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The Commonwealth of Massachusetts  
Executive Office of Health and Human Services  
Department of Public Health  
Bureau of Environmental Health  
Radiation Control Program  
Schrafft Center, Suite 1M2A  
529 Main Street, Charlestown, MA 02129  
(617) 242-3035 (617) 242-3457 - Fax

May 31, 2012

John Jankovich  
SS&D Team Leader  
Division of Materials Safety  
and State Agreements  
Source Safety and Security Branch  
MS:T:8E24  
Office of Federal and State Materials and Environmental Management Programs  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555

**RE: New Sealed Source and Device  
Registration Number: MA-1059-S-944-S**

Dear Dr. Jankovich:

We have completed action on a Sealed Source and Device (SSD) registration certificate for the QSA Global, Inc. Models AMM.1001, AMM.1001D, AMM.1001H, and AMM foil sources. The number for this sheet is MA-1059-S-944-S. Please find enclosed a copy of this sheet. This registration supersedes # MA-1059-S-174-S and MA-1059-S-919-S and NR-0136-S-107-U which should be deleted from the National Registry.

If you have any questions please contact me at (617) 242-3035.

Sincerely,

A handwritten signature in blue ink that reads "John Sumares".

John Sumares  
Radiation Control Officer  
Radiation Control Program

JES/jes

Enclosure: (1)

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

NO: MA-1059-S-944-S DATE: May 29, 2012 PAGE 1 OF 10  
(Supersedes MA-1059-S-174-S,  
MA-1059-S-919-S, & NR-0136-S-107-U)

SOURCE TYPE: Foil Source

MODEL: AMM.1001; AMM.1001D; AMM.1001H; AMM

DISTRIBUTOR: QSA Global Inc.  
(Formerly AEA Technology-QSA Incorporated)  
40 North Avenue  
Burlington, MA 01803

MANUFACTURER: Shenzhen CIC-QSA Global  
Manufacturing Company Ltd.  
Nantou Guankou, Nanshan District  
Shenzhen, China 518067

<u>ISOTOPE:</u>	<u>MAXIMUM ACTIVITY:</u>	<u>MODEL NUMBER:</u>
Americium-241	200 $\mu\text{Ci}$ (7.4 MBq) and 50 $\mu\text{Ci} / \text{cm}^2$ (1.85 MBq / $\text{cm}^2$ )	AMM.1001, AMM.1001D, AMM.1001H
Americium-241	1 millicurie (37 MBq) and 250 $\mu\text{Ci} / \text{cm}^2$ (9.25 MBq / $\text{cm}^2$ )	AMM

LEAK TEST FREQUENCY: 3 months for foils greater than 10  $\mu\text{Ci}$  (0.37 MBq)

PRINCIPAL USE: (P) Ion Generators, Smoke Detectors

CUSTOM SOURCE: YES \_\_\_\_ NO X

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SOURCE TYPE: Foil Source

DESCRIPTION: These sources are no longer manufactured or distributed. The following description was active at the time of manufacture.

Model AMM.1001

The Model AMM.1001 primary foil consists of americium oxide uniformly distributed and sintered in a fine gold matrix at temperatures in excess of 800° C. This matrix is further contained between layers of silver, gold, and palladium by hot forging. The result is a foil, which is typically 1 meter (39.34 in.) long and 4 centimeters (1.57 in.) wide. There are two primary foil designs whose dimensions depend on the particular choice of materials contained within the various layers and the target thickness of each layer.

Model AMM.1001 - Type 1

The Type 1 primary foil is shown in Attachment 1. The target thickness of each layer and the overall thickness are:

Overall thickness:	0.155 - 0.256 millimeters (6.1 - 10.1 mils)
Silver substrate:	0.15 - 0.25 millimeters (5.9 - 9.8 mils)
Gold backing:	0.001 millimeters (39.4 microns)
Americium-241 / gold matrix:	0.002 millimeters (78.8 microns)
Non-radioactive overplate:	0.002 - 0.003 millimeters (79 - 118 microns)

(Overplate is Gold, gold & palladium alloy, gold/palladium laminate, or palladium)

Model AMM.1001 - Type 2

The Type 2 primary foil uses the same layering concept as Type 1. However, in Type 2, there are more layers and there is a variation in the thickness of the overplate, matrix, and silver substrate layers as well as overplate components. The target thickness of each layer and the overall thickness are:

Overall thickness:	0.15 - 0.25 millimeters (5.9 - 9.8 mils)
Gold alloy backing:	~ 0.0005 millimeters (19.7 microns)
Silver substrate:	~ 0.2 millimeters (7.9 mils)
Gold alloy backing:	~ 0.0005 millimeters (19.7 microns)
Americium-241 / gold matrix:	~ 0.0005 millimeters (19.7 microns)
Gold alloy overplate:	~ 0.0002 millimeters (7.9 microns)
Palladium overplate:	~ 0.0018 millimeters (71 microns)



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SOURCE TYPE: Foil Source

DESCRIPTION (Cont'd.):

The primary foil (Type 1 or 2) is used to fabricate secondary foil sources by using various dies to punch a specific size and shape of secondary foil. Attachment 2 shows a typical secondary strip which has been fabricated from a Type 1 primary foil. Attachment 3 shows a typical secondary disc source which has been punched from a Type 1 primary foil. Attachment 4 shows a typical secondary disc source which has been punched from a Type 2 primary foil.

