FEB 03 1994

ALL AGREEMENT STATES

TRANSMITTAL OF STATE AGREEMENTS PROGRAM INFORMATION (SP-94-019)

Your attention is invited to the attached correspondence which contains:

INCIDENT AND EVENT INFORMATION.....

PROGRAM MANAGEMENT INFORMATION.....

TRAINING COURSE INFORMATION.....

TECHNICAL INFORMATION.....XX

OTHER INFORMATION.....

Supplementary information: The enclosed SS&D evaluations should be added to your catalog.

If you have further questions regarding this correspondence, please contact the individual named below.

POINT OF CONTACT: Lloyd Bolling
TELEPHONE: (301) 504-2327
FAX (301) 504-3502

/S/

Paul H. Lohaus
Office of State Programs

Enclosure:
As stated

Distribution:
RBangart
PLohaus
DIR RF
SA RF
ALL AS File
SS&D File
RSAOs
RSLOs

DCD (SP01) PDR (YES ✓ NO ___)

OFC	OSP:SA	OSP:PD						
NME	LBolling:gd	PLohaus						
DTE	02/03/94	02/ /94						

G:\LAB\SP94SSD.LAB

040050

SP01

9404050067 940203
PDR STPRG ESGGEN
PDR

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

February 3, 1994

ALL AGREEMENT STATES

TRANSMITTAL OF STATE AGREEMENTS PROGRAM INFORMATION (SP-94-019)

Your attention is invited to the attached correspondence which contains:

INCIDENT AND EVENT INFORMATION.....

PROGRAM MANAGEMENT INFORMATION.....

TRAINING COURSE INFORMATION.....

TECHNICAL INFORMATION.....XX

OTHER INFORMATION.....

Supplementary information: The enclosed SS&D evaluations should be added to your catalog.

If you have further questions regarding this correspondence, please contact the individual named below.

POINT OF CONTACT: Lloyd Bolling
TELEPHONE: (301) 504-2327
FAX (301) 504-3502

Paul H. Lohaus
Office of State Programs

Enclosures:
As stated

SP-94-019 Enclosure 1

1. IL-136-S-191-S AMENDED IN ENTIRETY 1/20/94
2. IL-136-D-333-B AMENDED IN ENTIRETY 1/11/94
3. NR-160-D-101-E AMENDED IN ENTIRETY 1/6/94
4. IL-235-D-101-G AMENDED IN ENTIRETY 12/30/93
5. NR-375-D-103-S ISSUED 1/7/94
6. IL-449-D-101-G AMENDED IN ENTIRETY 3/17/93
7. CA-471-D-103-B AMENDED IN ENTIRETY 10/27/93
8. NR-794-D-101-B ISSUED 1/7/94

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ENTIRETY)

NO: IL-136-S-191-S DATE: January 20, 1994 PAGE: 1 of 10
(Supersedes NR-136-S-191-S)

SOURCE TYPE: Oil Well Logging Source

MODEL: CDC.CYN (N=2 through 14; uniquely identifies a specific outer capsule design)

DISTRIBUTOR: Amersham Corporation
2636 South Clearbrook Drive
Arlington Heights, IL 60005-4692

MANUFACTURER: Amersham International
White Lion Road
Buckinghamshire, England HQ79LL

ISOTOPE: Cesium-137 MAXIMUM ACTIVITY: up to 3 curies (see Limitations and/or Considerations of Use)

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: (F) Oil Well-Logging

CUSTOM SOURCE: _____ YES _X_ NO

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ENTIRETY)

NO: IL-136-S-191-S (Supersedes NR-136-S-191-S) DATE: January 20, 1994 PAGE: 2 of 10

SOURCE TYPE: Oil Well Logging Source

DESCRIPTION:

Cesium-137 is incorporated into an inorganic ceramic matrix which is sealed by firing at high temperature to form a hard, insoluble, radiation and thermally resistant pellet or slug. This pellet, contained in a 316L stainless steel cup, is doubly encapsulated in Monel K500 alloy, Armco 17.4PH stainless steel, MP35N zirconium and its alloys, titanium, 316 or 304 stainless steel. These capsules are sealed by tungsten inert gas welding or by laser welding. In some cases, the outer capsule is designed per the specifications of the user.

Model CDC.CY4 may also be distributed within tertiary (third outer) encapsulations as identified in Amersham Corporation Drawing Numbers MAL150 and MAL151. Regarding the tertiary encapsulations, Amersham states the following:

- ANSI classifications of the sources are valid with the tertiary encapsulations and the principal use of the sources is oil well logging.
- Tertiary capsules are manufactured of ARMCO stainless steel in accordance with Amersham QA/QC protocols and are labelled to the same specifications as inner secondary capsules.
- Inner capsules of sources with tertiary encapsulation are manufactured, tested, and labelled in the same manner as sources that do not have tertiary encapsulations.

LABELING:

All sources are permanently marked with serial numbers and details of the nuclide and activity. Additionally, when the secondary capsule is used as the pressure vessel, the vessel is labeled in accordance with Section 340.940 32 Illinois Administrative Code and the user's specifications. For tertiary capsules, engraved labelling includes the nuclide, activity, unique serial number, "Danger", "Radioactive" and a trefoil. For Model CDC.CY13 capsules, in addition to the items engraved on the tertiary capsule, labeling will include the manufacturer's logo and the statements, "Do Not Handle", and "Notify Civil Authorities."

DIAGRAMS:

See Attachments 1 through 5.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ENTIRETY)

NO: IL-136-S-191-S DATE: January 20, 1994 PAGE: 3 of 10
(Supersedes NR-136-S-191-S)

SOURCE TYPE: Oil Well Logging Source

CONDITIONS OF NORMAL USE:

The Model CDC.CYN sealed source is designed for use in oil and gas well logging operations. These uses subject the source to high pressures, high temperatures and corrosive environments.

PROTOTYPE TESTING:

Model CDC.CY2 - CDC.CY12 prototype sources have been tested by Amersham in accordance with ANSI N542-1977. Based on these test results, a classification of ANSI 77C66534 is claimed. Model CDC.CY13 and CDC.CY14 sources have been assessed the ANSI ratings of 77C66646 and 77C66545 respectively, based on experimental data obtained for the Amersham capsule designation X2074 source and the Amersham capsule designation X2103/1 source, respectively.

EXTERNAL RADIATION LEVELS:

The dose rate at 5 cm from a 3 Ci source of Cs-137 is approximately 390 R/hr, at 30 cm the dose rate is approximately 10.8 R/hr, and at 100 cm the dose rate is approximately 972 mR/hr.

QUALITY ASSURANCE AND CONTROL:

The weld integrity is checked by visual inspection, and by vacuum bubble leak test methods. Finished sources are checked for freedom from leakage and contamination by wipe and immersion test methods (ANSI N542-1977, Appendix A). Sources are also subjected to a high pressure test (at least 25,000 psi). Source activities are checked by measurement of the dose rate in a 4π re-entrant ion chamber. This instrument is checked against standards which are traceable to national standards.

LIMITATIONS AND OTHER CONSIDERATIONS OF USE:

1. This source shall be distributed only to specific licensees of the NRC or Agreement States.

2. Leak Testing: The source shall be leak tested at six month intervals using techniques approved by the licensing authority and capable of detecting 0.005 microcurie of activity.

SOURCE TYPE: Oil Well Logging Source

LIMITATIONS AND OTHER CONSIDERATIONS OF USE (Continued):

3. Handling, storage, use, transfer and disposal: To be determined by the licensing authority. However, in that these sealed sources exhibit high surface dose rates when unshielded, they should be handled only by experienced, licensed personnel using adequate remote handling equipment and procedures.

4. The source Model CDC.CYN (series) shall be distributed only by the model numbers and corresponding activities listed below.

Amersham Model Designation	Maximum Activity (Curies)
CDC.CY2	2
CDC.CY3	3
CDC.CY4	3
CDC.CY5	3
CDC.CY6	2
CDC.CY7	2.5
CDC.CY8	3
CDC.CY9	3
CDC.CY10	3
CDC.CY11	2
CDC.CY12	0.1
CDC.CY13	2.5
*Capsule codes:	
X2112/1	
X2112/2	
X2112/3	
CDC.CY14	1.08
**Capsule Codes:	
X2020	
X2020/2	

*Capsule codes denote three different configurations for the CDC.CY13 source. Each source uses the same outer capsule, but there are three different assemblies within the outer capsule. The source shall be licensed according to the model number and not by the capsule code.

**Capsule codes denote two different versions of the CDC.CY14 source. There are two different outer capsules, which differ only in the metal from which they are made. The source shall be licensed according to model number and not by the capsule code.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ENTIRETY)

NO: IL-136-S-191-S DATE: January 20, 1994 PAGE: 5 of 10
(Supersedes NR-136-S-191-S)

SOURCE TYPE: Oil Well Logging Source

5. The manufacturer shall notify the **Illinois Department of Nuclear Safety**, in writing, of modification to the outer capsule design that resulted from an individual customer request.

6. This registration sheet and the information contained within the references shall not be changed or transferred without the written consent of the **Illinois Department of Nuclear Safety**.

7. **The recommended working life of Model CDC.CY13 and CDC.CY14 capsules is 15 years.**

SAFETY ANALYSIS SUMMARY:

Based on our review of the information and test data cited in the references listed below, we conclude that Model CDC.CYN source design is acceptable for licensing purposes and should maintain its integrity for normal conditions of use and accidental conditions which might occur.

REFERENCES:

The following documents for the Amersham Corporation Model CDC.CYN (series) are hereby incorporated by reference and are made a part of this registry document:

1. Amersham letters dated July 28, 1980, January 19, 1981, February 17, 1981, June 29, 1981, October 30, 1981, April 14, 1982, September 22, 1983, October 19, 1983, January 4, 1984 and November 5, 1984.

2. Amersham Corporation letters, with attachments, dated April 19, 1985, **January 25, 1991, June 17, 1991, September 20, 1991, December 1, 1993 and December 30, 1993.**

ISSUING AGENCY: Illinois Department of Nuclear Safety

DATE: 01-20-94 REVIEWED BY: Sandra M. Frasinger

DATE: 1/21/94 CONCURRENCE: Joseph G. Klinger

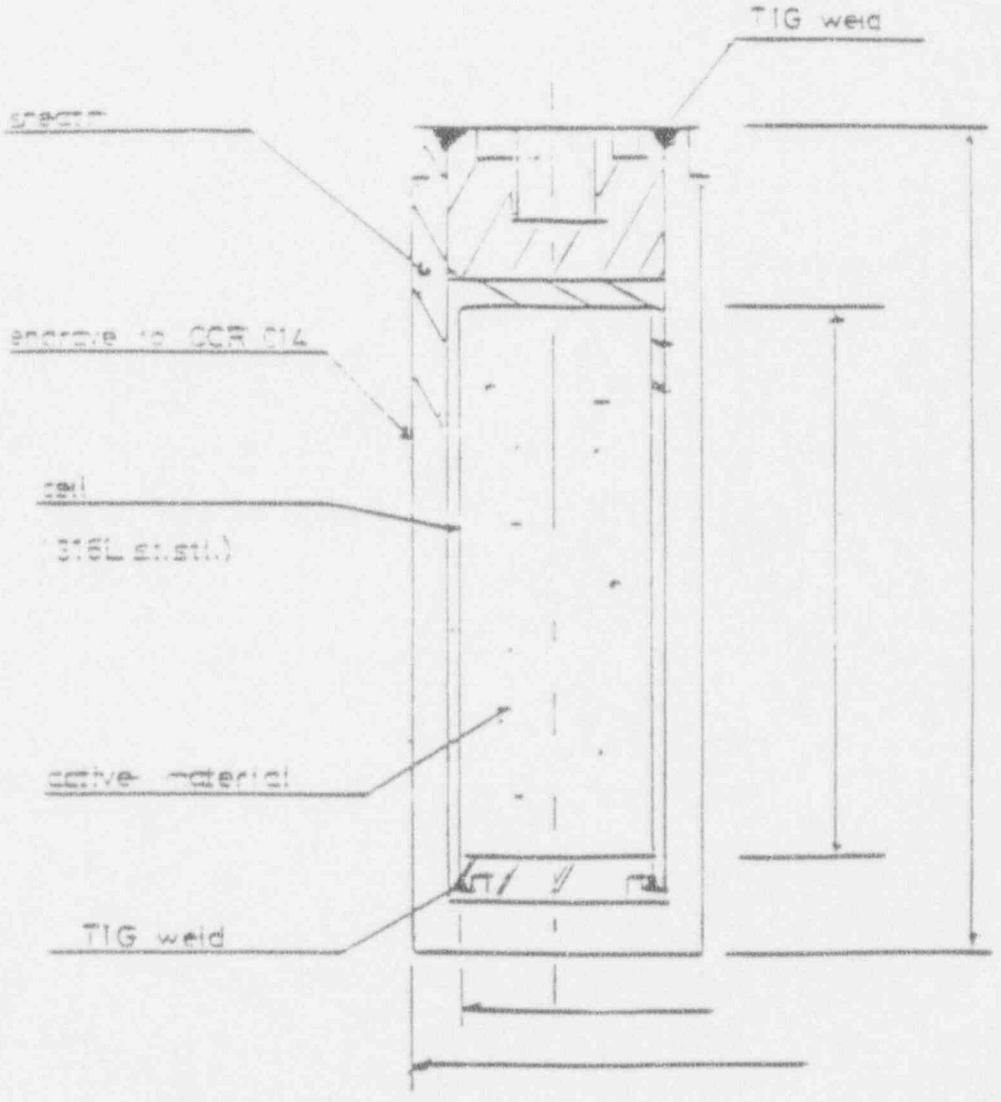
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ENTIRETY)

NO: IL-136-S-191-S DATE: January 20, 1994 PAGE: 6 of 10
(Supersedes NR-136-S-191-S)

SOURCE TYPE: Oil Well Logging Source

ATTACHMENT 1

Generic Source Diagram



NOTE: Dimensions vary with user requirements.

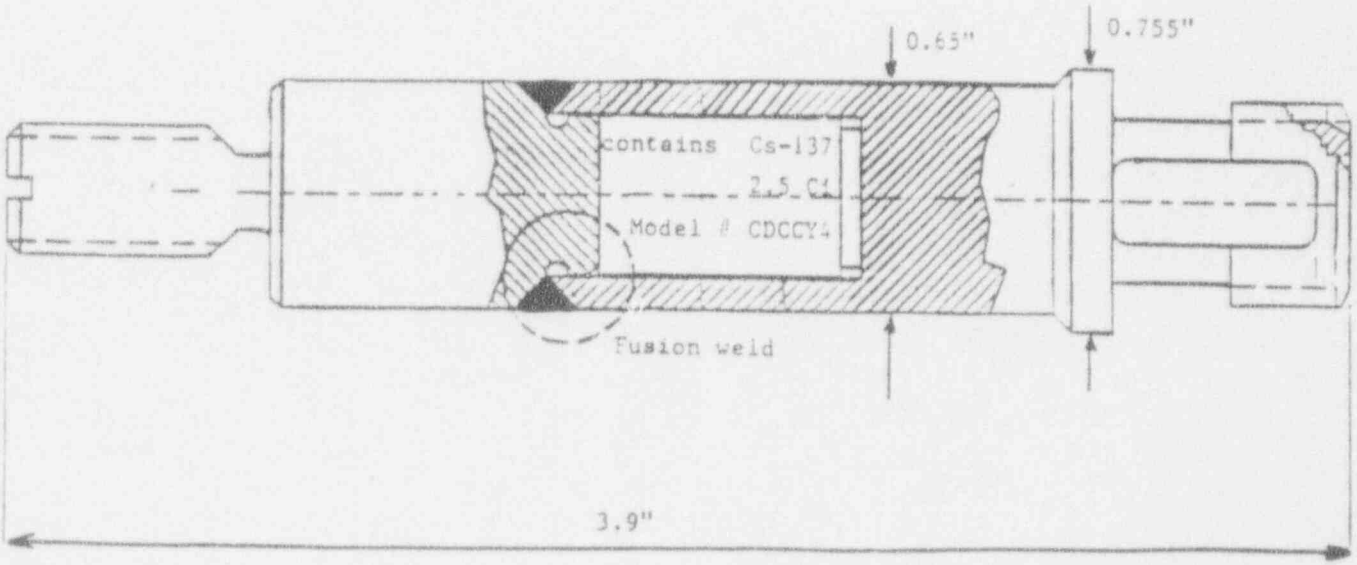
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ENTIRETY)

NO: IL-136-S-191-S DATE: January 20, 1994 PAGE: 7 of 10
(Supersedes NR-136-S-191-S)

SOURCE TYPE: Oil Well Logging Source

ATTACHMENT 2

Tertiary Encapsulation of Model CDC.CY4
Amersham Drawing No. MAL150, Issue 1, dated Sept. 5, 1991



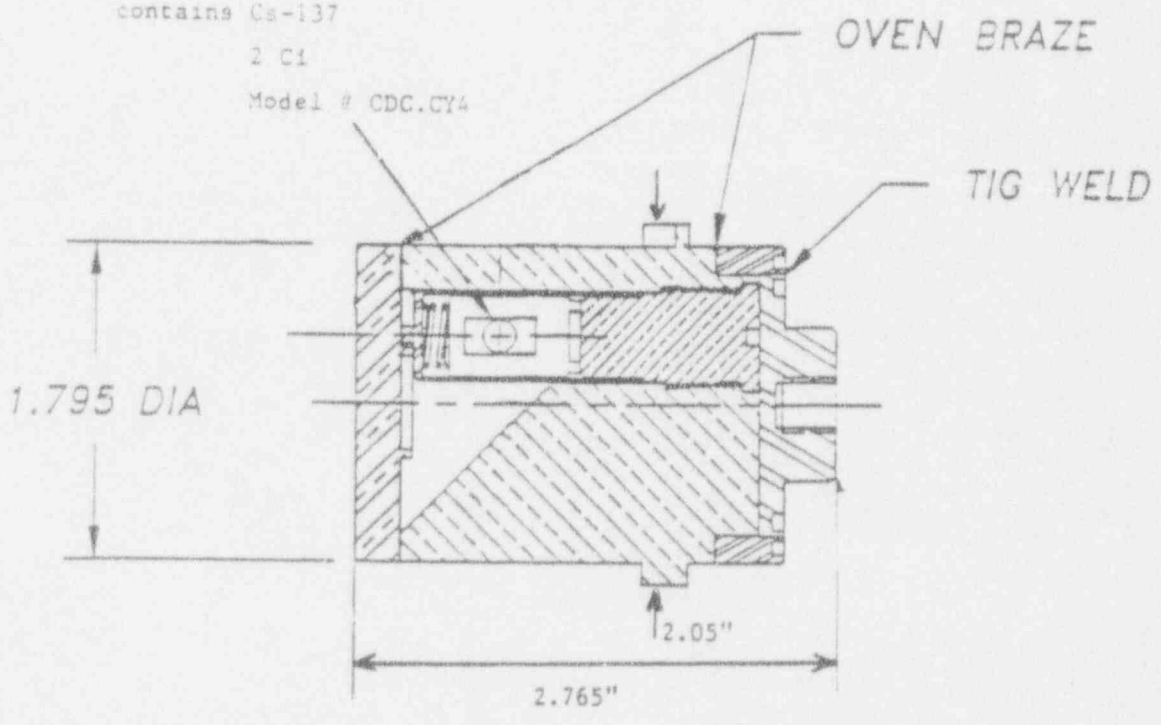
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ENTIRETY)

NO: IL-136-S-191-S (Supersedes NR-136-S-191-S) DATE: January 20, 1994 PAGE: 8 of 10

SOURCE TYPE: Oil Well Logging Source

ATTACHMENT 3

Tertiary Encapsulation of Model CDC.CY4
Amersham Drawing No. MAL151, Issue 1, dated Sept. 5, 1991



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ENTIRETY)

