enclosure B1, part m of June 7th, 1996 application) is designed such that upon locking into the Enclosure ( see enclosure B1, part j of June 7th, 1996 application) via 4 tabs located on it's underside, can not be removed without the use of a special tool available only through Hochiki America. This prevents any tampering by the consumer. The Outer Cover cannot be removed without the use of this tool or by destroying the unit.

The AIE type detector is different from most units in that it does not require removal of the Outer Cover in order to attach it to a ceiling etc. This is achieved through the use of a separate base device in which the detector is attached. The base unit is mechanically attached to the ceiling etc. There is both a mechanical connection and electrical continuity via the use of metal fittings. These base units will vary dependent upon the application in which it is used. ***A drawing of a typical base unit is enclosed.***

### Counts per Minute versus Bequerel Equivalent

Our application of June 7th, 1996 states that the wipe test limit for our quality control program is 10 count per minute (CPM). The following calculation shows the curie equivalent:

disintegration/ minute (DPM) = CPM/ efficiency of survey meter

thus,

DPM = 10 CPM/ 28.7% eff. ( *see attached calibrations certificate*)

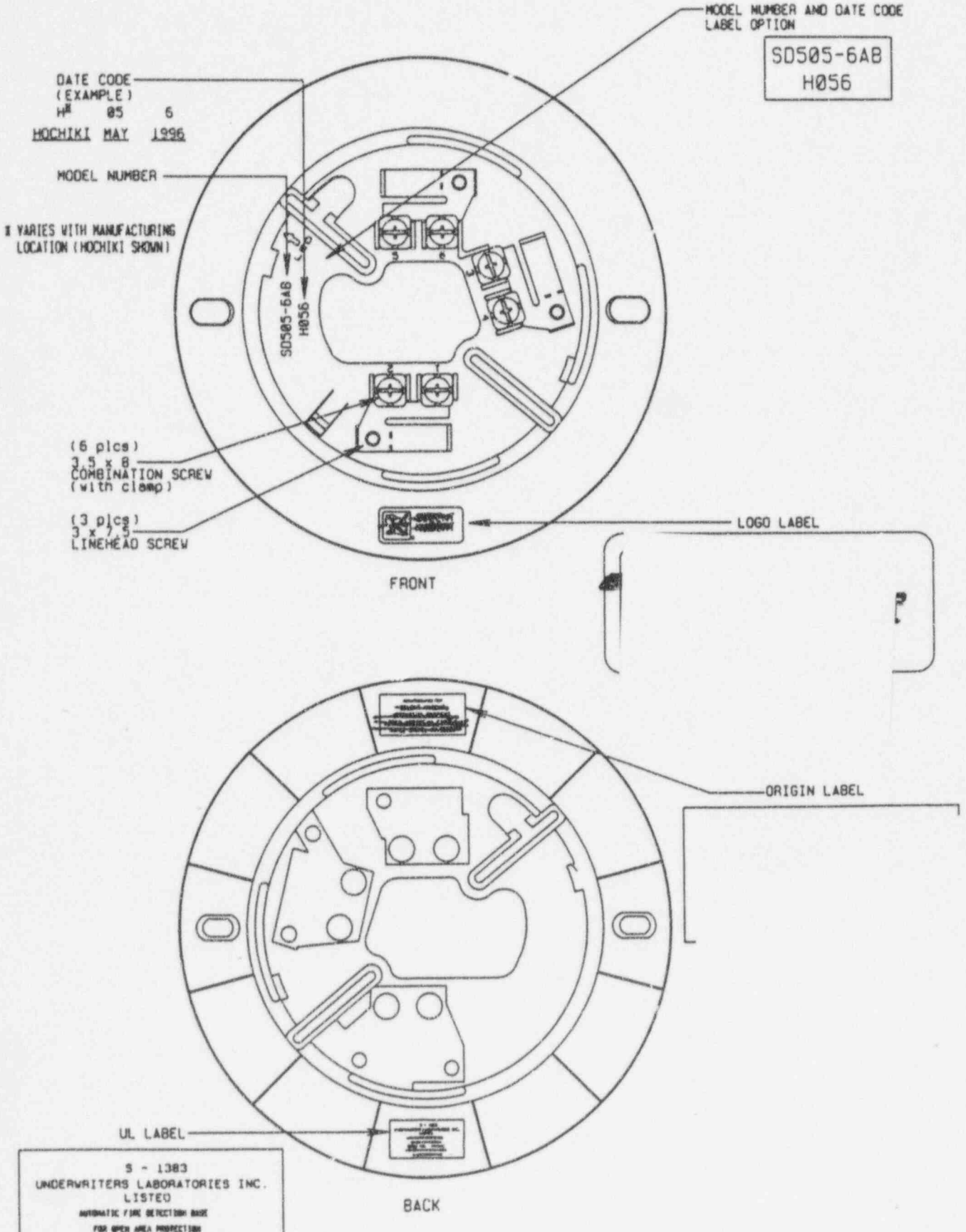
= 35.97 DPM

given that 1 $\mu$Ci = $2.22 \times 10^{-6}$ DPM

35.97 DPM/ ($2.22 \times 10^{-6}$ DPM/ $\mu$Ci )

= $16.2 \times 10^{-5}$ $\mu$Ci

Therefore 10 CPM is well below the NRC limit of 5 nanocuries.






DRAWING # HA-11-089

Eberline Instrument Corporation

# CERTIFICATION OF CALIBRATION

Instrument SRM-100 / HP-210L

Serial Number 328

Calibration Standards: Am-241 S/N 9468
Cs-137 10mCi S/N 733
Cs-137 10 Ci S/N 375
MP-2 S/N 174

Test Equipment: FLUKE 8010A S/N 2650076

| Range | Calibration Point | Reading |
|---|---|---|
| CNT/MIN | 262000 CPM (2π) | 7.29+04 CNT/MIN (27.8%) |
| | | |
| | | |

Readings Taken in SH-4A Sample Holder

When the Calibration Constant is 1.00, the 2 π counting efficiency is:

$$\frac{\text{Reading}}{\text{Calibration Point CPM (2 π)}} \times 100 = \text{Per Cent Efficiency}$$

Calibration Constant 1.00+00 High Voltage 9.00+02 Volts

Dead Time (Sec.) 6.00-05 Input Sensitivity 10 mV

Overrange 4.77+06 CNT/MIN

Calibration Standards used have calibration traceable to N.I.S.T.

EIS TEST S

Date 7-25-96 Signature

P.O. Number 6776 OP

7-25-96 EIS Q.C. 1

NRD INC.
A Subsidiary of Mark IV Industries Inc.
2937 Alt Blvd. North
Grand Island, NY 14072
(716) 773-7634

Certificate No. 056873 Purchase Order No. 6750
Hochiki

# CERTIFICATE FOR SEALED RADIOACTIVE SOURCES

ISO Classification designated by Code No. ISO\C 32222

Model No. A001 ; Radionuclide Americium-241

Activity per unit 18.5 KBq ; Total activity 0.0925 MBq

Chemical and physical form: Solid Metal Foil

Leak results, per ISO/RR 4826 < 37 Bq ; Date 8-1-96

Total Units/sources tested 5000

We certify that this sealed source complies with requirements of (ISO 1677 or relevant national standards) and the above information is correct.

We declare that we hold "IAE Certificate of Compentent Authority" No. USA-0036-S, in respect to sealed sources of Special Form Non-dispersible Radioactive Material;

**Issued on 8-25-82, by U.S. Department of Transportation Office of Hazardous Materials Regulations.**

Date 8-1-96 Signature Carl Wanjewski

Title QC

N-118