Model AMM.1001D

The Model AMM.1001D is manufactured by power rolling two AMM.1001 Type 1 primary foils back-to-back to produce a primary double sided foil with an overall thickness of approximately 0.38 millimeters (15 mils). The layers of the double sided foil are hot forged together prior to rolling with one active insert on either side of the silver block. The design of a typical Model AMM.1001D is shown in Attachment 5. Each foil side has an overplate of either gold/palladium alloy or palladium with a thickness of approximately 0.002 millimeters (79 microns).

Model AMM.1001H

The Model AMM.1001H consists of Model AMM.1001 or AMM.1001D discs (or similarly-shaped foils) mounted into a holder which is constructed of tin plated brass or stainless steel. The mounting is done by either rolling or by staking the edge of the holder so that the outer edges of the foil discs are not exposed. Designs of typical Model AMM.1001H sealed source assemblies are shown in Attachments 6 through 9.

Model AMM

The Model AMM.foil consists of americium oxide uniformly distributed and sintered in a fine gold matrix at temperatures in excess of 800° C. It is further contained by a hot forging process between layers of gold, gold palladium alloy, or palladium. The laminate is mounted, again by hot forging, onto a supporting substrate of silver, gold, palladium, or any combination of those three metals alloyed together. The metal layers, now continuously welded, are extended in area by means of a power rolling mill to give the required active and overall areas. The rolled foil may be distributed over the whole area of the foil piece. See Attachment 10 for a typical example of foil construction.



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SOURCE TYPE: Foil Source

LABELING:

The source foils are transferred to device manufacturers in containers which are labeled with the model number, trefoil, isotope, the **QSA Global** name or logo, the batch number, and the quantity of secondary source foils or source assemblies in the container.

Each source shipment is accompanied with a Test Report listing the model number, nuclide, activity assay results, a reference date, batch number, leak test results, and other pertinent information. The sources are distributed with 'Handling Instructions for Radiation Sources'.

DIAGRAM:

Attachment 1 - Model 1001 Type 1 primary foil  
Attachment 2 - Typical secondary strip  
Attachment 3 - Typical secondary disc source punched from a Type 1 primary foil  
Attachment 4 - Typical secondary disc source punched from a Type 2 primary foil  
Attachment 5 - Model AMM.1001D  
Attachments 6 through 9 - Typical Model AMM.1001H sealed source / holder assemblies  
Attachment 10 - Model AMM

CONDITIONS OF NORMAL USE:

The Models AMM.1001, AMM.1001D, and AMM.1001H foils sources are designed for use in ionization smoke detectors. The sources will be used in industrial and residential environments. The normal conditions of use should not exceed the ANSI performance classification of C64444. The foils sources are not designed for use in corrosive environments and cyclic thermal and mechanical conditions which must be avoided. The Model AMM foil source is intended for use as an alpha particle emitter in ionization chambers and related devices located in industrial and military environments which have been granted a specific approval by a licensing authority.

The recommended working life of the Models AMM.1001 (AMM.1001D and AMM.1001H inclusive) foil sources is 10 years and 15 years for Model AMM; after which the user should arrange for the foil source to be inspected and assessed by a qualified authority to extend its working life, or dispose of the product through a suitable disposal route.

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SOURCE TYPE: Foil Source

PROTOTYPE TESTING:

Prototype models AMM.1001, AMM.1001D secondary foils and AMM.1001H source assemblies have been tested to conditions described by ANSI standard N5.10-1968, ANSI N542-1977, and ISO 2919, and the classification of C64444 was demonstrated. Results of wipe tests of the tested foils for all models were acceptable to less than 0.005  $\mu\text{Ci}$  (185 Bq).

The following additional tests were also performed on Model AMM.1001 foils:

1. Immersion in water of prototype foils for 3 weeks at room temperature; less than 0.001  $\mu\text{Ci}$  (37 Bq) per foil loaded at maximum activity was found in the water.
2. Immersion in 0.1 N hydrochloric acid for 24 hours at room temperature; less than 0.004  $\mu\text{Ci}$  (156 Bq) activity was detected in the solution.
3. Foils were subjected to tests in moist air, dry air, sulfur dioxide, ammonia vapor, and hydrochloric acid vapor. Less than 0.005  $\mu\text{Ci}$  (185 Bq) of contamination was detected in each case.
4. Foils were subjected to repetitive wipe tests (5000X). All single wipes were less than 0.005  $\mu\text{Ci}$  (185 Bq) of removable contamination.
5. Shelf-life tests of foils with 50  $\mu\text{Ci} / \text{cm}^2$  loading show no deleterious aging effects after 6 years.
6. Application of solder (used in printed circuit boards of smoke detectors) resulted in less than 0.005  $\mu\text{Ci}$  (185 Bq) of detectable contamination.
7. Foils and mounted foils have been subjected to ozone at 0.75 ppm for a period of 60 days and salt spray for 16 days without deleterious results.