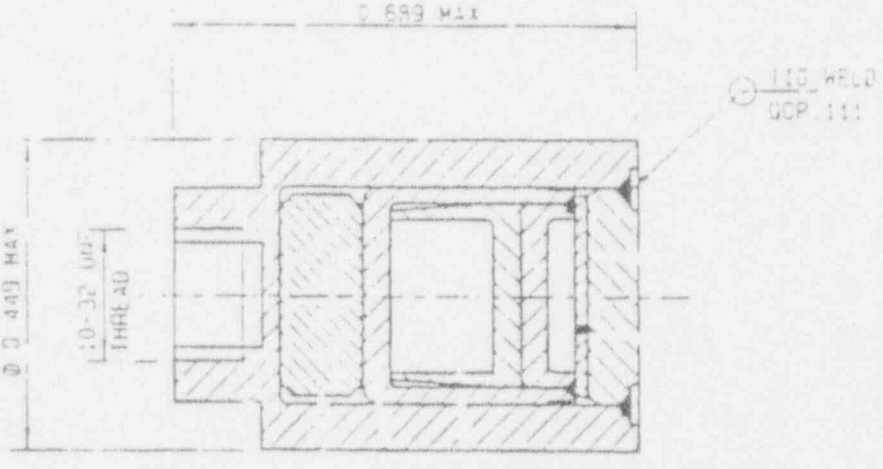
NO: IL-136-S-191-S (Supersedes NR-136-S-191-S) DATE: January 20, 1994 PAGE: 9 of 10

SOURCE TYPE: Oil Well Logging Source

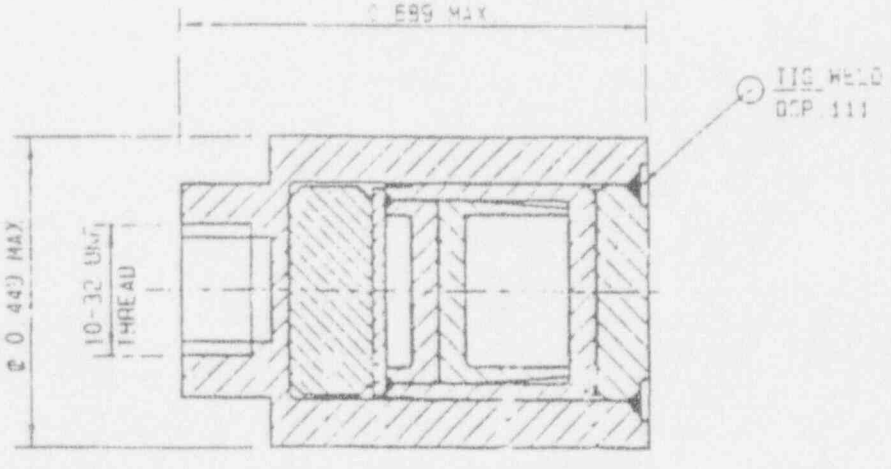
ATTACHMENT 4

CDC.CY13

Capsule Codes: X2112/1 and X2112/2



Capsule Code: X2112/3



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ENTIRETY)

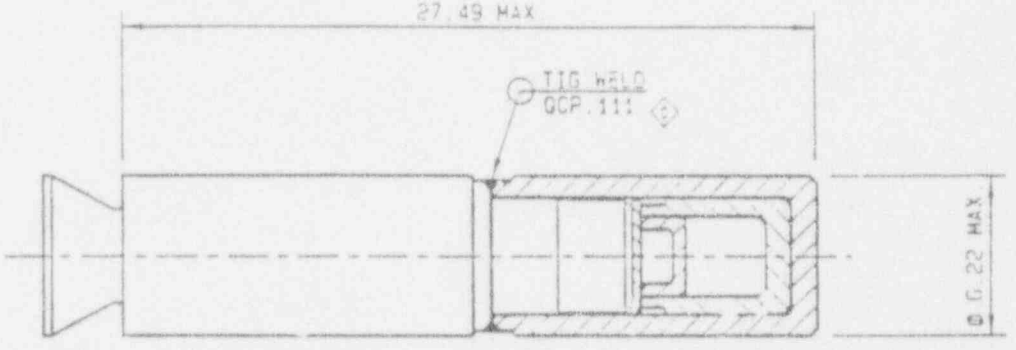
NO: IL-136-S-191-S DATE: January 20, 1994 PAGE: 10 of 10
(Supersedes NR-136-S-191-S)

SOURCE TYPE: Oil Well Logging Source

ATTACHMENT 5

CDC.CY14

Capsule Codes: X2020 and X2020/2



NOTE: The maximum length of the X2020/2 capsule is 27.48 mm maximum

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
AMENDED IN ENTIRETY

NO.: IL-136-D-333-B DATE: January 11, 1994

DEVICE TYPE: Static Eliminator

MODEL: PDM.1002Hn Series (n identifies a specific holder design)

DISTRIBUTOR: Amersham Corporation
2636 South Clearbrook Drive
Arlington Heights, IL 60005-4692

MANUFACTURER: Amersham International
White Lion Road
Buckinghamshire, England HQ79LL

SEALED SOURCE MODEL DESIGNATION: PDM.1002 Foil

ISOTOPE:	MAXIMUM ACTIVITY:
Polonium-210	200 mCi total activity/device

LEAK TEST FREQUENCY: 14 months

PRINCIPAL USE: (O) Ion Generators, Static Eliminators

CUSTOM DEVICE: _____ YES ___X___ NO

DEVICE TYPE: Static Eliminator

DESCRIPTION:

A static eliminator device consists of two basic parts:

A. Foil source: a rolled laminated metal foil which provides the primary containment for the radioactive polonium-210.

B. A steel case which houses the foil and protects it from mechanical damage.

- Attachments 1 through 8 depict the various model numbers with corresponding product codes.

Model Number PDM.1002H1 consists of Product Codes PDV.01002-PDV.01088 and PDV.02002-PDV.02088 (see Attachment 1). These are bar devices of various lengths and activities, which consist of one or more Po-210 strip sources each of which has been incorporated into a stainless steel carrier bar and which, in turn, has been loaded into a stainless steel channel bar. A protective stainless steel wire mesh is placed over the active foil.

These bars vary in activity and length from 4 mCi and 60 mm up to 200 mCi and 225 cm. No device will exceed the A_2 quantity of 200 mCi for polonium-210.

The longer bars are made up of shorter sections which are joined together by means of stainless steel connectors and spacers. For example, Product Codes PDV.01013 through 18, nominal activity of 26 mCi, is made up of one channel bar, two carrier bars, two lengths of foil, one spacer bar (center of assembly) and two connectors (at each end of the assembly) which are spot welded to the channel bar to lock all components together. The end connectors contain drilled and tapped holes so the bar can be secured to surrounding equipment.

There is also a plastic cover which further protects the active surface during transport and when the bar is not in active use.

Active bars can also be used in combination with passive (non-radioactive) static eliminators. These devices have Product Codes PDV.02002-PDV.02088. The active bar is joined to the passive eliminator by means of stainless steel coupling brackets.

DEVICE TYPE: Static Eliminator

DESCRIPTION: (continued)

The various lengths and activities for PDV.01002-PDV.01088 and PDV.02002-PDV.02088 are given below.

EFFECTIVE LENGTH (in inches)	NOMINAL CONTENT ACTIVITY mCi (2 mCi/inch)	ACTIVE BAR PRODUCT CODES	COMBINATION BAR PRODUCT CODES
2"	4	PDV.01002	PDV.02002
4"	8	PDV.01004	PDV.02004
5-6"	10-12	PDV.01005/6	PDV.02005/6
7-12"	14-24	PDV.01007/12	PDV.02007/12
13-18"	26-36	PDV.01013/18	PDV.02013/18
19-24"	38-48	PDV.01019/24	PDV.02019/24
25-30"	50-60	PDV.01025/30	PDV.02025/30
31-36"	62-72	PDV.01031/36	PDV.02031/36
37-42"	74-84	PDV.01037/42	PDV.02037/42
43-48"	86-96	PDV.01043/48	PDV.02043/48
49-60"	98-120	PDV.01049/60	PDV.02049/60
61-72"	122-144	PDV.01061/72	PDV.02061/72
73-78"	146-156	PDV.01073/78	PDV.02073/78
79-84"	158-168	PDV.01079/84	PDV.02079/84
85-88"	170-176	PDV.01085/88	PDV.02085/88

Model Number PDM.1002H2 consists of Product Code PDV.03611 (see Attachment 2). This is a disc device which consists of an active foil loaded into an aluminum alloy source holder with a stainless steel mesh disc and aluminum alloy spacer ring being first positioned over the active face and an aluminum alloy backing disc being placed behind the foil which is press fitted into the source holder to effect closure.

Model Number PDM.1002H3 consists of a static eliminator nozzle, Product Code PDV.01412, and a film cleaner, Product Code PDV.01512 (see Attachment 3). The basic assembly process of the static eliminator nozzle involves introducing an active foil into the internal surface of a stainless steel tube, which conforms to the inside contour of the tube when a stainless steel spacer disc is positioned approximately mid-way along the foil length. End plugs are then inserted into both ends of the active plug and locked in placed by means of four screws. The nominal content of the PDV.01412 is 10 mCi.

Product Code PDV.01512 is a film cleaner which incorporates an ionizing nozzle (Product Code PDV.01412, Model Number PDM.1002H3) as shown in Attachment 3.

DEVICE TYPE: Static Eliminator

DESCRIPTION: (continued)

Model Number PDM.1002H4 consists of Product Codes PDV.01312 and PDV.01313 (See Attachment 4). These are static eliminator guns. Air supply connectors are joined to the PDV.01312 and PDV.01313 and an air stream carries the ionized air produced by the active foil to the work surface. The active foil is wrapped around the inside surface of a stainless steel cylindrical tube with a stainless steel spacer disc placed approximately mid-way along the foil length for mechanical support. Stainless steel plugs are inserted into both ends of the active tube to secure the foil in the tube, and this assembly is then mounted into the handle and secured by means of screws. The stainless steel plug at the exit end of the tube is secured to the tube by means of screws. A black plastic nose is finally press fit into the exit end of the plug to complete the assembly. Product Code PDV.01313 is a Schrader Ionizing Gun which consists of an ionizing nozzle (Product Code PDV.01412, Model Number PDM.1002H3) attached to a Schrader 601 air gun, as shown on the diagram, (see Attachment 4). The nominal content of the PDV.01312 and PDV.01313 is 10 mCi.

Model Number PDM.1002H5 consists of Product Codes PDV.0700 and PDV.0710 (see Attachments 5 and 6). These are ionizer ring devices which consist of an aluminum alloy source holder, aluminum alloy front ring, Po-210 foil, stainless steel mesh, and tamper proof screws. The foil is loaded into the source holder, the protective stainless steel mesh is placed over the active face and the front ring is placed over the top of the source holder, securing the foil and mesh. The front ring is secured to the source holder by means of three tamper proof screws. A product label is also affixed to the source holder.

Product Code PDV.0700 consists of a PDV.0710 unit press-fitted into a ringjet mover.

Model Number PDM.1002H6 consists of Product Codes PDV.0400 and PDV.0600 (see Attachment 7). These are semicircular devices which consist of 2 cadmium-plated mild steel side plates with opposing sides of an active foil inserted into channels cut into the faces of the plates and a protective stainless steel mesh inserted into additional channels in the plate faces which is positioned in front of the foil's active face and a stainless steel backing plate placed in contact with the inactive face of the foil and inserted into the same side plate channels as the foil's. Two stainless steel end plates, two spacers and six rivets are used to lock together the loaded side plates. Two semicircular devices can be joined at the end plates to form a complete ring.

DEVICE TYPE: Static Eliminator

DESCRIPTION: (continued)

Model Number PDM.1002H7 consists of Product Codes PDV.011 and PDV.012 (see Attachment 8). These are static eliminator air movers which contain nominal activities of 30 mCi and 60 mCi, respectively. Product Code PDV.0111 is a 30 mCi replacement active bar for the PDV.011 and PDV.012. These devices are comprised of a static eliminator bar of the general type described above under Product Codes PDV.01002-PDV.01088 (see Attachment 1 for design), which has been installed by means of screws in the interior of a housing which also contains an electric fan that forces air over the active bar to produce a stream of ionized air.

LABELING:

Each device is labeled in accordance with the requirements of 32 Illinois Administrative Code 330.280(d)(1)(C) (10 CFR 32.51) or 340.2030 (10 CFR 20.203).

DIAGRAMS:

See Attachments 1 through 8.

CONDITIONS OF NORMAL USE:

The normal conditions of use for these devices will be standard temperature and pressure and within the limits of the ANSI rating C34444. They will be used to eliminate static electricity in such operations as paper rolling mills, paint spraying, label printing, electronic metal oxide semi-conductor component and circuit manufacturing, photographic film processing and printing.

The expected useful life is at least 14 months. The devices will be leased, with replacement devices being supplied within 12-14 months, when customers return the original device supplied.

DEVICE TYPE: Static Eliminator

CONDITIONS OF NORMAL USE: (continued)

The Model PDM.1002Hn source holder may be used in the following configurations.

Model Number	Product Code	Description
PDM.1002H5	PDV.0700	Ringjet Ionized Air Mover
PDM.1002H5	PDV.0710	Replacement Ionizer Ring
PDM.1002H7	PDV.011	Ionized Air Blower
PDM.1002H7	PDV.012	Ionized Air Blower
PDM.1002H7	PDV.0111	Replacement bar for Blower
PDM.1002H3	PDV.01412	Ionizing Nozzle
PDM.1002H4	PDV.01312	P.M. Ionizing Gun
PDM.1002H4	PDV.01313	Schrader Ionizing Gun
PDM.1002H3	PDV.01512	Film Cleaner
PDM.1002H1	PDV.01002 - PDV.01088	Active Bars
PDM.1002H1	PDV.02002 - PDV.02088	Combination Bars
PDM.1002H2	PDV.03611	Active Disc
PDM.1002H6	PDV.0400	Semi-circular Source (rings)
PDM.1002H6	PDV.0600	Semi-circular Source (rings)

PROTOTYPE TESTING:

Foil sources were subjected by Amersham to tests in accordance with ANSI N542-1977 and were designated ANSI 77 C34444. The devices were tested in trichloroethane solvent. The samples were immersed for 24 hours in the solvent. In no case did the activity removed exceed ɔ.24 nanocuries. Amersham states that their experience is that these solvents remove much less activity when short duration cleaning is done rather than long soak periods.

The Model Number PDM.1002Hn type static eliminator device has been distributed by Amersham in Europe for several years. The returned units have been tested by Amersham and found to exhibit less than 5 nanocuries of removable contamination.

EXTERNAL RADIATION LEVELS:

See Attachment 9.

DEVICE TYPE: Static Eliminator

QUALITY ASSURANCE AND CONTROL:

Quality control, quality assurance and ANSI testing are conducted by the Quality Control Department, which is independent of the Production Department. The Quality Management System of Amersham International, Industrial Products Division, Amersham Laboratories, has been assessed and approved by Lloyd's Register Quality Assurance Limited against a number of quality assurance standards, including ISO 9001-1987, which is equivalent to the ANSI/ASQC N90 quality assurance standards.

LIMITATIONS AND OTHER CONSIDERATIONS OF USE:

1. Devices listed in this certificate shall not be subjected to conditions which exceed ANSI 77 C34444 Classification for static eliminator sources.

2. Devices described herein may be distributed to either general or specific licensees of NRC or Agreement States on a lease-only basis.

3. Devices containing licensed materials and described herein shall be leak tested at intervals not to exceed 14 months using techniques approved by the licensing authority and capable of detecting the presence of 0.005 microcuries of removable contamination.

4. Users of the Model PDM.1002Hn device should avoid contacting foil sources with corrosive powders such as polyvinylchloride (PVC).

5. Users of Model PDM.1002Hn devices should avoid prolonged contact of foil sources with organic solvents such as methanol or acetone.

6. Devices to be used in conjunction with compressed air systems shall have a trapping system installed into the air line.

7. Amersham Corporation will provide a questionnaire to each of its customers for evaluation of operating conditions prior to installation of the device.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
AMENDED IN ENTIRETY

NO.: IL-136-D-333-B DATE: January 11, 1994

DEVICE TYPE: Static Eliminator

SAFETY ANALYSIS SUMMARY:

The Amersham Corporation Model PDM.1002Hn mounted foil sources are used as sources of ionization to reduce static buildup in various industrial and research environments. The foil source holders are mounted in a variety of housings (see Attachments 1 through 8). In these housings, the foil sources are protected from direct contact by personnel and the source cannot be inadvertently removed without the use of special tools and extraordinary effort.

These static eliminator devices are manufactured and tested in accordance with an acceptable quality assurance and control program and are distributed to persons either specifically or generally licensed by NRC or Agreement States. Based on our review, we believe that these devices can be safely used by persons not having training in radiological protection provided specific precautions outlined in the manufacturer's instructions are followed.

Since the Po-210 source for the static eliminator device is an alpha emitter, the external radiation exposure from the normal use of the device is considered to be of no radiological significance. Furthermore, under ordinary conditions of use, this Po-210 foil cannot be individually removed for routine or emergency conditions of use, and it is unlikely that any person will receive an external radiation dose or dose commitment in excess of 10% of the limits specified in 32 Illinois Administrative Code 340.210(a) (10 CFR 20.101(a)).

The greatest potential for personnel exposure results from loss of integrity of the foil source; for example, if damaged by corrosive materials or fires. The Amersham test data shows that there is little likelihood of loss of integrity of the sources due to normal use provided the devices are used according to the manufacturer's instructions.

However, because of the volatile nature of polonium, it may be released if exposed to high temperature fires. For this reason, Amersham international contracted with the British National Radiological Protection Board (NRPB) to assess the consequences of fires involving Po-210 air static eliminators. The results of the NRPB study are reported in a June 1981 document by B. T. Wilkins and D. W. Dixon.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
AMENDED IN ENTIRETY

DEVICE TYPE: Static Eliminator

SAFETY ANALYSIS SUMMARY: (continued)

The authors of this study state that inhalation of resuspended activity following high temperature fires (800°C and higher) could result in measurable intakes. For example, the total amount of airborne activity released during a 600°C fire is less than one percent of the annual limit of intake for workers. However, at 800°C more significant amounts of activity are released. They postulate that the intake of a person 100 meters downwind could be about one percent of the annual limit depending upon the prevailing weather conditions.

Even though the authors of this study recommended and we concur that radiological protection precautions should be taken by personnel during clean up operations following high temperature (800°C and up) fires involving static eliminator devices, it does not appear likely that any person could receive a dose or dose commitment in excess of the limits specified in 32 Illinois Administrative Code 330.280 (d)(1)(B)(iii) (10 CFR 32.24, Column IV).

Therefore, based on these considerations and our review of the information and test data contained in the references cited below, we conclude that the Amersham Model PDM.1002Hn static eliminator device is acceptable for licensing in accordance with this Certificate of Registration and the provisions of 32 Illinois Administrative Code 330.220(d) (10 CFR 31.5) and 330.280(d) (10 CFR 32.51).

REFERENCES:

The following documents for the Amersham Model PDM.1002Hn are hereby incorporated by reference and are made a part of this registry document:

Amersham Corporation letters, with attachments, dated September 13, 1990, January 10, 1991, April 2, 1991, April 19, 1991, April 25, 1991, July 18, 1991, February 10, 1992, November 24, 1992 and September 1, 1993, and Amersham Corporation letter dated August 1, 1991.

ISSUING AGENCY: Illinois Department of Nuclear Safety

DATE: 01-11-94 REVIEWED BY: Sandra M Kessinger

DATE: 1/11/94 CONCURRENCE: Joseph G Klinger

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
AMENDED IN ENTIRETY

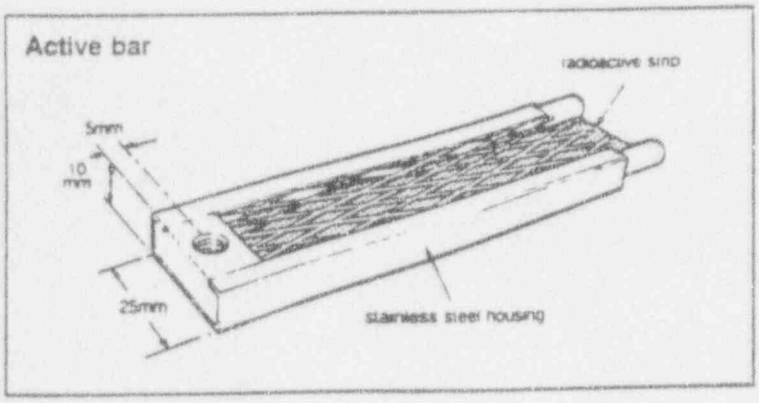
DEVICE TYPE: Static Eliminator

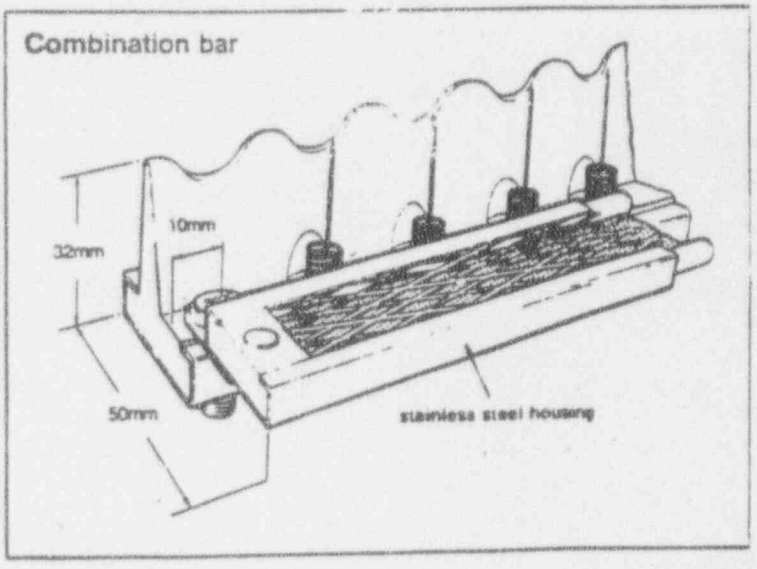
ATTACHMENT 1

PDM.1002H1

Bars devices and combination bar devices
Product codes: PDV.01002-PDV.01088 (Active Bars)
PDV.02002-PDV.02088 (Combination Bars)

ACTIVE AND COMBINATION STATIC ELIMINATORS			
EFFECTIVE LENGTH (in)	NOMINAL CONTENT	ACTIVE BAR	COMBINATION BAR
2"	4	PDV.01002	PDV.02002
4"	8	PDV.01004	PDV.02004
5-6"	10-12	PDV.01005/6	PDV.02005/6
7-12"	14-24	PDV.01007/12	PDV.02007/12
13-18"	26-36	PDV.01013/18	PDV.02013/18
19-24"	38-48	PDV.01019/24	PDV.02019/24
25-30"	50-60	PDV.01025/30	PDV.02025/30
31-36"	62-72	PDV.01031/36	PDV.02031/36
37-42"	74-84	PDV.01037/42	PDV.02037/42
43-48"	86-96	PDV.01043/48	PDV.02043/48
49-60"	98-120	PDV.01049/60	PDV.02049/60
61-72"	122-144	PDV.01061/72	PDV.02061/72
73-78"	146-156	PDV.01073/78	PDV.02073/78
79-84"	158-168	PDV.01079/84	PDV.02079/84
85-88"	170-176	PDV.01085/88	PDV.02085/88





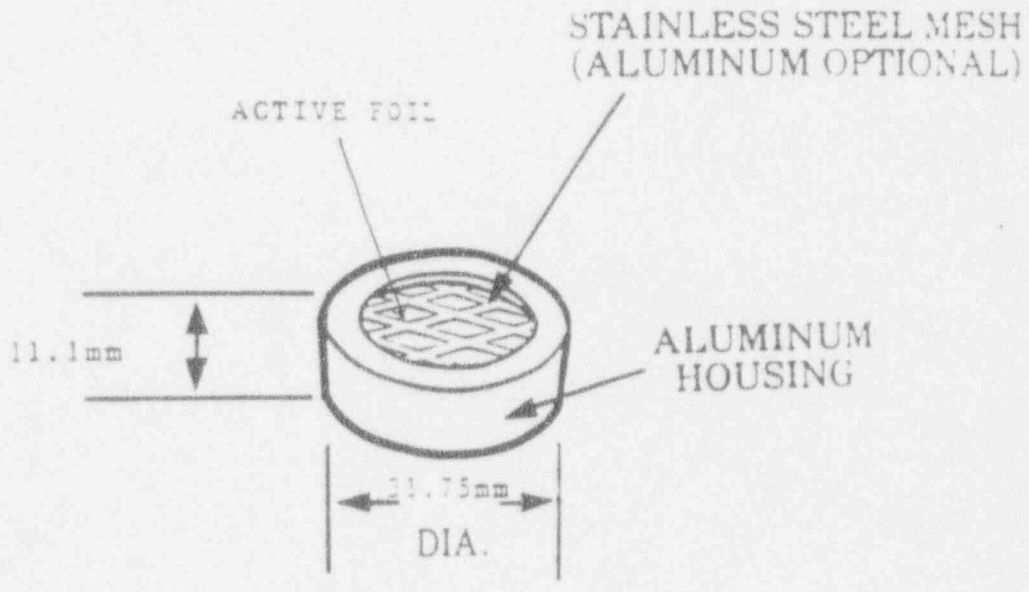
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
AMENDED IN ENTIRETY

DEVICE TYPE: Static Eliminator

ATTACHMENT 2

PDM.1002H2

Disc device:
Product code: PDV.03611

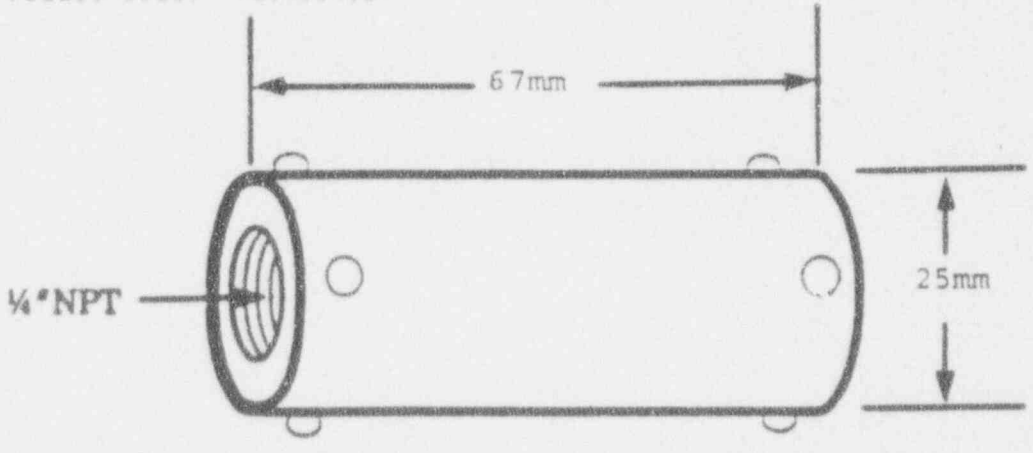


DEVICE TYPE: Static Eliminator

ATTACHMENT 3

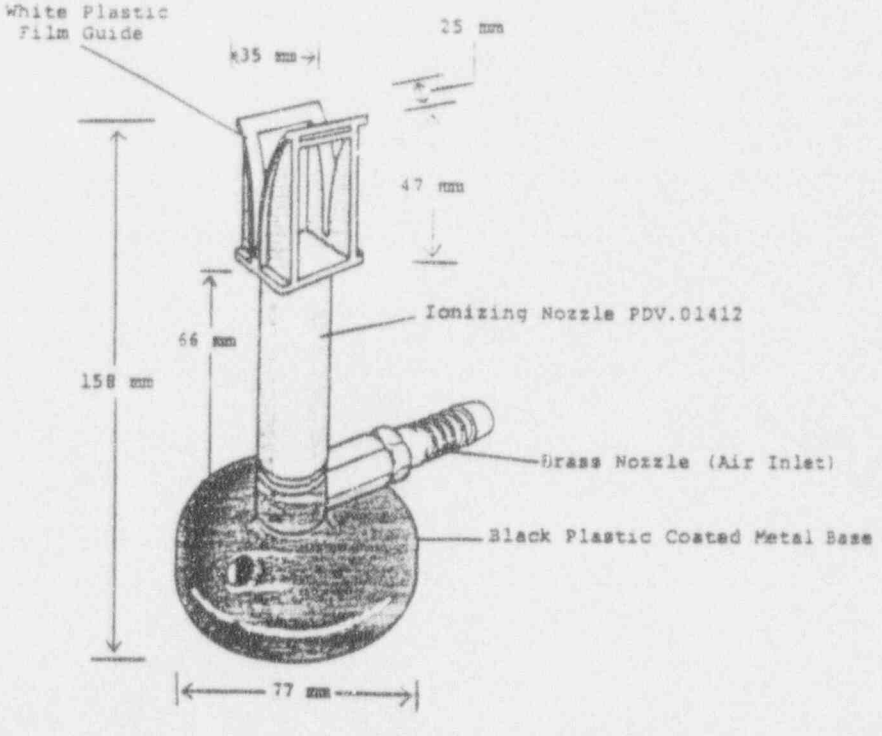
PDM.1002H3

Ionizing nozzle device
Product code: PDV.01412



PDM.1002H3

Film Cleaner
Product code: PDV.01512



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
AMENDED IN ENTIRETY

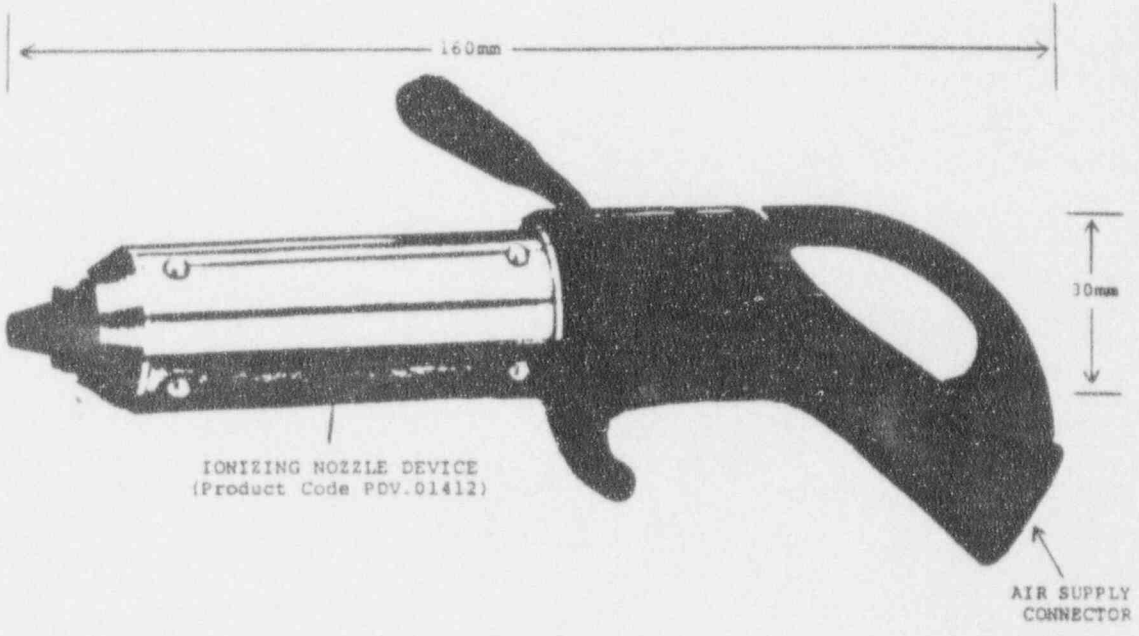
NO.: IL-136-D-333-B DATE: January 11, 1994

DEVICE TYPE: Static Eliminator

ATTACHMENT 4

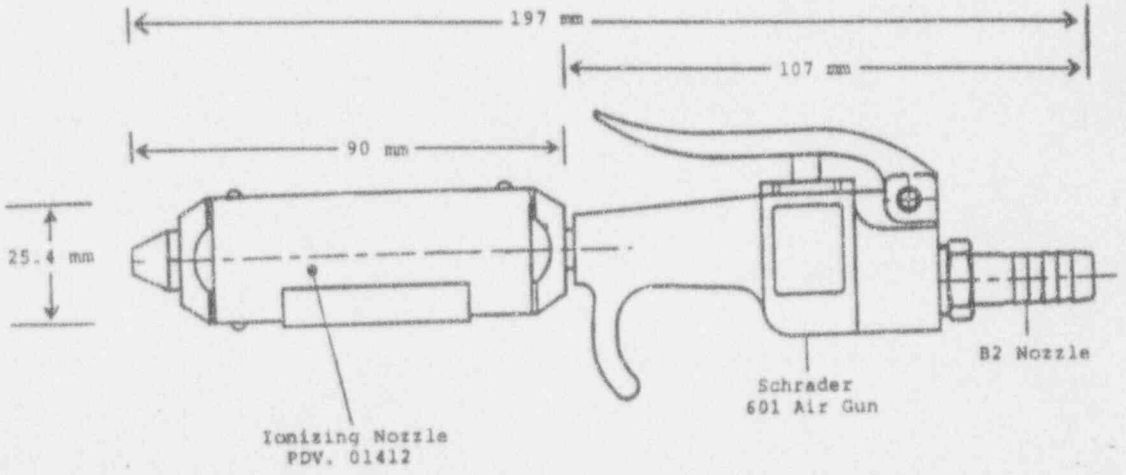
PDM.1002H4

Ionizing gun device
Product code: PDV.01312



PDM.1002H4

Schrader Ionizing gun
Product code: PDV.01313



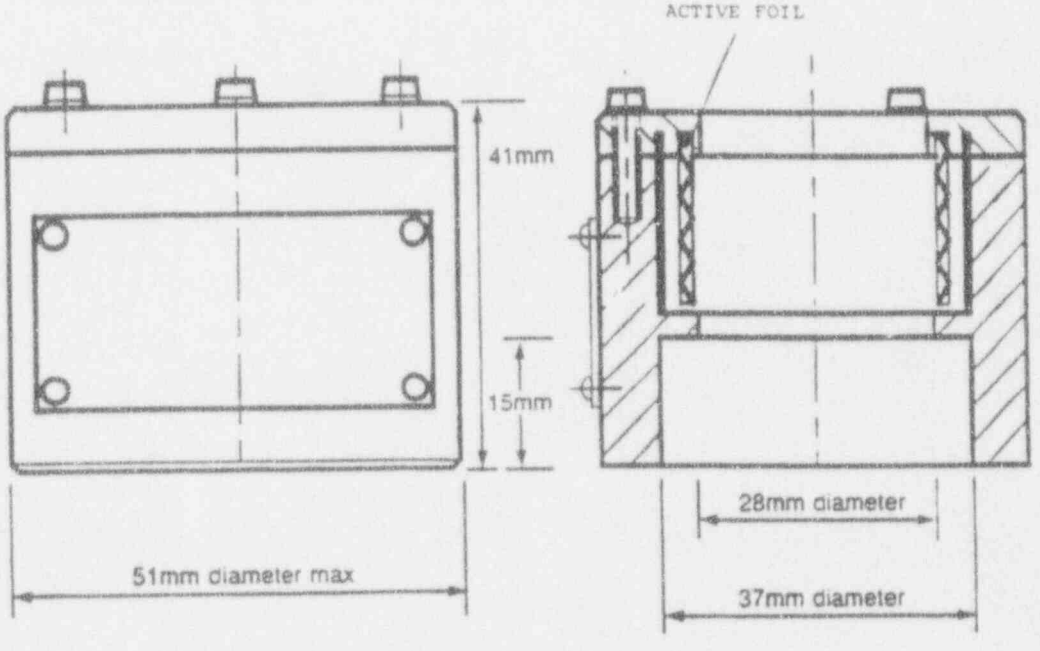
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
AMENDED IN ENTIRETY

DEVICE TYPE: Static Eliminator

ATTACHMENT 5

PDM.1002H5

Ionizing ring device
Product code: PDV.0710



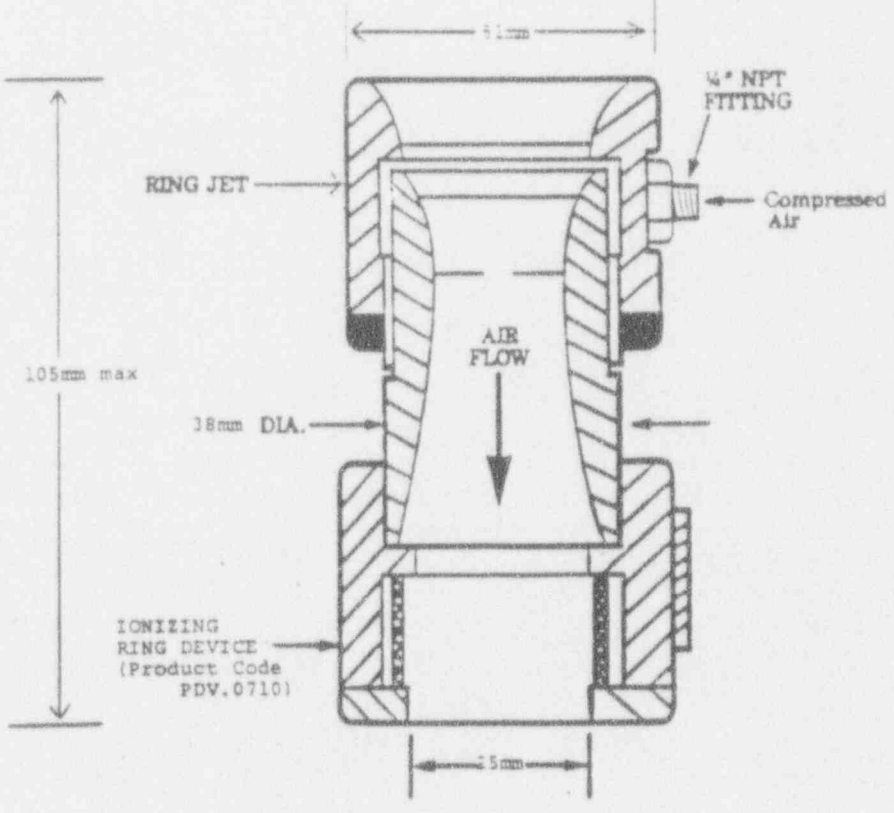
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
AMENDED IN ENTIRETY

DEVICE TYPE: Static Eliminator

ATTACHMENT 6

PDM.1002H5

Ringjet ionized air mover device
Product code: PDV.0700



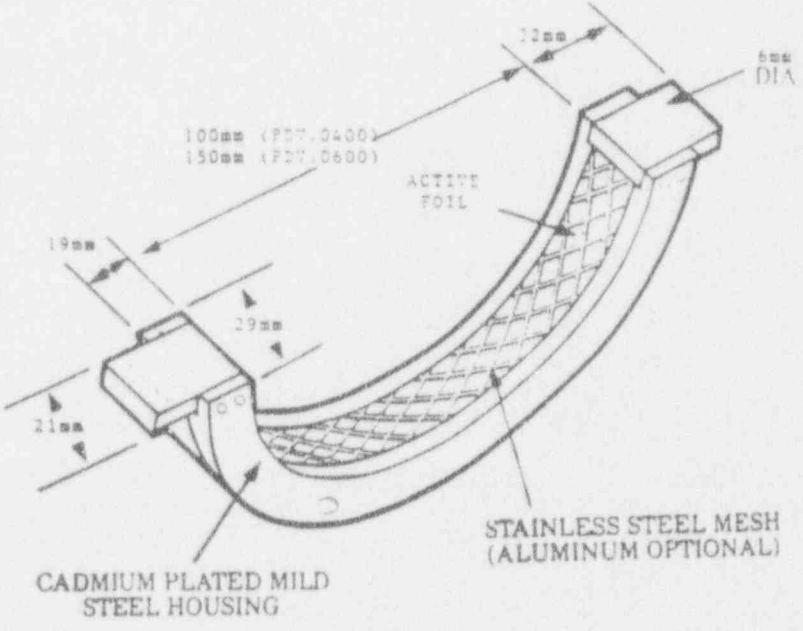
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
AMENDED IN ENTIRETY

DEVICE TYPE: Static Eliminator

ATTACHMENT 7

PDM.1002H6

Semicircular devices
Product codes: PDV.0400
PDV.0600

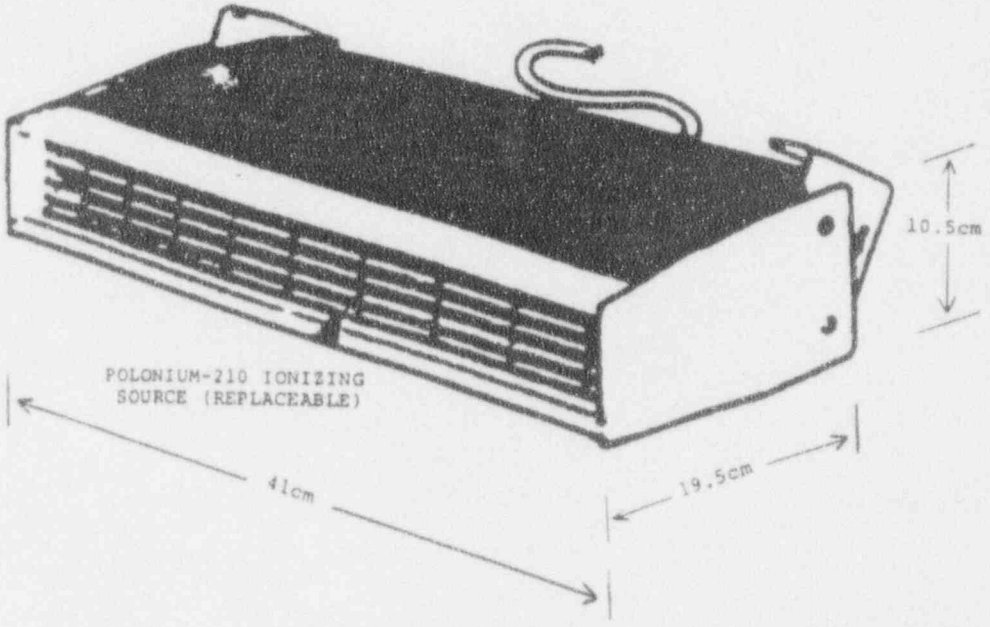


DEVICE TYPE: Static Eliminator

ATTACHMENT 8

PDM.1002H7

Ionized Air Blower Devices
Product codes: PDV.011
PDV.012



(Product Code PDV.012 is of the same design as Product Code PDV.011 except that it contains two foil sources.)