Prototype Model AMM sources containing up to 460  $\mu\text{Ci} / \text{cm}^2$  have been tested according to the requirements in ANSI N542-1977 and ISO 2919 and have qualified for performance classification C64344. Additional testing on closely related products has been completed and has been documented in the technical report # 379 dated September 1975 and entitled "Integrity Testing of Alpha Foil Used in the Ionization Chamber Smoke Detectors" which is on file with

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SOURCE TYPE: Foil Source

PROTOTYPE TESTING (Cont'd.):

the Agency.

A summary of the Model AMM testing is as follows:

1. The product has been approved as Special Form material by the United Kingdom Department of the Environment.
2. Two batches of five samples with activities up to  $200 \mu\text{Ci} / \text{cm}^2$  were subjected to high humidity atmospheres containing 1% sulphur dioxide for a period of 16 days. Wipe tests of the foil surface after testing produced results of between 3 nCi and 28 nCi from each sample. Immersion testing led to the removal of between 1 nCi and 15 nCi from each source.
3. Two batches of ten samples with activities up to  $200 \mu\text{Ci} / \text{cm}^2$  were subjected to an atmosphere maintained at  $45^\circ \text{C}$  with high humidity and high sulphur dioxide and hydrogen sulphide concentration for 2 periods of 8 days. Wipe tests of the foil surface after testing produced results of between 0.5 nCi and 105 nCi from each sample. Immersion testing led to the removal of between 0.1 nCi and 16.2 nCi from each source.

NOTE: These severe corrosion tests were conducted on source foils containing 25 and  $75 \mu\text{Ci}$  of activity and the tests resulted in removable contamination of less than 1 percent.

4. Two batches of ten samples with activities of 25 and  $75 \mu\text{Ci}$  or up to  $200 \mu\text{Ci} / \text{cm}^2$  were subjected to an environment in which they were sprayed intermittently with artificial sea water for a period of 16 days. Wipe tests of the foil surface after testing produced results of between 0.17 nCi and 4.1 nCi from each sample. Immersion testing led to the removal of between 0.002 nCi and 0.42 nCi from each source.
5. A batch of ten samples each containing  $75 \mu\text{Ci}$  at  $200 \mu\text{Ci} / \text{cm}^2$  was subjected to immersion in 0.1 N hydrochloric acid at  $37.5^\circ \text{C}$  for 4 hours. The amount of activity leached out was measured and the sources were wipe and immersion tested. This body fluid test was repeated on the same sources after a period of 17 days and in every case, the amount of activity leached out was reduced from 118 - 209 nCi to 27 - 44 nCi.



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SOURCE TYPE: Foil Source

PROTOTYPE TESTING (Cont'd.):

Wipe tests of the foil surface after testing produced results of between 0.43 nCi and 0.58 nCi and immersion testing removed between 0.06 nCi and 0.10 nCi from each source. The greatest amount of activity seen to leach from any source during either test was 0.25 percent of the source activity.

6. Samples of radioactive foil loaded at  $100 \mu\text{Ci} / \text{cm}^2$  were exposed to abrasion by silicon carbide particles until considerable contamination became evident and the conclusion was reached that the degree of abrasion to be expected in a normal working environment would lead to considerably less than 5 nCi of contamination based on a wipe test or immersion test.
7. As part of the test procedure involved in assessing the sources to the criteria outlined in ANSI N542-1977, samples of sources containing  $460 \mu\text{Ci} / \text{cm}^2$  have passed wipe and immersion tests at the 5 nCi level after being held at a temperature of  $800^\circ \text{C}$  for one hour. However, further testing at even higher temperatures has been conducted to determine the likely effects of exposure to the conditions encountered in major fires, and the conclusions to be drawn are that foils loaded to  $125 \mu\text{Ci} / \text{cm}^2$  releases less than 0.01 percent of its radioactive content when held at a temperature of  $1200^\circ \text{C}$  for ten minutes. However, the results also highlight the fact that it is necessary to consider the nature of other materials (eg. tin) which may be in close proximity to the source. In the event that these very high temperatures should occur, the source material may alloy with its immediate surroundings, possibly leading to a greater release of activity.

EXTERNAL RADIATION LEVELS:

The distributor has calculated the following radiation exposure rates for a 1 millicurie (37 MBq) source:

<u>Distance</u>	<u>Dose Rate</u>
5 centimeters (1.97 in.)	1.26 mSv / hr (0.13 rem / hr)
30 centimeters (11.8 in.)	34.9 mSv / hr (0.35 rem / hr)
100 centimeters (39.37 in.)	3.14 $\mu\text{Sv}$ / hr (0.31 mrem / hr)

The calculations were performed using a specific gamma ray constant of  $3.14 \mu\text{Sv} / \text{hr} / \text{mCi}$  at 1 meter; from the Health Physics and Radiological Health Handbook, Revised Edition, 1992.

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SOURCE TYPE: Foil Source

QUALITY ASSURANCE AND CONTROL: The sources are no longer manufactured or distributed.

Sources were manufactured and distributed in accordance with the Quality Assurance program of QSA Global Incorporated which is in compliance with the requirements of ISO9001:2000. For operations performed by vendors, these actions were controlled to QSA Global Incorporated specifications through the Quality Assurance program. The program has been deemed acceptable for licensing purposes by the Agency and a copy of the program is on file with the Agency.

The following tests were performed on foil sources (primary and/or secondary foils) by random samples of production lots:

1. Visual inspection to ensure the foil source surface is free from defects and/or ensure the integrity of the foil in the holder.
2. Wipe test to ensure contamination is less than 0.005  $\mu\text{Ci}$  (185 Bq).
3. Measurement by alpha spectroscopy and/or autoradiography to ensure uniform distribution of radioactivity, thickness of the overplate, and foil source activity are within specifications.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The Models AMM.1001, AMM.1001D, AMM.1001H, and AMM sources shall no longer be commercially distributed or manufactured.
- The foil sources shall only be used by persons specifically licensed by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State.
- Handling, storage, use, transfer, and disposal: to be determined by the licensing authority.
- The foil sources with activity greater than 0.37 MBq (10  $\mu\text{Ci}$ ) shall be leak tested at intervals not to exceed 3 months using techniques capable of detecting 185 Bequerels (0.005  $\mu\text{Ci}$ ) of removable contamination.

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SOURCE TYPE: Foil Source

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE (Cont'd.):

- The foil sources shall not be exposed to environments which exceed their ANSI N43.6-1997 classification.
- Users of these foil sources should avoid source contact with corrosive powders such as polyvinylchloride (PVC); prolonged contact of sources with organic solvents such as methanol or acetone; or use in cyclic thermal or mechanical conditions.
- This registration certificate and the information contained within the references shall not be changed without the written consent of the Commonwealth of Massachusetts, Radiation Control Program.

SAFETY ANALYSIS SUMMARY:

Based on our review of the Models AMM.1001, AMM.1001D, AMM.1001H, and AMM foil sources, their ANSI classifications, and the information and test data cited below, we continue to conclude that the foil sources are acceptable for licensing purposes. Furthermore, we continue to conclude that these foil sources would be expected to maintain their containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

In December 2011, the manufacturer reported that Models AMM.1001, AMM1001D, AMM.1001H, and AMM sources are no longer manufactured or distributed; that based on available records, distribution of this source design in the USA has not occurred since 2011; that millions of sources remain in use in the field, and that no design changes have been made since the last registration amendment. The manufacturer states they will provide technical information as needed on the source designs and will investigate problems or complaints related to these sources, but will not provide any replacements.



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SOURCE TYPE: Foil Source

REFERENCES:

The following supporting documents for the models AMM, AMM.1001, AMM.1001D, and AMM.1001H foil sources are hereby incorporated by reference and are made part of this registry document.

- Amersham letters dated March 18, 1971, November 4, 1974, November 8, 1974, March 10, 1975, September 20, 1979, March 15, 1995, June 6, 1997, November 24, 1997, and November 13, 1998, with attachments.
- Amersham Corporation letters dated January 11, 1982 and January 28, 1982, with attachments.
- Amersham letters dated October 23, 1997, August 13, 1999, September 30, 1999, and October 28, 1999, with enclosures thereto.
- AEA Technology letter dated December 2, 1999, with enclosures thereto.
- QSA Global letter dated November 23, 2005 and March 14, 2006, with enclosures thereto.
- QSA Global, Inc. letters dated June 30, 2005 and December 13, 2011.

ISSUING AGENCY: Massachusetts Department of Public Health Radiation Control Program

Date 5/29/2012

Reviewer John Sumares  
John Sumares

Date 5/29/2012

Concurrence Kenath Traegde  
Kenath Traegde

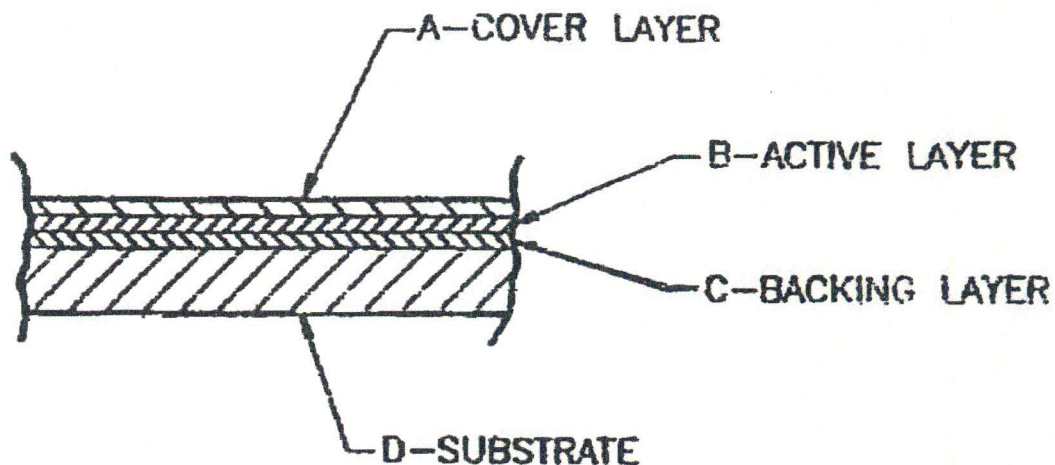
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Attachment 1 of 10