DEVICE TYPE: Static Eliminator

ATTACHMENT 9

The external radiation level for the maximum loading of each PDM.1002Hn device has been either measured, as in the case of bar and nozzle devices at 10cm, or calculated based on the results of the bar measurements. Radiation level data is tabulated below for distances of 5cm and 30cm, at the location over the surface of each device where it is estimated that the maximum radiation intensity will be found at 5cm and 30cm.

Model Number	Product Code	Maximum Activity	Distance	Dose Equivalent Rate	
				μSv/hr	mrem/hr
PDM.1002H1	PDV.01002-PDV.01088 Bars	1.25 mCi/cm	5	4.3	0.43
			30	0.2	0.02
	PDV.02002-PDV.02088 Combination Bars	1.25 mCi/cm	5	4.3	0.43
			30	0.2	0.02
PDM.1002H2	PDV.03611 Disc	2.2 mCi	5	1.2	0.12
			30	0.04	0.004
PDM.1002H3	PDV.01412 and PDV.01512 Nozzle	12.5 mCi	5	2	0.2
			30	0.04	0.004
PDM.1002H4	PDV.01312 and PDV.01313 Gun	12.5 mCi	5	2	0.2
			30	0.04	0.004
PDM.1002H5	PDV.0710 Ionizer Ring	12.5 mCi	5	2	0.2
			30	0.05	0.005
	PDV.0700 Ringjet Air Mover	2.5 mCi	5	2	0.2
			30	0.05	0.005
PDM.1002H6	PDV.0400 Ring	17.5 mCi	5	10	1
			30	0.4	0.04
	PDV.0600 Ring	25 mCi	5	10	1
			30	0.4	0.04
PDM.1002H7	PDV.011 Air Blower	37.5 mCi	5	4	0.4
			30	0.2	.02
	PDV.012 Air Blower	75 mCi	5	8	0.8
			30	0.4	0.04

The external radiation level data given for the PDV.01002-PDV.01088 and PDV.02002-PDV.02088 bar devices are based on a maximum loading of 1.25mCi/cm and are derived from bar device (containing 1mCi/cm) TLD measurements at 10cm.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-160-D-101-E DATE: January 6, 1994

DEVICE TYPE: Smoke Detector

MODEL: Series 60A, Series XP95A and TP90

MANUFACTURER/DISTRIBUTOR: RES Company
1749 E. Highwood
Pontiac, MI 48340

MANUFACTURER: Apollo Fire Detectors Ltd.
6 Solent Road
Havant, Hampshire, England PO9 1JH

SEALED SOURCE MODEL DESIGNATION: NRD Foil Model Number A-001
Amersham Model AMM-1001

ISOTOPE:	MAXIMUM ACTIVITY:
Americium-241	1.0 microcurie (37 kBq)

LEAK TEST FREQUENCY: Not Required

PRINCIPAL USE: (P) Ion Generators, Smoke Detectors

CUSTOM DEVICE: _____ YES ___X___ NO

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-160-D-101-E DATE: January 6, 1994

DEVICE TYPE: Smoke Detector

DESCRIPTION:

The Apollo Series 60A, Series XP95, and the TP90 are all ionization smoke detectors differing only in the electronic communications between the source and the control unit. The source is mounted within a stainless steel holder and riveted to the printed circuit board. The source holder is enclosed in a polycarbonate case. The polycarbonate lid is secured with tamper resistant screws. The complete unit is approximately 3.94 inches (100 mm) in diameter, and 1.97 inches (50 mm) in height. Some Series 60A units will bear the name of other marketing firms on the label, detector lid, and point-of-sale package. All labels applied by the distributor conform to the requirements of section 32.29, 10 CFR Part 32, and contain the license number of the licensed distributor. The TP90 will be marketed by Thorn Automated Systems, Inc. under the model 550 series. The point-of-sale package will contain the RES Company NRC license number.

REFERENCES:

The following supporting documents for the Models Series 60A, Series XP95A, and TP90 are hereby incorporated by reference and are made a part of this registry document.

- RES Company's application dated February 1992.
- RES Company's letters dated March 3, 1992, June 15, 1992, June 25, 1992, July 8, 1992, July 21, 1992, and June 2, 1993, with enclosures thereto.
- Apollo Fire Detectors LTD's letters dated March 2, 1993, May 18, 1993, and November 26, 1993, with enclosures thereto.
- Apollo Fire Detectors LTD's facsimile dated May 21, 1993, with enclosures thereto.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-160-D-101-E DATE: January 6, 1994 PAGE 3 OF 3

DEVICE TYPE: Smoke Detector

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: January 6, 1994 Reviewer: Steven L. Baggett

Date: January 6, 1994 Concurrence: John W. Lubinski

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ENTIRETY)

NO: IL-235-D-101-G DATE: December 30, 1993
(Supersedes NR-235-D-101-G)

SOURCE TYPE: Beta Backscatter Thickness Gauge

MODEL: GM-1

MANUFACTURER/DISTRIBUTOR:

CMI International Corp.
2301 Arthur Avenue
Elk Grove Village, IL 60007

ISOTOPE:	MAXIMUM ACTIVITY:
Promethium-147	600 microcuries
Thallium-204	75 microcuries
Strontium/Yttrium-90	5 microcuries

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: (E) Beta Gauge

CUSTOM SOURCE: ____ YES ___X___ NO

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ENTIRETY)

NO: IL-235-D-101-G DATE: December 30, 1993 PAGE: 2 of 5
(Supersedes NR-235-D-101-G)

SOURCE TYPE: Beta Backscatter Thickness Gauge

DESCRIPTION:

The GM-1 is a portable probe which consists of a delrin (a type of plastic) cylindrical housing with the measuring opening at one end and a cable coming out of the other end. The cable supplies the operating voltage to the geiger tube and conducts the signal back to the electronics unit. The radioactive source is mounted behind the measuring opening so that it will "shine" on the work to be measured, and the beta-particles will be backscattered from the work, back through the measuring opening, and into the geiger tube which is mounted behind the source. A cover plate is positioned over the top of the housing tube and secured with three tamper resistant screws. A protective cap is removed prior to placing the probe into the material to be measured. The user is not required to replace the source to make measurements as is the case with other devices.

LABELING:

The label is placed around the cable assembly. The information on the label conforms to the requirements of 32 Ill. Adm. Code 330.280(d) (10 CFR 32.51) and 32 Ill. Adm. Code 340.2030 (10 CFR 20.203).

DIAGRAMS:

See Attachment 1.

CONDITIONS OF NORMAL USE:

The primary use of the probes and associated electronics is to accurately measure the thickness of coatings on various substrates the principal industries using this principle today are electronics, plating, aircraft, and automotive.

PROTOTYPE TESTING:

These devices have already been deemed acceptable for licensing by the State of New York, no testing data was submitted by the manufacturer. The device has been manufactured and distributed since 1979 without a report of loss of activity. Rutgers University in New Jersey performed the radiation profiles on the sources and devices. CMI International will acquire the assets of Magnaflux Sigma and continue to manufacturer the probes.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ENTIRETY)

NO: IL-235-D-101-G DATE: December 30, 1993 PAGE: 3 of 5
(Supersedes NR-235-D-101-G)

SOURCE TYPE: Beta Backscatter Thickness Gauge

EXTERNAL RADIATION LEVELS:

Rutgers University performed an evaluation on the expected worst case of exposure to users of the device. The following are calculated worst case exposure to the hands:

Sr/Y-90	1007 mrem/qtr
Pm-147	153 mrem/qtr
Tl-204	923.6 mrem/qtr

32 Ill. Adm. Code 330.280(d)(1)(ii) (10 CFR 32.51) requirements are a maximum of 1875 mrem/qtr.

The following are calculated worst case exposure to the whole body:

Sr/Y-90	17.4 mr/qtr
Pm-147	0.2 mr/qtr
Tl-204	11.5 mr/qtr

32 Ill. Adm. Code 330.280(d)(1)(ii) (10 CFR 32.51) requirements are a maximum of 125 mrem/qtr. This is the same study that was used by UPA Technology and Magnaflux Sigma to support their license applications.

QUALITY ASSURANCE AND CONTROL:

CMI International submitted an acceptable quality assurance and control program, a copy of which is on file with the Material Licensing Branch. The basic topics of the program are listed below:

- Design
- Document control
- Control of purchased material, parts and components, and manufactured devices
- Inspections
- Test control
- Transportation control
- Records maintenance

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ENTIRETY)

NO: IL-235-D-101-G DATE: December 30, 1993 PAGE: 4 of 5
(Supersedes NR-235-D-101-G)

SOURCE TYPE: Beta Backscatter Thickness Gauge

LIMITATIONS AND OTHER CONSIDERATIONS OF USE:

- The device shall be distributed only to persons generally licensed by the Department, the Nuclear Regulatory Commission (NRC), an Agreement State, or a Licensing State, pursuant to 32 Ill. Adm. Code 330.220(b).
- This registration sheet and the information contained within the references shall not be changed without the written consent of the Department.

SAFETY ANALYSIS SUMMARY:

Based on our review of the information and test data cited below, this design was previously distributed by Magnaflux Sigma under an NRC license and by Sigma under a New York license, we therefore conclude that CMI International Corp. has provided sufficient information to provide reasonable assurance that:

- The device can be safely operated by persons not having training in radiological protection.
- Under ordinary conditions of handling, storage, and use of the device, the byproduct material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one calendar quarter a dose in excess of 10 percent of the limits specified in the table in 32 Ill. Adm. Code 340.1010(a) [10 CFR 20.101(a)].

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ENTIRETY)

NO: IL-235-D-101-G DATE: December 30, 1993
(Supersedes NR-235-D-101-G)

SOURCE TYPE: Beta Backscatter Thickness Gauge

SAFETY ANALYSIS SUMMARY: (continued)

- Under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified below:

Part of Body	rem
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	15
Hands and forearms; feet and ankles; and localized areas of skin averaged over areas no larger than 1 square centimeter	200
Other organs	50

Furthermore, we would expect the device to maintain its containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

REFERENCES:

The following supporting documents are hereby incorporated by reference and are made a part of this registry document:

- Magnaflux Corporation letters dated January 23, 1984 and August 31, 1983, with enclosures thereto.
- CMI International Corp. application dated November 12, 1985 with enclosures thereto.
- CMI International Corp. letter, with attachments, dated December 14, 1993.

ISSUING AGENCY: Illinois Department of Nuclear Safety

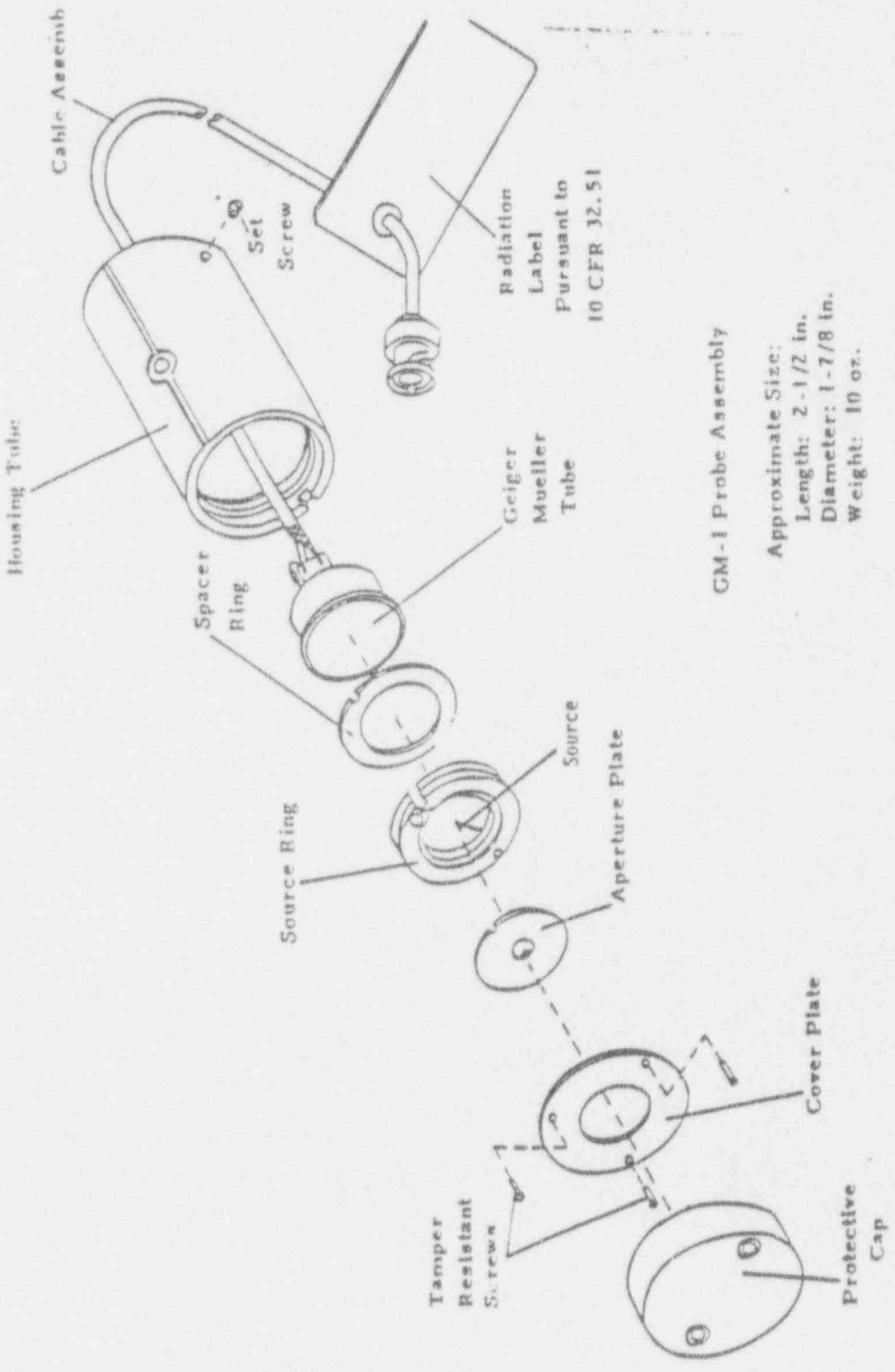
DATE: 12-30-93 REVIEWED BY: Charles A. Ui

DATE: 12-30-93 CONCURRENCE: Steven C. Collins

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ENTIRETY)

NO: IL-235-D-101G DATE: December 30, 1993 ATTACHMENT 1
(Supersedes NR-235-D-101G)

SOURCE TYPE: Beta Backscatter Thickness Gauge



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: NR-375-D-103-S DATE: January 7, 1994

DEVICE TYPE: Tube Thickness Gauge

MODEL: 5301

DISTRIBUTOR: Isotope Measuring Systems, Inc. (IMS)
108 Blue Ridge Drive
Mars, Pennsylvania 16046

MANUFACTURER: Isotope Measuring Systems
Dieselstrasse 55
Heiligenhaus, D-42568
Germany

SEALED SOURCE MODEL DESIGNATION: Amersham Corporation: CDC.PE2 or CDC.711M

ISOTOPE:	MAXIMUM ACTIVITY:
Cesium-137	10 Curies (370 GBq) 2 sources; 5 Ci (185 GBq) each

LEAK TEST FREQUENCY: 6 Months

PRINCIPAL USE: (D) Gamma Gauge

CUSTOM DEVICE: _____ YES ___X___ NO

DEVICE TYPE: Tube Thickness Gauge

DESCRIPTION:

The Model 5301 tube wall thickness gauge is a C-Frame gauge which may be used for the measurement of the thickness of hot metal tubing on a continuously running production line.

The device consists of a source housing installed in a carbon or stainless steel C-Frame which is mounted on a rail transport system. The C-Frame has a minimum plate thickness of 0.236" (6 mm). The dimensions of the C-Frame may vary from 59.1" to 82.7" (1.5 m to 2.1 m) in length by 39.4" to 63.0" (1.0 m to 1.6 m) in height by 23.6" to 39.4" (0.6 m to 1.0 m) in width. The two steel rails and a pneumatic system allow the entire C-frame to be moved from the stored position to the measuring position and back. The C-frame is placed i the stored position when not in use, for maintenance or in the case of an emergency.

The source housing is bolted to a drawer which is bolted into the upper part of the C-frame. The source housing is constructed of sintered tungsten alloy, SM-18, and associated carbon or stainless steel components. The source housing contains heavy metal shielding (SM-18), a shutter wheel (SM-18), a pneumatic rotary actuator and shutter return coil springs for shutter positioning, and houses the two Model CDC.PE2 or CDC.711M source capsules in matching tungsten alloy (SM-18) source holders. Each capsule/source holder is subsequently held in place in the source housing by a tungsten alloy (SM-18) locking bolt, pressure spring and cover plate. The CDC.PE2 and CDC.711M source capsules contain either compressed cesium chloride (CDC.PE2) or cesium sulfate pellets (CDC.PE2) or cesium in a ceramic matrix (CDC.711M). Both the CDC.PE2 and CDC.711M capsules are doubly encapsulated in stainless steel.

A 3.54" (90 mm) cylindrical tungsten shutter is positioned directly below the sources in the source housing. Two cylindrical shafts are cut out of the shutter and allow for transmission of the radiation beam when the shutter is rotated to the "OPEN" position. Flanges mounted to the shutter are connected to the coil return springs at both ends and to the pneumatic actuator at one end via shafts which ride on ball bearings.

DEVICE TYPE: Tube Thickness Gauge

DESCRIPTION: (Cont'd)

When the shutter open command is received from the operator a switch allows compressed air to enter the actuator which rotates the shutter 90 degrees to the "OPEN" position. If air pressure is lost, either by an accident or by the shutter close command being initiated by the operator, air pressure is automatically bled off and the coil springs automatically return the shutter to the "CLOSED" position.

Mechanical shutter status flags attached to the shutter shaft end opposite the pneumatic cylinder and visible from the front of the C-frame provide a positive indication of the shutter position (Green for "OPEN" or Yellow for "CLOSED"). Shutter position is also indicated by a shutter status lamp box permanently installed near the C-Frame. The lamp box is divided into three sections. A white section in the upper part of the lamp box contains the radiation trefoil symbol and is illuminated whenever the tube gauge is on. The section below this is yellow and the words "SHUTTER OPEN" are engraved on it. This section is illuminated whenever the shutter is in the "OPEN" position. The bottom section of the light box is green and is engraved with the words "SHUTTER CLOSED". This section is illuminated whenever the shutter is in the "CLOSED" position.

Additional indications of shutter position are given at the operators station and the gauge local control station. These include illuminated control panel indicators and a listing on a monitor.

DIAGRAM:

See attachments 1 and 2.

LABELING:

The gauge contains seven labels. Two radiation caution labels containing the radiation trefoil symbol and the words "RADIATION-DANGER" are attached to either side of the gauge. Three labels; one containing the manufacturer's source identification number, isotope, activity, and date of assay for each source; one containing the distributors name, address and the device ANSI

DEVICE TYPE: Tube Thickness Gauge

LABELING: (Cont'd)

classification, and one containing the statement:

> "THE RECEIPT, POSSESSION, USE AND TRANSFER OF THIS DEVICE MODEL 5301 GAUGE, SERIAL NUMBER xx, ARE SUBJECT TO A SPECIFIC LICENSE OR THE EQUIVALENT AND THE REGULATIONS OF THE U.S. N.R.C. OR OF A STATE WITH WHICH THE N.R.C. HAS ENTERED INTO AN AGREEMENT FOR THE EXERCISE OF REGULATORY AUTHORITY. THIS LABEL SHALL BE MAINTAINED ON THE DEVICE IN A LEGIBLE CONDITION."

are attached to the back of the gauge. All labels listed above contain the statement "Removal of This Label is Prohibited." The tray that the source housing is mounted to contains the radiation trefoil, with the center being the sight window for the mechanical shutter status, and the word "RADIOACTIVE". A label mounted to the source housing contains the radiation symbol, source model number, serial number, activity and type, and the number of sources contained in the housing. All labels are constructed of metal (aluminum, steel, stainless steel, or brass), are etched, engraved, or stamped, and are attached by threaded metal fasteners.

CONDITIONS OF NORMAL USE:

The Model 5301 tube thickness gauge will be used in industrial environs for the measurement of tube wall thickness and eccentricity. These environs may be harsh including high temperatures up to 2012°F (1100°C), dirt and other contaminants, high humidity, and corrosive liquids and gasses. To keep temperatures within the C-frame below 212°F (100°C), an optional water cooling system will be installed when necessary. Since the source housing/shutter mechanism is mounted within the C-frame, the sources are normally not directly exposed to these conditions. In addition an "Air Purge" system is installed on all gauges. This system cools the gauge electronics and helps to keep the interior of the C-frame free of contaminants by blowing compressed air through the C-frame and over the shutter and detector windows.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

DEVICE TYPE: Tube Thickness Gauge

PROTOTYPE TESTING:

IMS claims the Model 5301 has been tested to ANSI-N538. The source capsules used in the test were Amersham model VZ-92/3 sources instead of model CDC.PE2 sources (X60/2 capsule). The model VZ-92/3 is the predecessor to the X60/2 capsule. IMS reported the integrity of the source capsules were maintained throughout and that there were no defects observed after the test that would affect the safety features of the sources.

IMS reports the source housing received an ANSI-SS-SSS-785-R3 classification and the C-frame received an ANSI-SS-254-985-R3 classification. The source manufacturer claims the models CDC.PE2 and CDC.711M have been tested in accordance with ANSI N542-1977 and achieved classifications of E63635 and C64444 respectively.

IMS claims that Model 5301 gauges with CDC.PE2 sources have been in use in other countries since 1990 under similar or more severe conditions of use with no reported instances of failure. In addition, IMS has manufactured similar gauges since 1976 and claims there have been no problems with installed gauges in regards to radiation safety.

EXTERNAL RADIATION LEVELS:

The following are the dose rates reported by the manufacturer for the Model 5301 tube thickness gauge:

	Max. Radiation Level (mrem/hr)/(μSv/hr)	
Distance (in/cm)	Shutter open*	Shutter closed
2.36/6	119/1190	0.3/3
11.81/30	5/50	0.1/1
39.37/100	0.4/4	background

* In Beam

QUALITY ASSURANCE AND CONTROL:

IMS has submitted quality assurance (QA) programs for the manufacturer and distributor of the Model 5301 tube thickness gauge that have been deemed acceptable for licensing purposes by the NRC. Copies of both programs are on file with the Source

DEVICE TYPE: Tube Thickness Gauge

QUALITY ASSURANCE AND CONTROL: (Cont'd)

Containment and Devices Branch of the NRC. The distributor's QA program is independent of the manufacturer's program and serves to verify that the devices are manufactured according to the specifications submitted to the NRC.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The device shall be serviced only by Isotope Measuring Systems, Inc., or persons specifically licensed by the NRC or an Agreement State to perform service on these devices.
- The device is to be distributed only to persons specifically licensed by the NRC or an Agreement State.
- The CDC.PE2 source is to be used only in applications where a measurement of tube eccentricity is essential. If this measurement is not essential or if only a measure of thickness is necessary, the CDC.711M source is to be used.
- The optional cooling system must be installed and operational prior to gauge operation in applications where the inner temperature of the C-frame may exceed 212°F.
- REVIEWER NOTE: Initial installation and verification of the operability of the device safety features will be performed by the distributor. If additional barriers are required in order to limit the possibility of collision from the process material, IMS shall verify these barriers are in place prior to initial operation. Additionally, if a source change from a CDC.PE2 to a CDC.711M, or vice versa, is performed, the source holder must be changed as well to accommodate the new source.
- The device shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcurie (185 Bq) of removable contamination.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

DEVICE TYPE: Tube Thickness Gauge

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

- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

SAFETY ANALYSIS SUMMARY:

The Model 5301 tube thickness gauge incorporates several safety features which will help to minimize health and safety risks from the radioactive sources. These include a temperature monitor which automatically closes the shutter if the inner C-frame temperature reaches 212°F, an optional cooling system for situations where the inner C-frame temperature may exceed 212°F, an air purge system which helps to keep contaminants out of the C-frame, shutter return springs which automatically close the shutter on loss of air or electricity, and a mechanical shutter status indication. In addition, the shutter will also automatically close whenever the C-frame is retracted from the measuring position or if no tubing passes through the gauge within a preset time frame (fifteen seconds to fifteen minutes). In the event of fire and a failure of the temperature monitor in the C-frame, the air feed hoses would melt and cut off the supply of compressed air. The return springs would automatically close the shutter.

The distributor claims that no individual should receive more than 0.5 rem/year (5 mSv/year) under normal operating conditions.

Based on these safety features, the information and test data cited below, the claimed ANSI classifications, and that the manufacturer has approximately 40 years experience with these and similar gauges, we conclude that the Model 5301 tube thickness gauge is acceptable for licensing purposes as specified in this certificate.

Furthermore, we conclude that the Model 5301 would be expected to maintain its integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

DEVICE TYPE: Tube Thickness Gauge

REFERENCES:

The following supporting documents for the Model 5301 are hereby incorporated by reference and are made a part of this registry document.

- Engelhardt & Associates, Inc.'s letter, sent on behalf of Isotope Measuring Systems Inc., dated April 21, 1993, with enclosures thereto.
- IMS letters dated August 3, 1993, August 17, 1993, August 27, 1993, November 15, 1993, December 13, 1993, December 20, 1993, January 4, 1994, and January 6, 1994, with enclosures thereto.

ISSUING AGENCY:

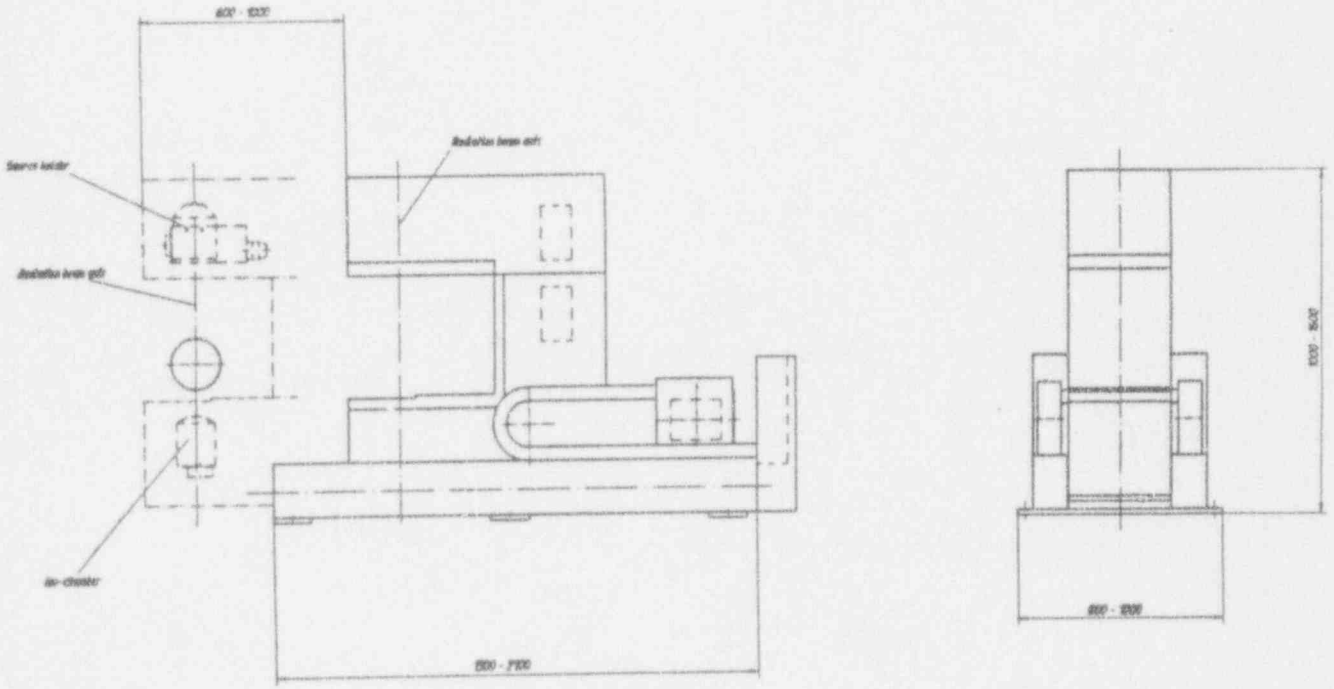
U.S. Nuclear Regulatory Commission

Date: January 7, 1994 Reviewer: Douglas A. Broaddus

Date: January 7, 1994 Concurrence: John W. Lubinski

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

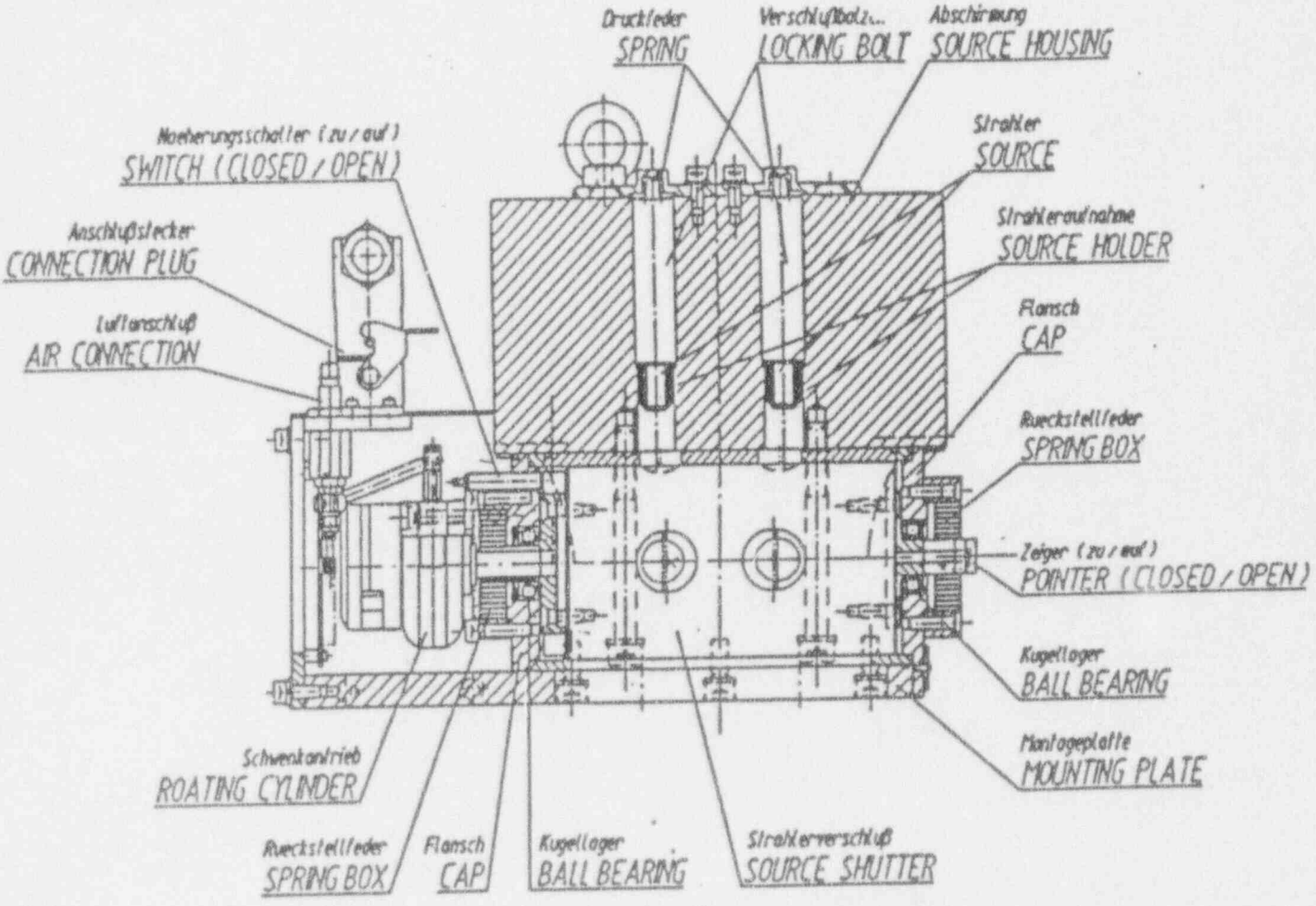
NO.: NR-375-D-103-S DATE: January 7, 1994 ATTACHMENT 1



MODEL 5301

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: NR-375-D-103-S DATE: January 7, 1994 ATTACHMENT 2



SOURCE HOUSING/SHUTTER MECHANISM

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
AMENDED IN ENTIRETY

NO: IL-449-D-101-G DATE: March 17, 1993
Previously NR-449-D-101-G

SOURCE TYPE: Fill Level Gauge

MODEL: Checkmat Model 150

SEALED SOURCE MODEL DESIGNATE: Amersham Model AMC.25

DISTRIBUTOR:

Krones Incorporated
Kroneseder Farms
24605 River Road
Marengo, Illinois 60152

MANUFACTURER:

Stratec Elecktronik GmbH
7534 Birkenfield 2
Federal Republic of Germany

ISOTOPE:

Americium 241

MAXIMUM ACTIVITY:

50 millicuries

LEAK TEST FREQUENCY: 36-month intervals

PRINCIPAL USE: (D) Gamma Gauge

CUSTOM SOURCE: ____ YES X NO

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
AMENDED IN ENTIRETY

SOURCE TYPE: Fill Level Gauge

DESCRIPTION:

The Krones Checkmat 150 level gauge is manufactured by Stratec Elecktronik GmbH in the Federal Republic of Germany and distributed to manufacturers, in the United States, by Krones, Inc. The Checkmat 150 is used as a level detector for the measurement of liquid and semi-liquid products.

The Checkmat 150 incorporates a 50 millicurie Americium 241 sealed source and a scintillation detector to generate a rapid, efficient inspection of the fill level of moving containers without contact. The American National Standards Institute (ANSI) classifications for the source and device are:

Source:	77C64444
Device:	33-985-985-R-3

The gauge incorporates a shielded beam source and an analyzer target positioned in an inverted "U"-shaped housing. The shielded beam source is mounted in one leg to produce a collimated beam that is aimed at the opposite leg where the analyzer is mounted to receive the entire beam diameter. The analyzer also provides operator shielding for the collimated beam.

The radiation-source-holder consists of a lead lined brass tube which immediately surrounds the source capsule and collimates the incident beam. The opposite end of the tube is enclosed with a lead plug that provides shielding in the opposite direction of the beam and serves as the locking device that holds the source capsule securely in the holder. Surrounding the lead tube is a brass block that provides the main structural support for the source and the lead shield.

The beam port of the source holder is bolted to a vertical brass plate of 2 mm thickness which serves as the mounting bracket for the 2 mm thick, stainless steel instrument housing.

A 1 mm thick stainless steel shutter covers the beam port in the "off" or "safe" condition. The shutter mechanism is designed as a fail-safe device. The shutter is spring loaded in the closed position and is opened by a solenoid that can only be activated when power is applied to the gauge. When the electrical power is removed, the shutter closes automatically. The instrument housing has a viewing window with an indicator flag, which is connected to the shutter to verify the position of the shutter.

The radiation-source-holder is housed within the inspection head. The inspection head comprises a 2mm thick stainless steel housing which surrounds the radiation-source-holder. Access to the radiation-source-holder is controlled by fasteners that require special tools for removal. Access is accomplished by removing three acorn-type cap nuts from the removable cover of the inspection head. Inside the inspection head the radiation-source-holder is held in place by another set of fasteners.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
AMENDED IN ENTIRETY CORRECTED COPY

NO: IL-449-D-101-G DATE: December 20, 1993 PAGE: 3 of 6
Previously NR-449-D-101-G

SOURCE TYPE: Fill Level Gauge

LABELING:

A. Each device shall be provided with a label containing information as follows:

(1) The receipt, possession, use, and transfer of this device, model number 150 and serial number _____, are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission (NRC) or an Agreement State. and serial number may be omitted from this statement p are elsewhere specified in labeling affixed to the device.

(2) Abandonment or disposal prohibited unless transferred to persons specifically licensed by the U.S. NRC or an Agreement State.

(3) Operation prohibited if there is indication of failure of, or damage to, radioactive material contained or ON-OFF mechanism or indicator.

(4) Device shall be tested for leakage of radioactive material and for proper functioning of the ON-OFF mechanism at the time of installation, replacement of the radioactive material, and thereafter at no longer than 36-month intervals.

(5) Installation, dismantling, relocation, maintenance, or tests shall be performed by persons specifically licensed by the U.S. NRC or an Agreement State.

B. Each device shall be provided with a label containing the radiation symbol in conventional colors magenta, purple, or black on yellow background, the word "CAUTION (OR DANGER) - RADIOACTIVE MATERIAL", the identity and quantity of radioactive material and its date of measurement, and the name of the distributor of the device.

C. Each label by items (A) and (B) of above shall contain a statement "Removal of this label is prohibited."

DIAGRAMS:

See Attachments 1 through 4.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
AMENDED IN ENTIRETY

SOURCE TYPE: Fill Level Gauge

CONDITIONS OF NORMAL USE:

The anticipated uses of the Checkmat 150 include environmental conditions ranging from 0 - 100 percent relative humidity and temperatures ranging from 0° C to 70° C. The most likely condition of use is at room temperature, 20° C. The typical users will be workers on product-filling lines in the vicinity of the Checkmat 150. The Checkmat 150 is used to control automated equipment and is not operated directly by the filling line worker. It is extremely unlikely that under circumstances of normal use, the source in the Checkmat 150 will be incorporated as a component in other products.

The radiation source is enclosed in a water resistant source housing. Although severe accidents such as fire may damage the housing and source, it is unlikely that the radioactive content, in the form a fused ceramic bead, could be dispersed under these severe accident conditions.

The most likely failure under severe conditions would be one involving the shutter mechanism. Such a failure could leave the source in the "on" condition. Due to the narrowly defined, short beam path, it is unlikely that any long-term inadvertent exposure to the direct beam will occur.