Model AMM.1001 Type 1 Primary Foil



SECTION OF ACTIVE AREA

A-GOLD OR GOLD PALLADIUM ALLOY OR GOLD  
PALLADIUM LAMINATE (Pd ON SURFACE) 0.002 OR 0.003mm  
B-AMERICIUM OXIDE PLUS GOLD 0.002mm

C-GOLD 0.001mm  
D-SILVER 0.15-0.25mm

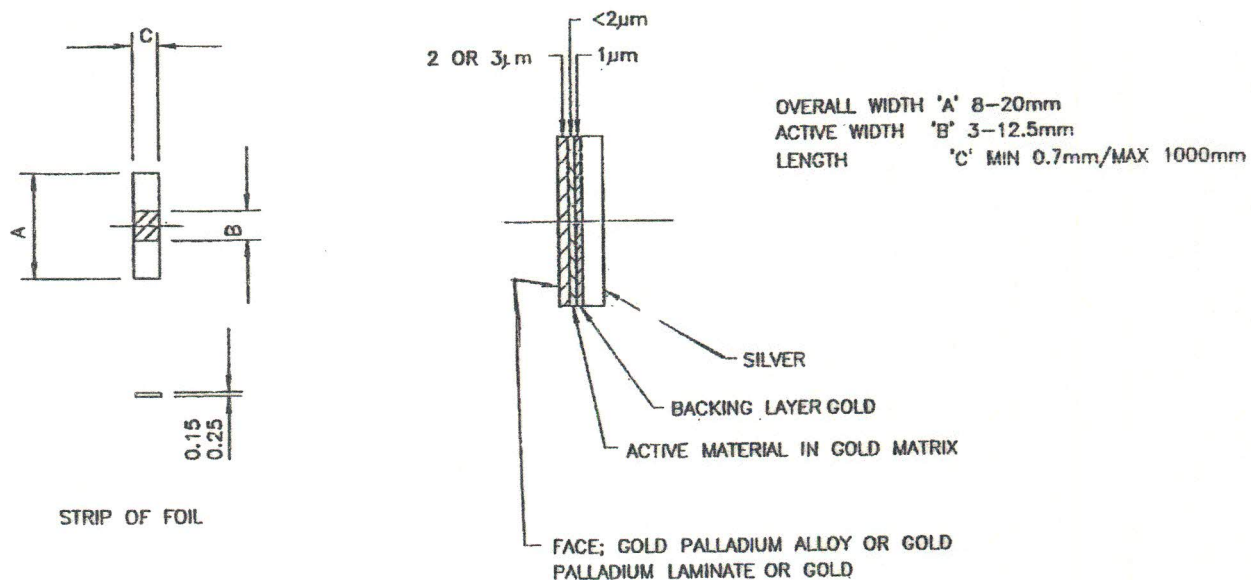
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Attachment 2 of 10

Typical Secondary Strip





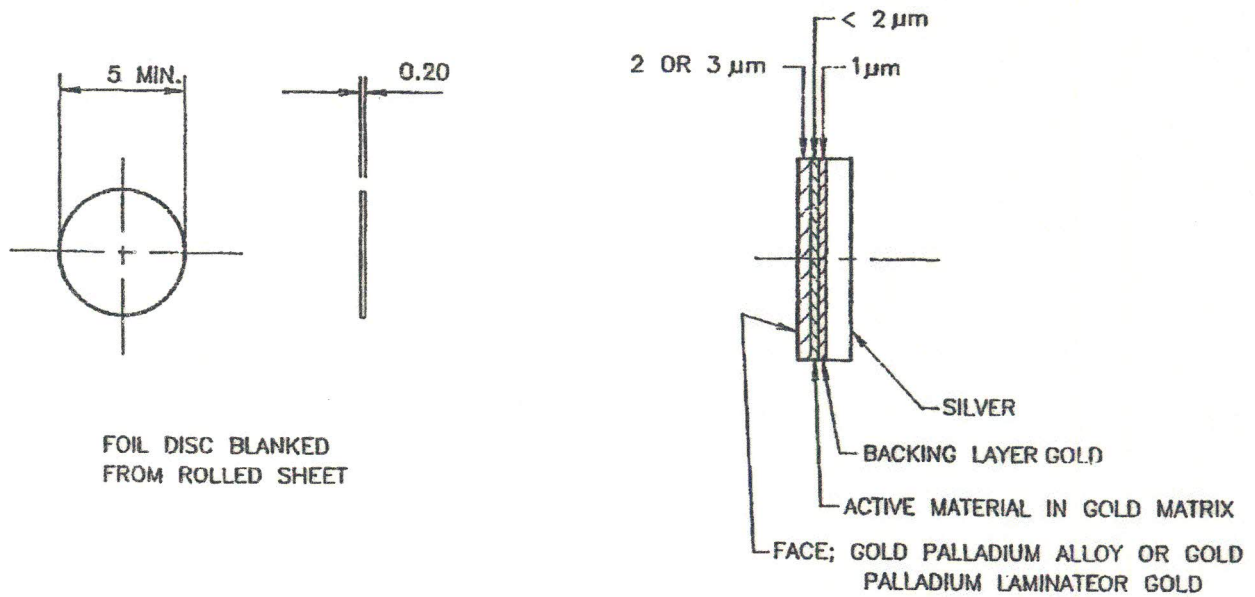
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
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Typical Secondary Disc Source  
(punched from a Type 1 primary foil)



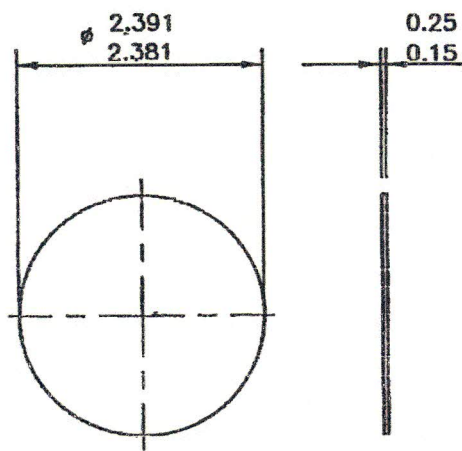
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
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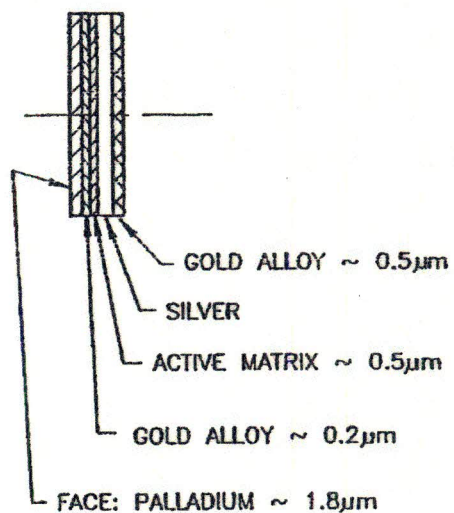
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Typical Secondary Disc Source  
(punched from a Type 2 primary foil)



FOIL DISC BLANKED  
FROM ROLLED SHEET



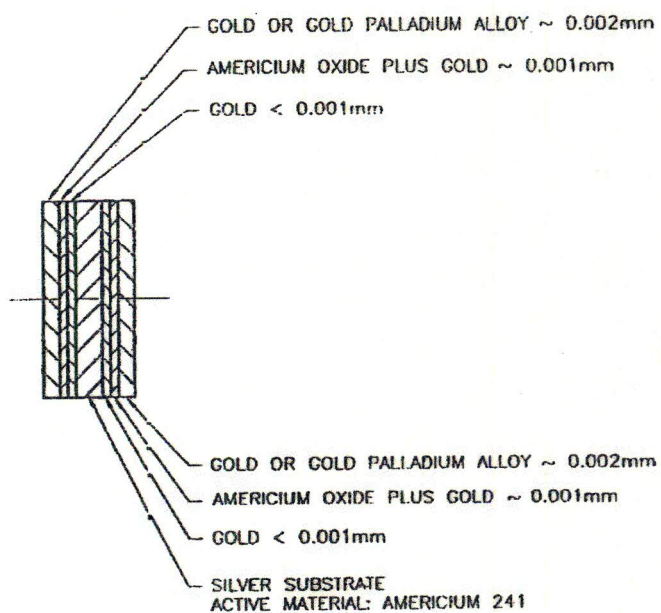
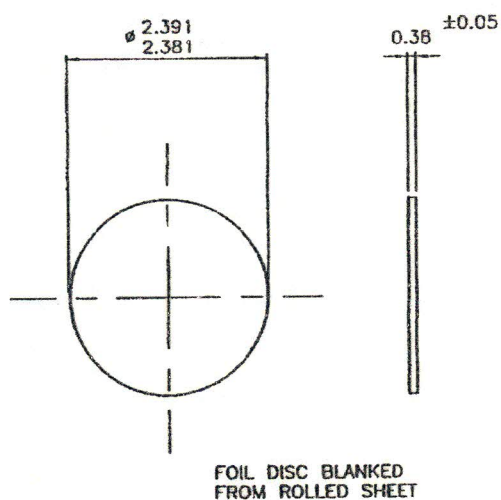
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Typical Model AMM.1001D





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SAFETY EVALUATION OF SEALED SOURCE