PROTOTYPE TESTING:

The Amersham Model AMC.25 source achieved an ANSI N542-1977 classification of C64444. The gauge achieved an ANSI N538-1979 classification of 33-985-985-R-3. The gauge withstood a maximum temperature of 800° C and a maximum pressure of 7 mega pasculs.

The Krones Checkmat is normally not accessible to users while in operation and the shutter indicator, which is rigidly attached to the shutter mechanism, will indicate a shutter failure to an individual attempting maintenance. The combination of these factors make it unlikely that any significant exposure would result should a shutter failure occur. The gasketed enclosure would prevent the spread of contamination even if the radioactive material in the source was not a fused ceramic bead.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
AMENDED IN ENTIRETY

NO: IL-449-D-101-G DATE: March 17, 1993 PAGE: 5 of 6
Previously NR-449-D-101-G

SOURCE TYPE: Fill Level Gauge

EXTERNAL RADIATION LEVELS:

With the exception of the useful beam, the exposure rate around the inspection head is less than 0.075 mR/hour measured at a 10 cm radius from the surface of the inspection head. At a 100 cm radius from the surface of the inspection head, the exposure rate is less than 0.05 mR/hour (see Isotope plot, Attachment 3). The useful beam is shielded by the opposite arm of the inspection head.

QUALITY ASSURANCE AND CONTROL:

The device is assembled by Krones, Inc. of Franklin, Wisconsin who will be responsible for:

- Determining if the device has been manufactured properly.
- Loading of the source at the licensee's facility.
- Performing tests for removable contamination.
- Verifying proper operation of the shutter.
- Verifying proper operation of the device as a whole.
- Performing an initial radiation survey of the device.

LIMITATIONS AND OTHER CONSIDERATIONS OF USE:

- This device is authorized for distribution only to persons generally licensed under the provisions of the regulations contained in 32 Ill. Adm. Code 330.220 or equivalent NRC or Agreement State regulations.

- A copy of the Checkmat 150 "Operations and Maintenance Manual" must be supplied by Krones prior to use. (Manual will include a copy of the general license, a copy of pertinent state regulations, etc.)

- Loading of the Checkmat 150 with the radioactive source must be performed by persons specifically licensed by the Illinois Department of Nuclear Safety, the NRC, or an Agreement State.

- The device shall be leak tested at thirty-six month intervals using techniques capable of detecting 0.005 microcurie of removable contamination.

- The useful life of the source is in excess of 50 years.

- This registration sheet and the information contained within the references shall not be changed without the written consent of the Illinois Department of Nuclear Safety.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
AMENDED IN ENTIRETY

NO: IL-449-D-101-G DATE: March 17, 1993
Previously NR-449-D-101-G

SOURCE TYPE: Fill Level Gauge

SAFETY ANALYSIS SUMMARY:

Based on our review of these facts and the information contained in the references cited below, we conclude that the device design is acceptable for general licensing purposes. Furthermore, we conclude that the device is likely to retain containment of the radioactive contents under foreseeable conditions of use which might occur during uses specified in this certificate.

REFERENCES:

The following documents are hereby incorporated by reference and are made a part of this registry document:

- License application dated June 18, 1992 with attachments.
- Letter, with attachments, dated November 10, 1992, which includes:
  - Letters dated February 1, 1985 and February 4, 1985 from Krones, Inc.
  - Krones Checkmat 150 Operation and Maintenance Manual

ISSUING AGENCY: Illinois Department of Nuclear Safety

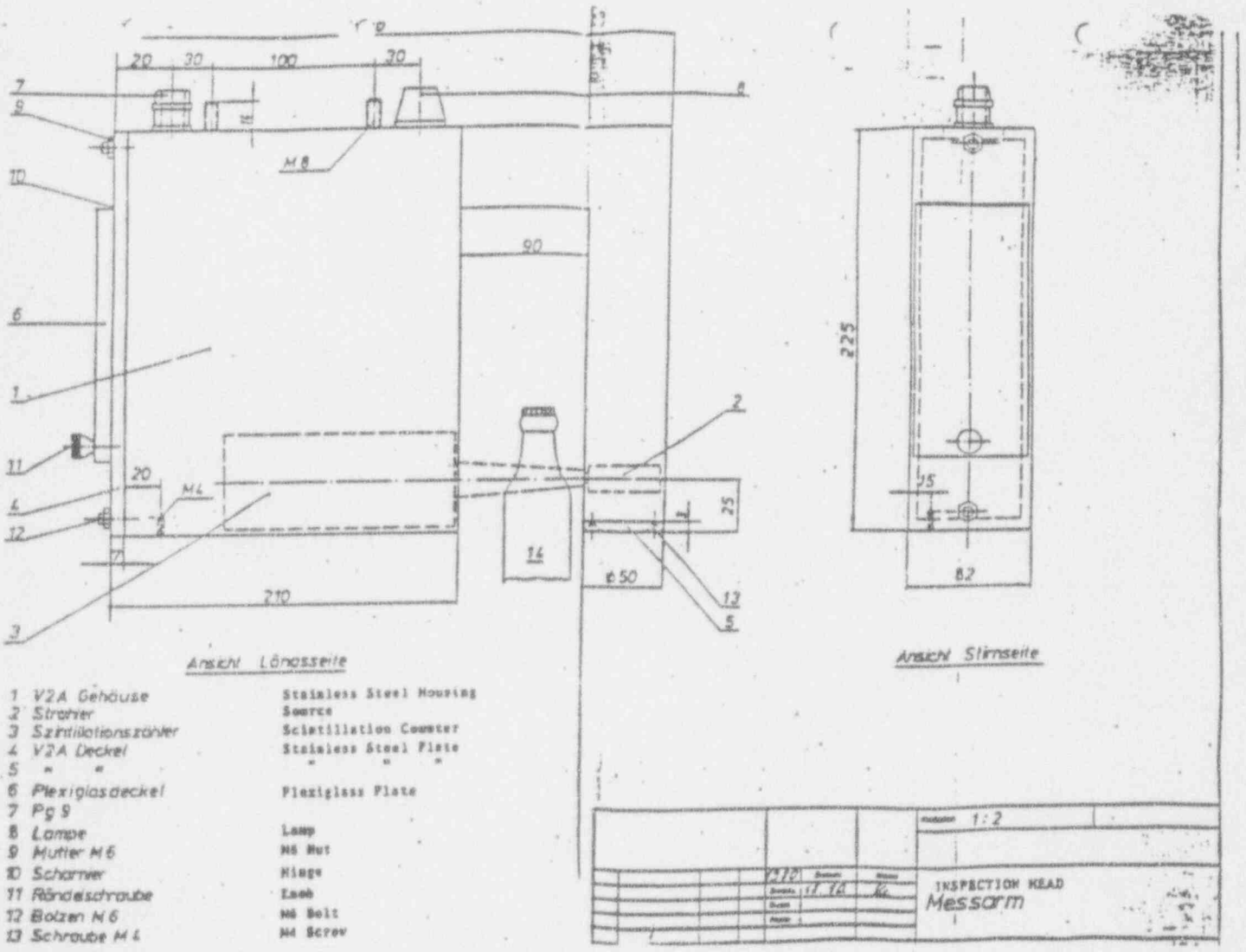
DATE: 3-22-93 REVIEWED BY: Mary E. Benkhart

DATE: 3/19/93 CONCURRENCE: Joseph G. Klinger

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
AMENDED IN ENTIRETY

NO: IL-449-D-101-G DATE: March 17, 1993 PAGE: ATTACHMENT 1
Previously NR-449-D-101-G

SOURCE TYPE: Fill Level Gauge



1	V2A Gehäuse	Stainless Steel Housing
2	Strahler	Source
3	Szintillationszähler	Scintillation Counter
4	V2A Deckel	Stainless Steel Plate
5	" "	" " "
6	Plexiglasdeckel	Plexiglass Plate
7	Pg 9	
8	Lampe	Lamp
9	Mutter M6	M6 Nut
10	Scharnier	Hinge
11	Rändelschraube	Knob
12	Bolzen M6	M6 Bolt
13	Schraube M4	M4 Screw

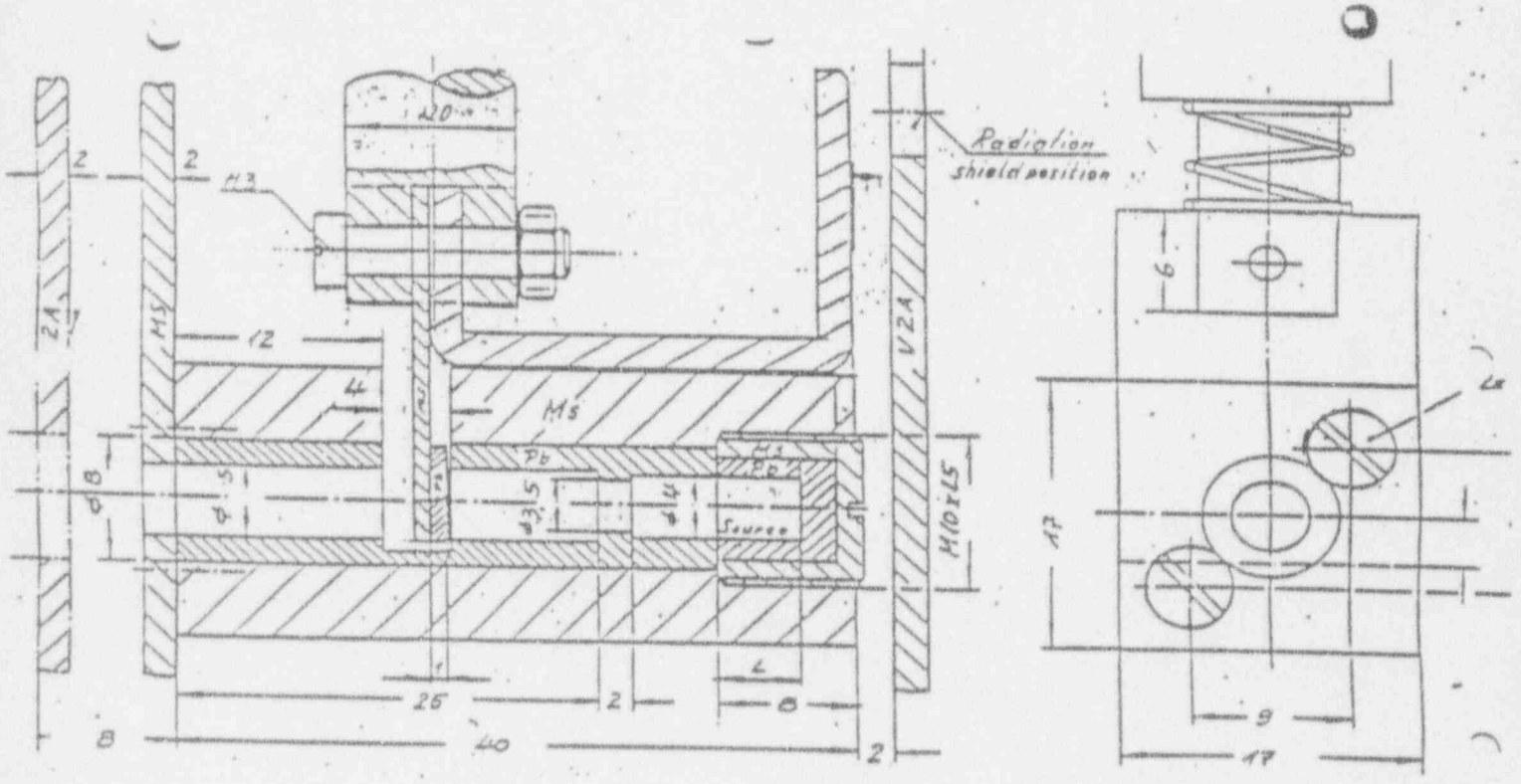
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
AMENDED IN ENTIRETY

NO: IL-449-D-101-G
Previously NR-449-D-101-G

DATE: March 17, 1993

PAGE: ATTACHMENT 2

SOURCE TYPE: Fill Level Gauge



Ms - Brass
Pb - Lead
VZA - Stainless Steel

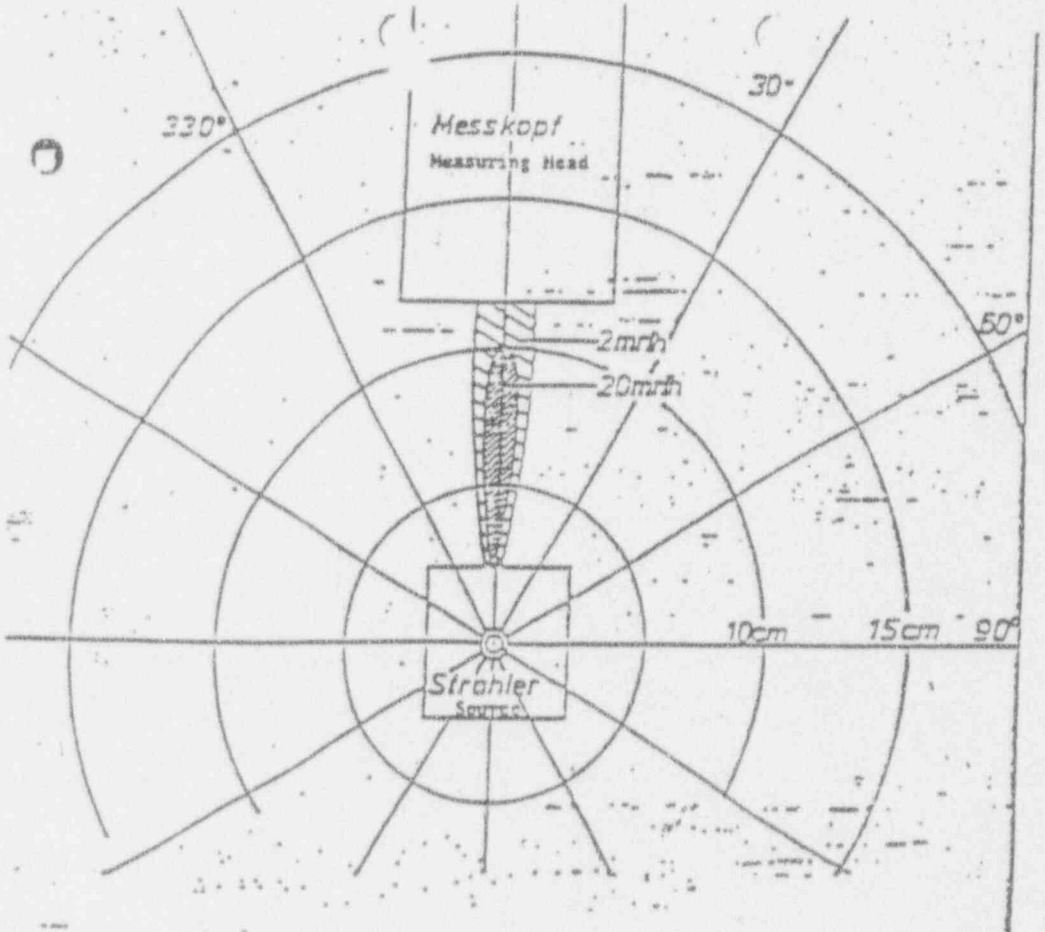
M3:1

1	FEDBA	20.10		Radiation-Source-holder	STRAT Elektronik G
				449-101	7534 Birkenf
				4.94	7.94

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
AMENDED IN ENTIRETY

NO: IL-449-D-101-G DATE: March 17, 1993 PAGE: ATTACHMENT 3
Previously NR-449-D-101-G

SOURCE TYPE: Fill Level Gauge



Radiation Intensity Curves
Strahlungsintensitätskurven

STRATEC Typ 150 Gammatast
Strahler ^{241}Am 45 mCi Punktstrahler -
Die Strahlungsintensität wird bei ausgeschaltetem Gerät auf 1/100 reduziert

STRATEC Model 150 Gamma Unit
Source: ^{241}Am 45 mCi Point source
The radiation intensity will be reduced to 1/100 when shutter is closed.

Stratec GmbH
7534 Birkenfeld 2
Tel. 07082/5512

RADIATION INTENSITY CURVES

Strahlungsintensitäts-kurven

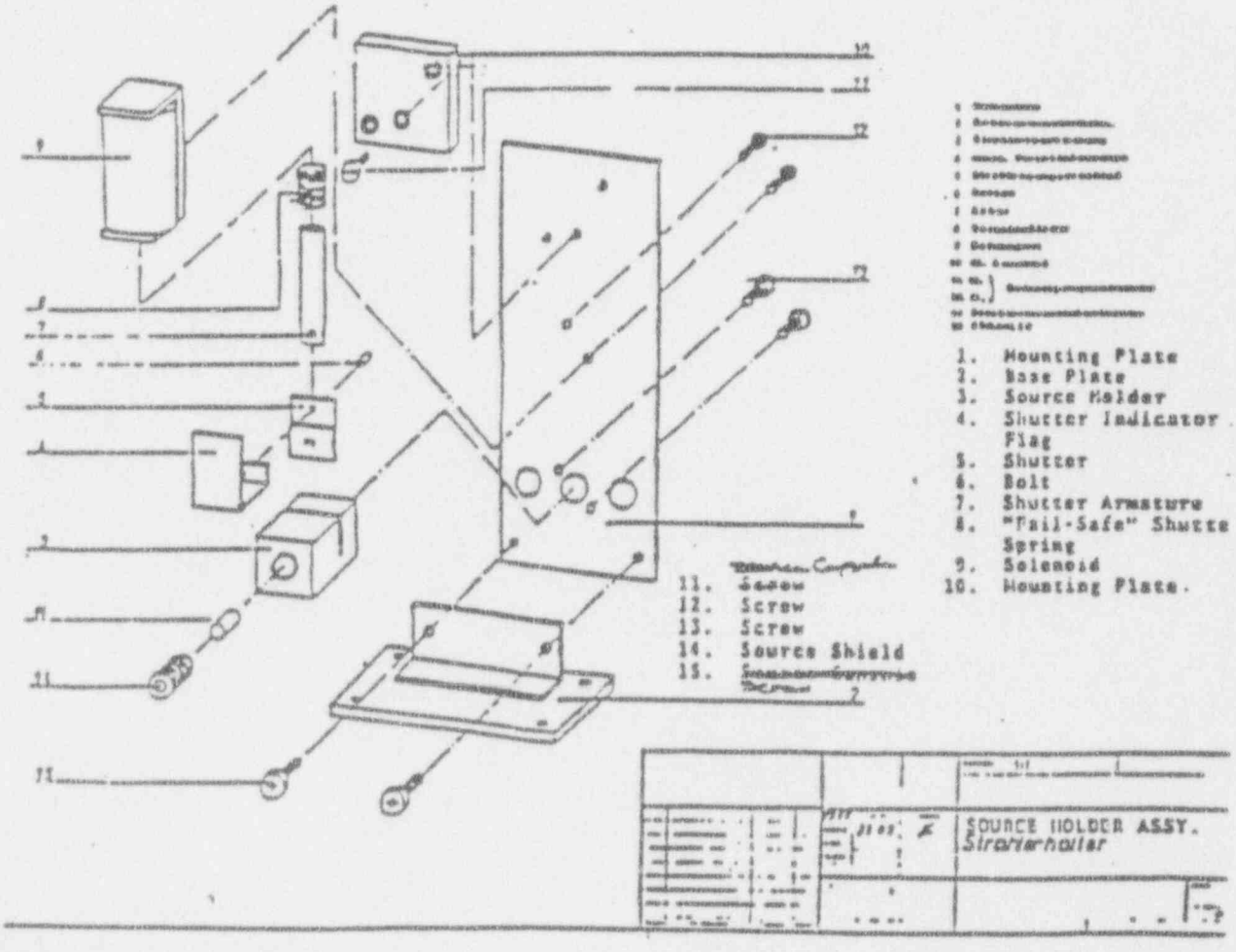
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
AMENDED IN ENTIRETY

NO: IL-449-D-101-G
Previously NR-449-D-101-G

DATE: March 17, 1993

PAGE: ATTACHMENT 4

SOURCE TYPE: Fill Level Gauge



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

(Amended in its entirety: October 27, 1993)

NO: CA471D103B DATE: January 21, 1993

DEVICE TYPE: Portable Mass Gauge

MODEL: 104P/104PD

MANUFACTURER/DISTRIBUTOR: NDC SYSTEMS
730 E. Cypress Ave.
Monrovia, CA 91016

SEALED SOURCE MODEL DESIGNATION: Amersham Model AMCP1 or
Isotope Products Model GFS

ISOTOPE: Americium 241 MAXIMUM ACTIVITY: 150 millicuries

LEAK TEST FREQUENCY: Six Months

PRINCIPAL USE: Gamma Gauge (D)

CUSTOM DEVICE: _____ YES ___X___ NO

DEVICE TYPE: Portable Mass Gauge

DESCRIPTION:

The Model 104P is the scintillation detector and source housing part of NDC gamma backscatter gauging systems. The radioactive source, crystal, and detection assembly consist of one unit (Figures 1 & 3). The radioactive source is epoxied into a tungsten collimator which is epoxied into the crystal well. A slip ring insert further anchors the collimator and source in the well. A .003 titanium cover is attached across the probe face providing further closure.