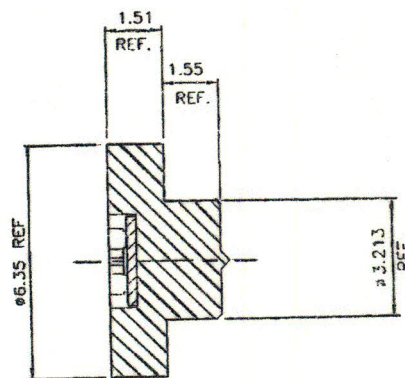
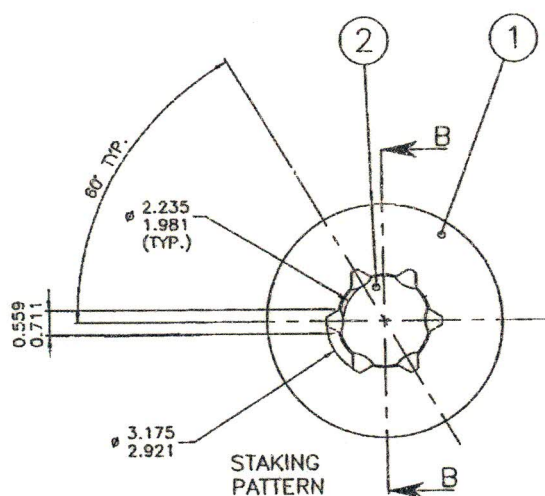
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Attachment 6 of 10

Typical Model AMM.1001H Source Assembly

ITEM	DESCRIPTION
1	SOURCE HOLDER
2	ALPHA FOIL DISC



SECTION B-B

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

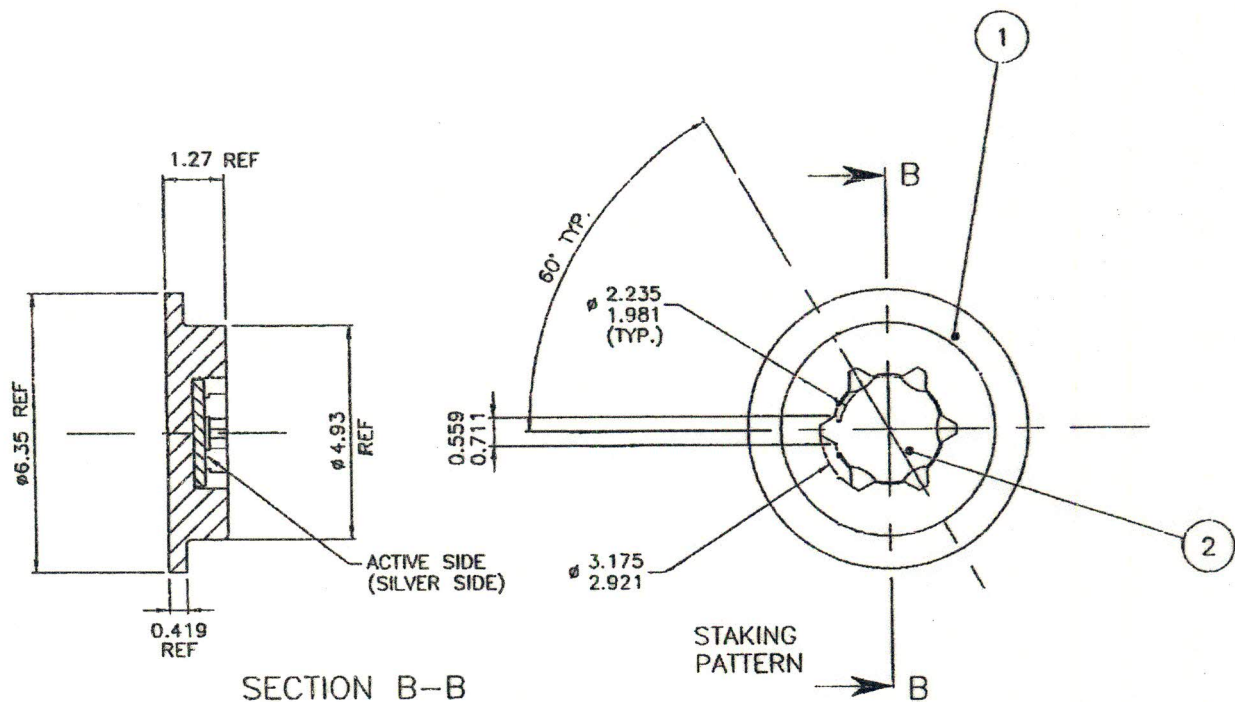
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Typical Model AMM.1001H Source Assembly

ITEM	DESCRIPTION
1	SOURCE HOLDER
2	ALPHA FOIL



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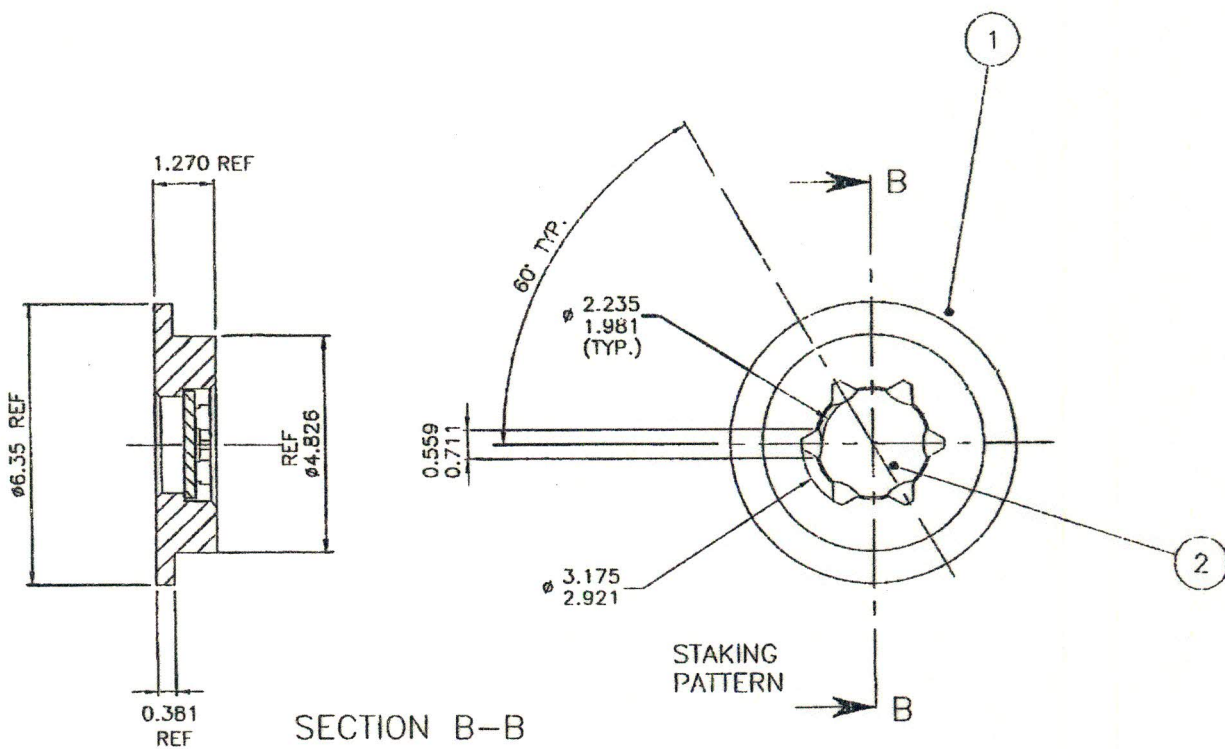
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Typical Model AMM.1001H Source Assembly

ITEM	DESCRIPTION
1	SOURCE HOLDER
2	ALPHA FOIL DISC (DOUBLE SIDED)





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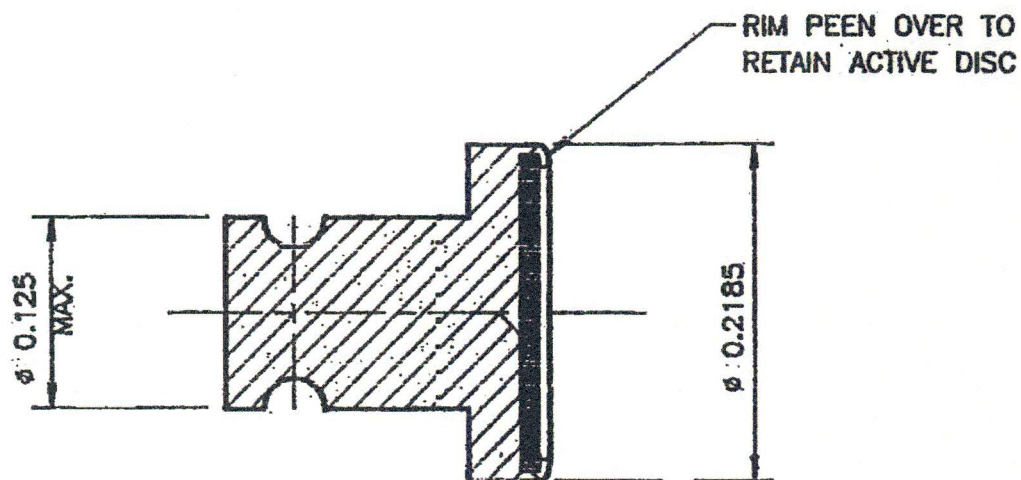
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Typical Model AMM.1001H Source Assembly

Item	Description	Material
1	HOLDER	SEE TABLE
2	ACTIVE FOIL DISC Am241	



X No.	MATERIAL
X268/1	BRASS TIN PLATED
X268/2	MONEL TIN PLATED
X268/3	STAIN.STL.

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

NO: MA-1059-S-944-S

DATE: May 29, 2012

Attachment 10 of 10

MODEL AMM FOIL SOURCE