The Models 104P/104PD are specifically designed for portable use in the measurement of drainage profiles on a paper line. The Models 104P & 104PD are identical except for the head fixture that contacts the product. This fixture is used in a different location on the production line. The Model 104 device, which has already been addressed by an existing device registry sheet, is constructed of stainless steel because it is intended to be a permanently fixed device in a harsh environment paper line. The Models 104P & 104PD, however, are constructed such that the probe is capable of being attached to the end of an extension pole by means of an aluminum right angle block, thereby, allowing for the probe's portability.

The crystal head containing the source screws onto the probe body. In turn, a hidden screw locks the head to the probe body.

The shutter is of the mechanical type and is shown in Figures 2 & 4. Shielding is provided by means of a 0.125" thick tungsten disc. The shutter is held shut by means of spring tension and, therefore, cannot be opened accidentally. The underside of the shutter, being red, indicates that the shutter is in the open position when the red is visible. The upper surface of the shutter, being green, shows green when the shutter is in the closed position.

LABELING:

The device is labeled in accordance with Sections 30192.1 and 30278 of the California Radiation Control Regulations (equivalent to 10 CFR 32.51 and 10 CFR 20.203 respectively). See Safety Labels, page 10 of 12.

DIAGRAMS: Figure 1 -- NDC Model 104P Sensor Probe Sideview Body Assembly.
Figure 2 -- NDC Model 104P Sensor Probe with Locking Shutter.
Figure 3 -- NDC Model 104P/D Sensor Probe.
Figure 4 -- Model 104 Probe with Shutter Opened and Closed.
Figure 5 -- Radiation Profile NDC Model 104 with Shutter Open.
Figure 6 -- Radiation Profile NDC Model 104 with Shutter Closed.
Figure 7 -- Safety Labels

DEVICE TYPE: Portable Mass Gauge

CONDITIONS OF NORMAL USE:

The device is intended to measure the mass of pulp on the Foudrinier or wire of a paper line, thereby, determining drainage profile. The following conditions apply:

Temperature:	15°C to 50°C
Humidity:	0 to 100%
Pressure:	Atmospheric
Vibration:	Normal plant machinery vibration
Corrosion:	Corrosive liquids sometimes used - probe materials designed to be resistant.
Dust:	From zero

The instrument is used by two people. The sensor is mounted to a 40" extension pole to allow the operator to take readings on the machine and still stay away from the radiation field. Typically a single user will use the instrument for approximately one hour a day. While the device itself is designed for portable use, shipping the unit must be performed by a specific licensee.

PROTOTYPE TESTING:

The units have been tested by the manufacturer for effects of severe vibration and at temperatures up to 100°C. Continuous vibration in accordance with the Class 4 test of ANSI, NBS Handbook No. 126 was carried out on a shake table. The unit was held at 60°C for several weeks. The shutter was operated in excess of 500 open-close cycles. The ANSI classification assigned by the manufacturer is 84-254-985-R3. This is based on tests in accordance with NBS 129, the ANSI classification of the Amersham source of 64444, the ANSI classification of the Isotope Products source of 64545, and materials of construction.

EXTERNAL RADIATION LEVELS:

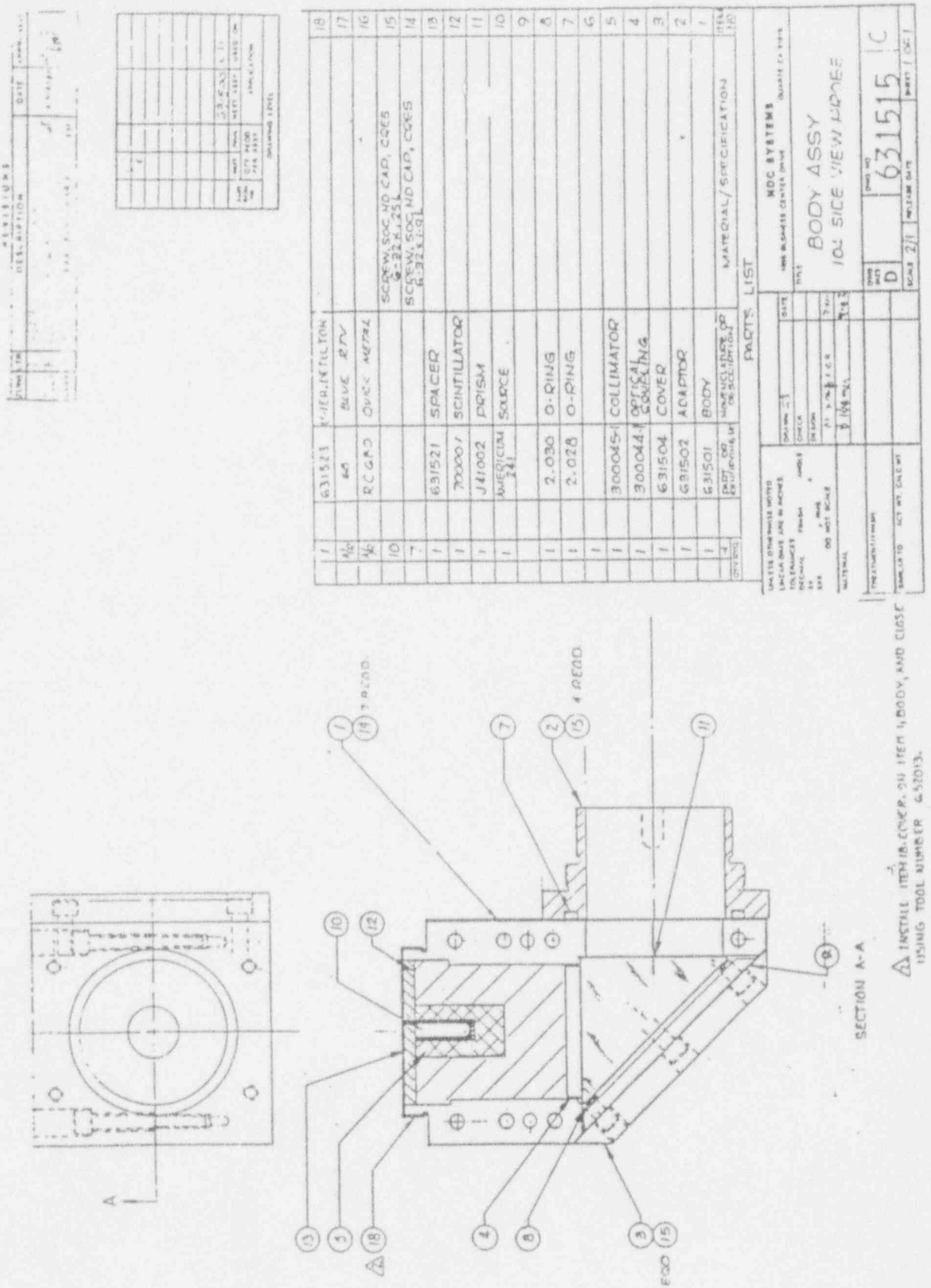
The radiation profile with the shutter open was taken with a Lansverk R Meter and is shown in Figures 5. With the source in the closed position, the radiation field is less than 1 mr/hour on any surface.

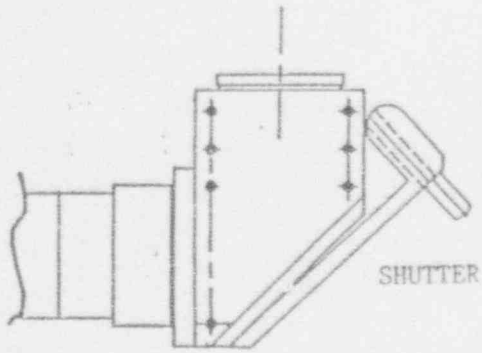
SAFETY EVALUATION OF DEVICE

(Amended in its entirety: October 27, 1993)

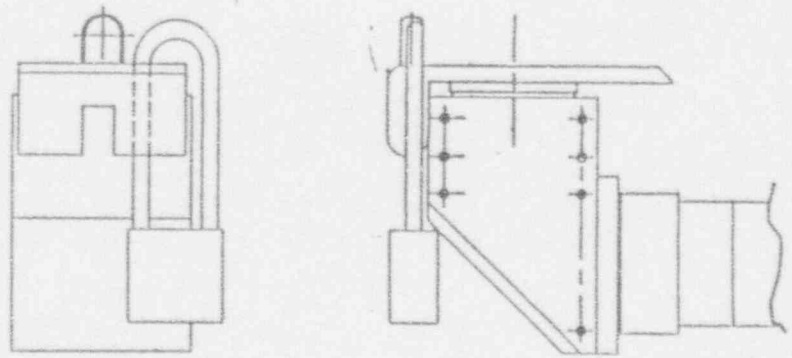
NO: CA471D103B DATE: January 21, 1993

DEVICE TYPE: Portable Mass Gauge





SHUTTER OPENED

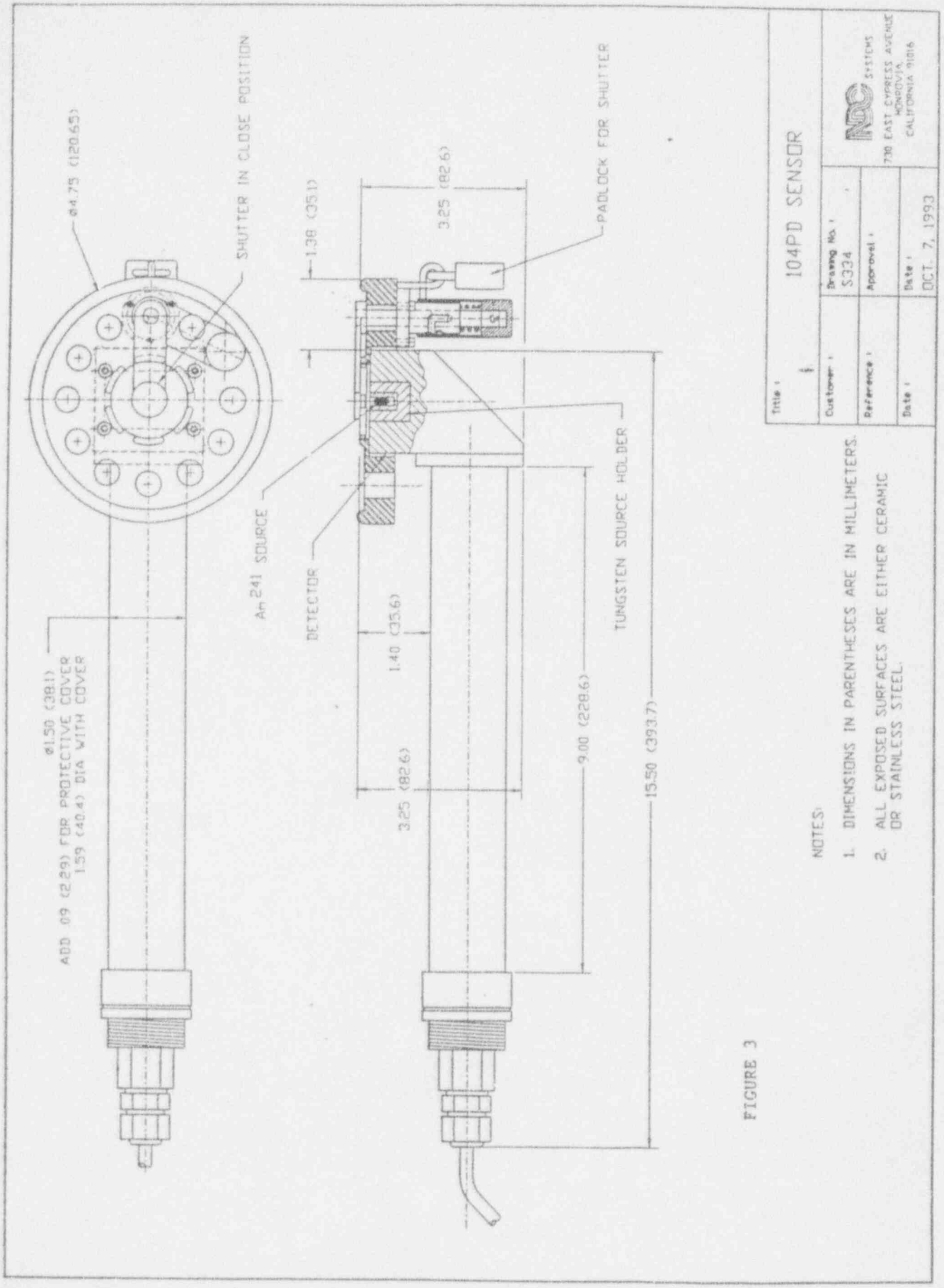


SHUTTER CLOSED

FIGURE 2

DESCRIPTION	ITEM NO.
BODY, ASSY	1
BODY, ASSY	1
LOCKABLE SHUTTER	2
LOCKABLE SHUTTER	2
BALL SCREW 'PIC'	3
PLUNGER	4
SPRING WASHER BELLEVILE 'ASSOC'	5
SCREW	6
PADLOCK McMASTER	7

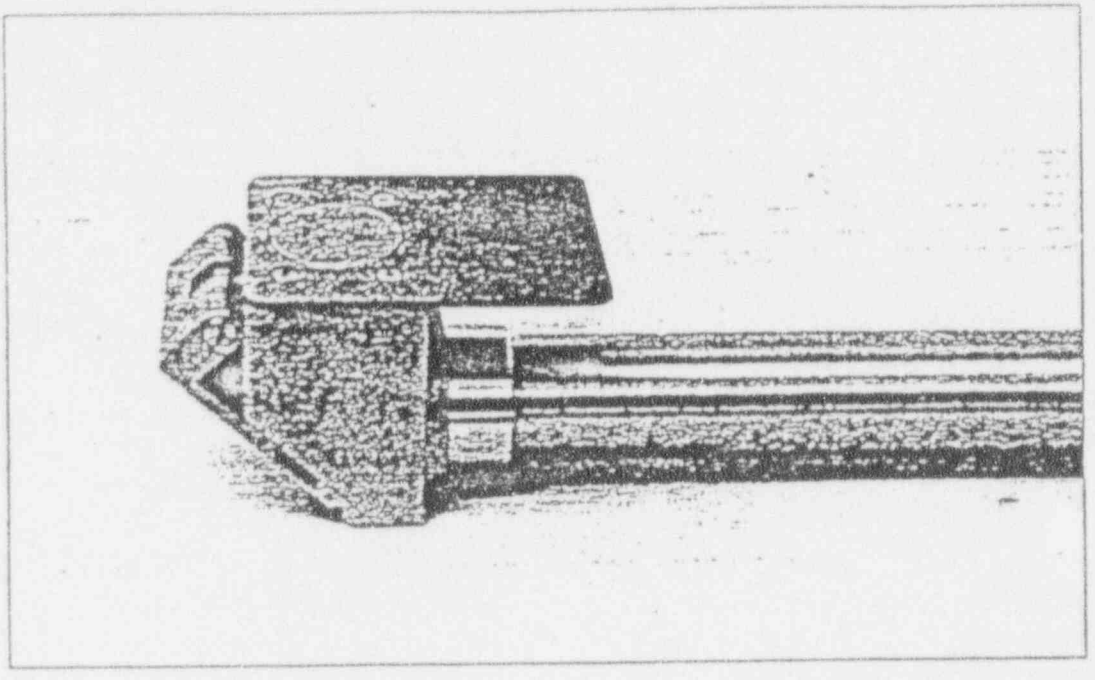
Title: ASSY, SHUTTER WITH LOCK FOR RIGHT ANGLE PROBE		
Customer:	Drawing No: 631543-1	NDC SYSTEMS
Reference:	Approval:	
Date: 19DEC91	Date:	

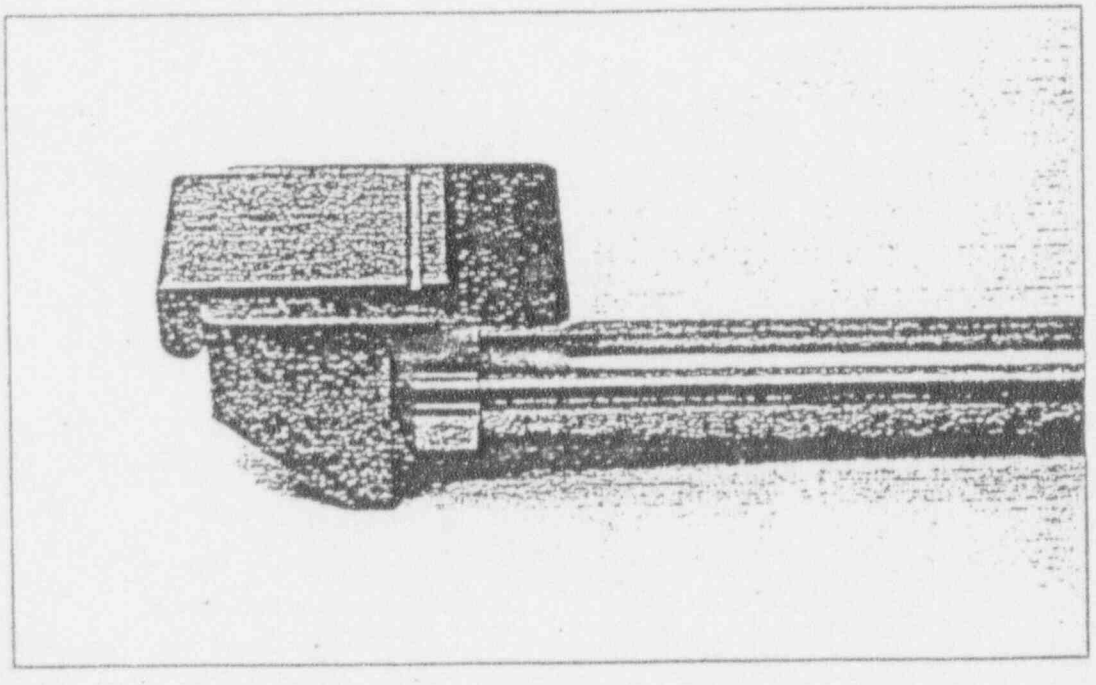


NOTES:

1. DIMENSIONS IN PARENTHESES ARE IN MILLIMETERS.
2. ALL EXPOSED SURFACES ARE EITHER CERAMIC OR STAINLESS STEEL.

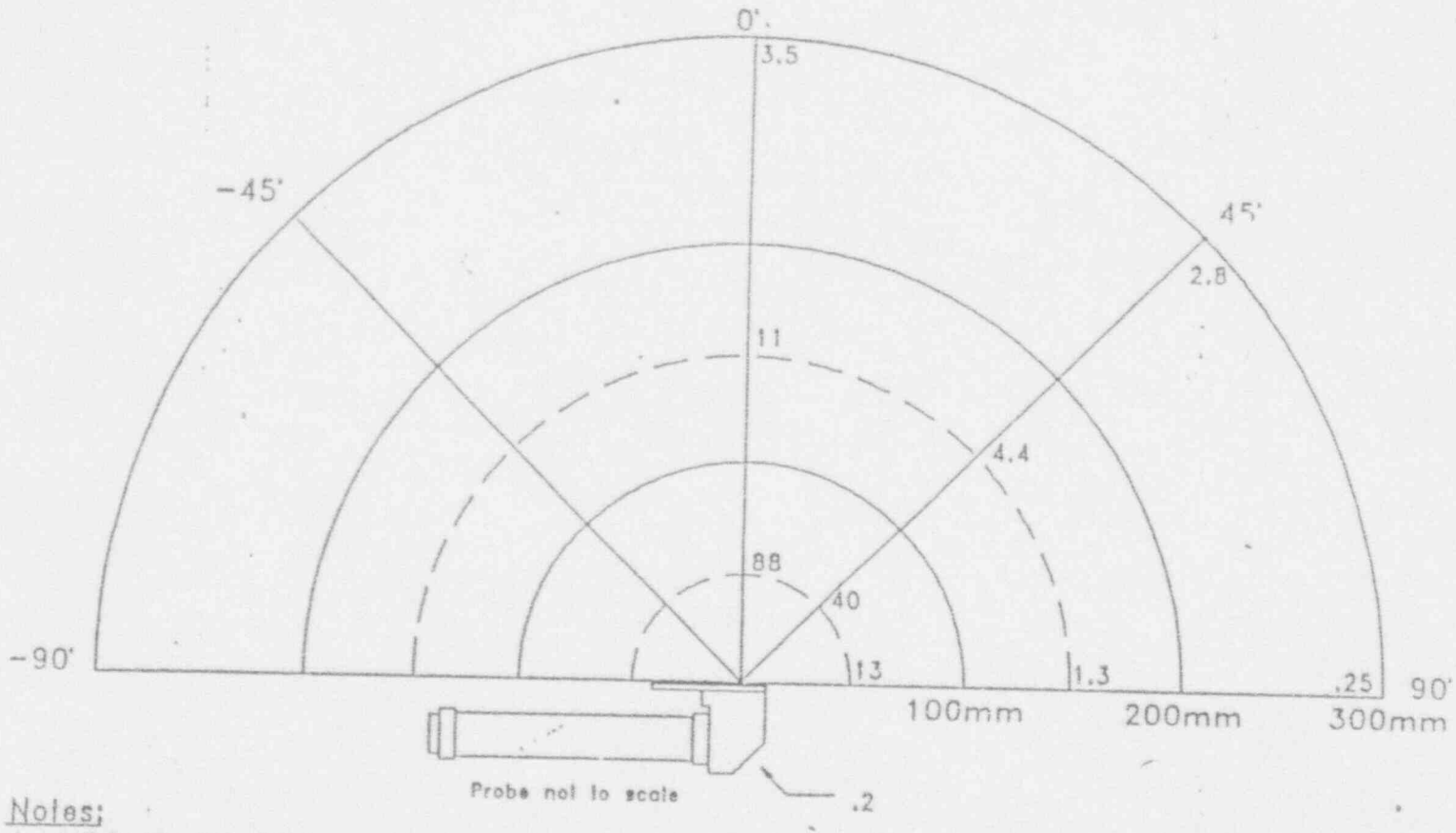
FIGURE 3





Probe with shutter open (top) and closed

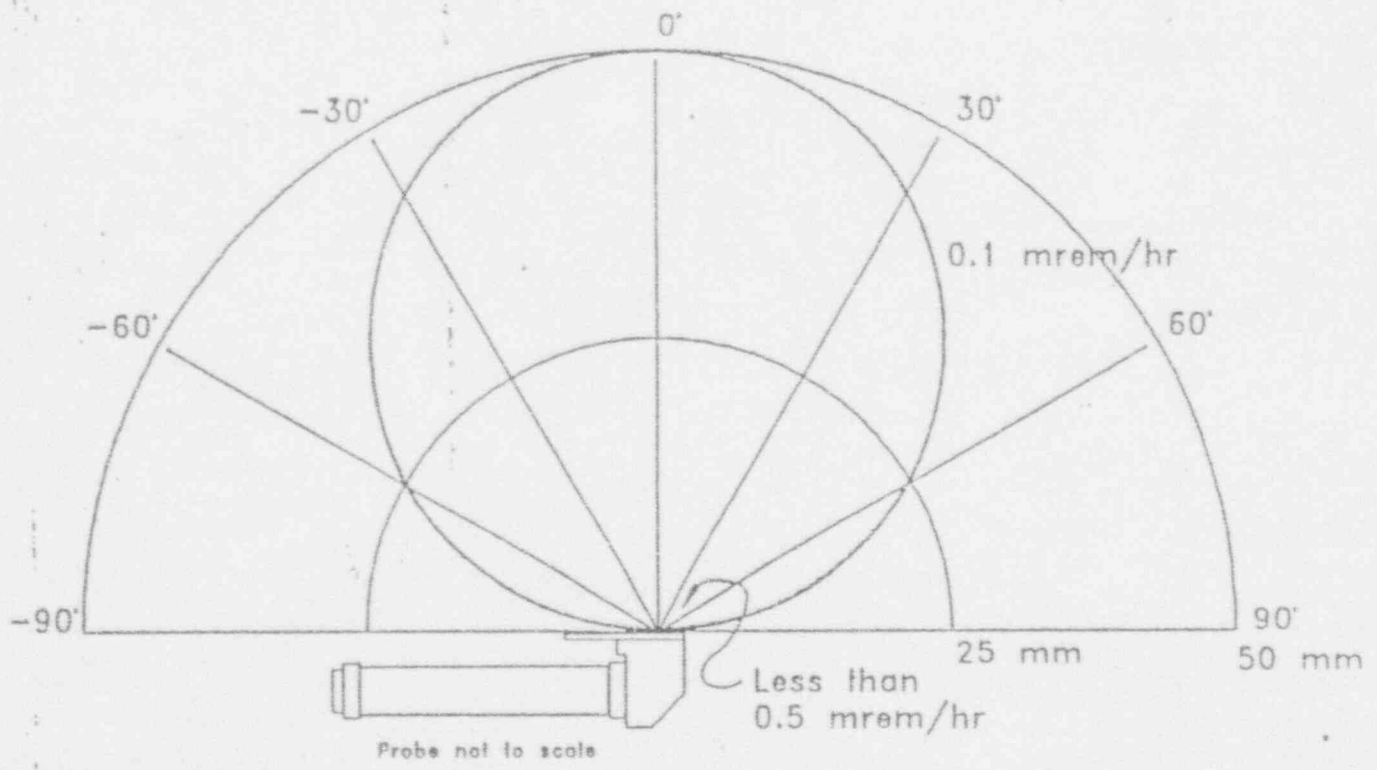
Figure 4



Notes;
1. NDC Model 104 probe
2. Shutter: Open
3. Source: Americium 241, 80 mCi (2.96 gBQ) .
4. Radiation pattern is symetrical about the main beam.
5. Readings in mrem/hr

FIGURE 5

Radiation Profile NDC Model 104 gage Shutter: open		
Customer:	Drawing No.: 5072	NDC NUCLEAR SYSTEMS
P.O. No.:	Date: 10 Jun 87	730 E. Cypress Monrovia, Ca. 91016 (818) 358-1871
W.O. No.:	Approval: JD Carlson	



Notes;
1. NDC Model 104 probe
2. Shutter: Closed
3. Source: Americium 241, 80 mCi (2.96 gBQ) .
4. Radiation pattern is symetrical about the main beam.
5. Readings in mrem/hr

FIGURE 6

Isodose curve NDC Model 104 Shutter: closed		
Customer: 7	Drawing No.: 5071	NDC SYSTEMS
P.O. No.:	Date: 13 Jun 93	730 E. Cypress Monrovia, Ca. 91016 (818) 358-1871
W.O. No.:	Approval:	

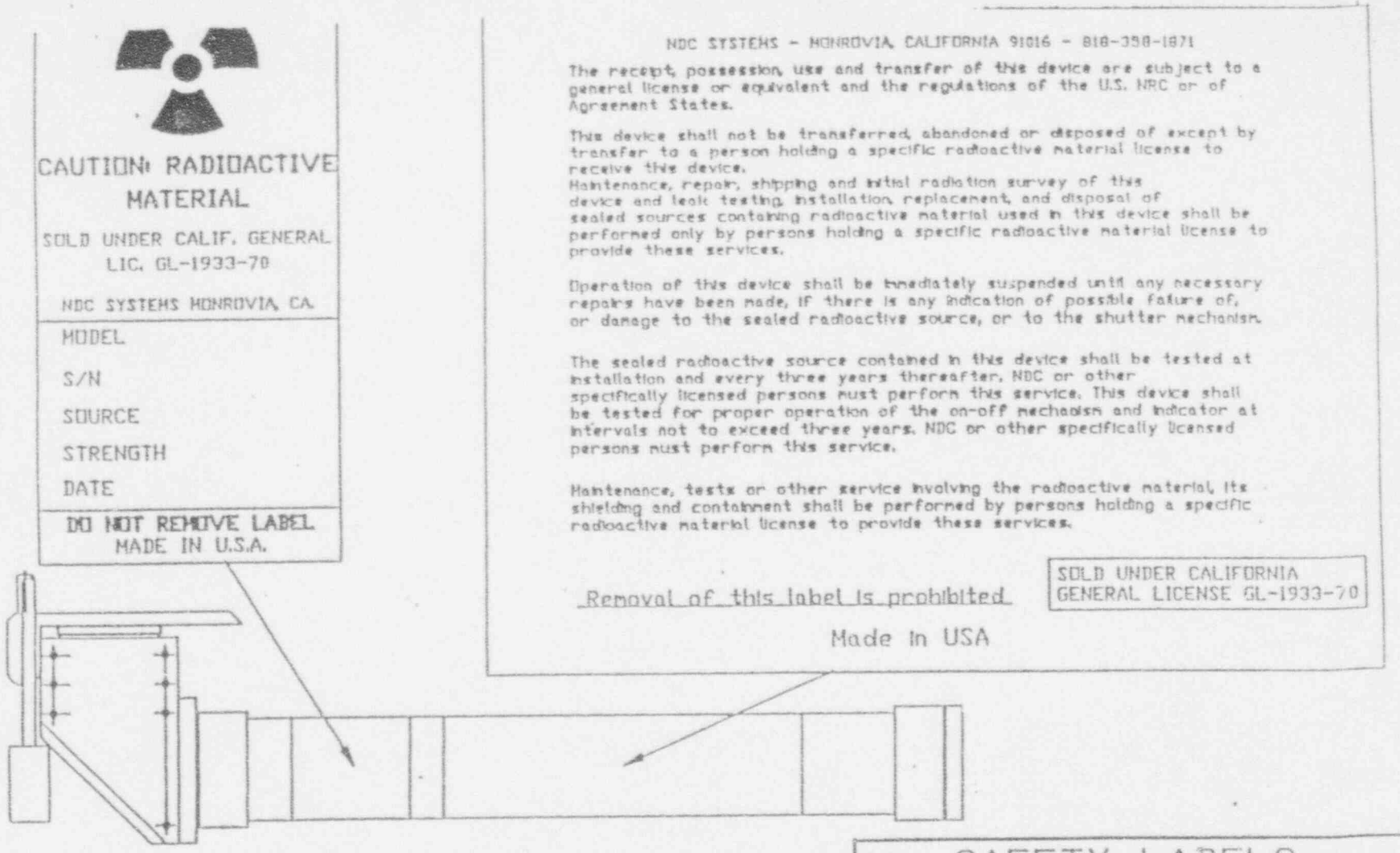


Figure 7

Title: SAFETY LABELS, RIGHT ANGLE PROBE	
Customer: 1	Drawing No: 631544
Reference:	Approval:
Date: 18DEC91	Date:

NDC SYSTEMS

DEVICE TYPE: Portable Mass Gauge

QUALITY ASSURANCE AND CONTROL:

There is a quality inspection of all incoming components as well as those manufactured by NDC. An independent check is made by a quality assurance inspector who verifies proper construction of each device using specific tests prior to shipment.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

1. These devices shall be distributed to persons specifically or generally licensed by the NRC or Agreement States.

2. Initial first use training and all repairs shall be performed by NDC or by persons specifically licensed to do so by the NRC or Agreement States.

3. Relocation outside the general licensee's facility shall be performed by NDC or by persons specifically licensed to do so by the NRC or Agreement States. General licensees may transport the device only within the registered location of use.

4. Disposal or transfer shall be only to NDC or to persons specifically licensed by the NRC or Agreement States to dispose of or receive the device.

5. The device shall be tested for radioactive leakage and proper functioning of the on/off mechanism at intervals of not longer than six months. The leak test shall be capable of detecting 0.005 microcuries/4.0 bequerels of removable contamination.

6. General licensees are provided with instructions on calibration and shutter manipulation. The requirement of specific licensure for leak tests, shutter checks, relocation, repair, and disposal is emphasized within the "User Manual".

7. Specific licensees of these devices are expected to seek authorization for leak test collection, shutter checks, and relocation. Such procedures are provided upon installation by NDC.

8. Generally licensed users are authorized to follow the manufacturers directions and collect a leak test sample from the device with the shutter closed. The test must be performed by persons with a specific license.

9. This registration sheet and the information contained within the references shall not be changed without the written consent of the California Department of Health Services.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

(Amended in its entirety: October 27, 1993)

NO.: CA471D103B DATE: January 21, 1993

DEVICE TYPE: Portable Mass Gauge

SAFETY ANALYSIS SUMMARY:

Based on our review of the information and test data cited below, we conclude that the portable mass gauges (NDC Model 104P and 104PD) are acceptable for licensing purposes.

REFERENCES:

The following supporting documents for the NDC Model 104P/104PD gauge are hereby incorporated by reference and are made part of the registry document.

1. NDC Systems letter dated November 1, 1991, with attached drawings (DWG No. 631515, 631543).
2. NDC Systems letter dated December 24, 1991, with attached user manual for Model 104P.
3. NDC Systems letter with attachments dated February 5, 1992.
4. NDC Systems letter with attachments dated April 17, 1992.
5. NDC Systems letters with attachments dated October 11 and 12, 1993.
6. NBS Handbook Number 129, "ANSI N538", Classification of Industrial Ionizing Radiation Gauging Devices, 1979.
7. NBS Handbook, Number 126, "ANSI N542", Sealed Radioactive Sources Classification, 1977.

DATE: 12/10/93 REVIEWED BY: David Wesley

DATE: 12/31/93 CONCURRENCE: [signature]

ISSUING AGENCY: California Department of Health Services

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: NR-794-D-101-B DATE: January 7, 1994

DEVICE TYPE: X-ray Fluorescence Analyzer

MODEL: 615 00 00

DISTRIBUTOR: Provalid Corporation
520 Herndon Parkway
Herndon, VA 22070

MANUFACTURER: Provalid AB
Avtalsvagen 15
S-227 61 LUND
SWEDEN

SEALED SOURCE MODEL DESIGNATION: Amersham Corporation
Model AMC.D3
Isotope Products Laboratories
Model GFS Series

ISOTOPE:	MAXIMUM ACTIVITY:
Americium-241	60 mCi total (2.22 GBq) in 2 sources at 30 mCi (1.11 GBq) each

LEAK TEST FREQUENCY: 36 Months

PRINCIPAL USE: (U) X-ray fluorescence

CUSTOM DEVICE: _____ YES ___X___ NO

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

DEVICE TYPE: X-ray Fluorescence Analyzer

DESCRIPTION:

The Model 615 00 00, which is commonly called the Renalyzer PRX90, is a portable x-ray fluorescence instrument used to measure the amount of iodine present in plasma samples. The instrument has approximate dimensions of 22" x 27" x 10" (55.88 cm x 68.58 cm x 25.4 cm) and weighs approximately 46 pounds (20.87 kg).

The front of the unit consist of a flip down keyboard and an LCD display. All patient information is entered using the keyboard and is displayed on the LCD screen. Iodine concentrations are also be displayed on the screen.

The device is operated by inserting a plasma sample into a hole in the top of the unit. An elevator device will lower the sample down into the measuring area within the device. Through keyboard operations, the device can be operated to evaluate the iodine concentration.

The inner components of the Renalyzer PRX90 consists of the following:

- Two (2) Am-241 Sealed Sources
- Sealed Source Housings
- NaI Detector
- Detector Mount
- Sample Turret
- Sample Elevator
- Protective Housing
- Mounting Plate
- Electronics

The unit is designed with the sealed sources (maximum 30 mCi each) mounted within cylindrical lead source housings. The housings are mounted within two holes, drilled at 45° angles, in the front face of the detector mount. The housings are held in place by screws and are oriented so that the paths of the radiations beams intersect directly in front of the NaI detector which is mounted in the center of the detector mount. This entire component is attached to the aluminum mounting plate at the bottom of the device.

DEVICE TYPE: X-ray Fluorescence Analyzer

DESCRIPTION (Cont.):

The sample turret is attached to the mounting plate in front of the detector mount in such a manner that the center line of the sample being measured will align with the intersection of the radiation beams. The turret can hold up to ten (10) samples (two (2) being calibration samples) and is able to rotate 260° so that each sample can be moved to the measuring position. The turret is designed with lead shielding at the top and bottom of the sample area for radiation protection.

The sample elevator is mounted beneath the turret. It's purpose is to lower and raise the samples into and out of the turret. It is activated by the keyboard on the front of the device.

The entire area in the front of the detector mount and surrounding the sample turret is covered by the protective housing. The housing is made of aluminum lined with lead and its main purpose is to provide shielding. One of three types of tamper resistant screws are used to fasten the cover.

The electronic workings of the device, which consist of the power supplies and the control board, are mounted toward the back of the device.

The principal behind how the device works is that the plasma sample is irradiated by 60 keV photons from the sealed sources. The photons may cause K-shell electrons to be ejected from the iodine atoms causing the atoms to go to an excited state. As the atoms return to a stable state, they will emit characteristic x-rays that can be detected by the NaI detector. The intensity of the x-rays is proportional to the iodine concentration in the sample.

DIAGRAM:

Attachments 1-3 show detailed drawings of the Renalyzer PRX90 Model 615 00 00, the sample turret, and the protective housing.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

DEVICE TYPE: X-ray Fluorescence Analyzer

LABELING:

FOR DEVICES DISTRIBUTED TO SPECIFIC LICENSEES:

The labeling consist of two labels. One mounted on top of the device at the front left corner containing the radiation symbol, isotope, activity, date of assay, and the words "CAUTION-RADIOACTIVE MATERIAL." This label is made of aluminum and is permanently attached to the device with screws. The second label is attached with screws to the rear of the unit and contains the device model number, serial number, and additional Provalid information.

FOR DEVICES DISTRIBUTED TO GENERAL LICENSEES:

The labeling consist of four labels. One mounted on top of the device at the front lower left corner containing the radiation symbol (black on yellow), isotope, activity, date of assay, and the words "CAUTION-RADIOACTIVE MATERIAL". The second label contains the device model number, serial number, and additional manufacturer information and is attached to the rear of the device. The third label is attached to the front upper right corner of the device and contains the instructions, precautions, and warnings. Each label is made of aluminum and is permanently attached to the device. Those on the top cover of the device are attached with bolts with locking nuts and the label on the rear of the device is attached with screws.

The fourth label is a self-adhesive solid aluminum foil. Space is provided for the owner's name and address. The label is preprinted that if the device is transferred a new owner's identification label is required.

CONDITIONS OF NORMAL USE:

The device is intended for use as a plasma analyzer to determine the amount of iodine present in plasma samples. It will be used in laboratories or offices in which the environmental conditions will be suitable for human occupancy.

DEVICE TYPE: X-ray Fluorescence Analyzer

CONDITIONS OF NORMAL USE (Cont.):

Since the device is moved between laboratories, it will be subjected to vibration encountered during normal transportation and handling.

PROTOTYPE TESTING:

The analyzer has been subjected to a drop test, a rigidity test, an impact test, and a vibration test. Each test simulated the conditions which the device would experience during its normal use. No adverse effects were observed after each test. The device has also been in use for over seven years in Sweden, Norway, and the United Kingdom. In this time span the device has experienced rough handling (e.g. being dropped from 1 foot and being stored in the trunk of a car when the car was involved in a car crash) but has experienced no significant damage.

The Amersham and Isotope Products sealed sources have been rated for ANSI-N542 classifications of 77C64444 and 77C64545, respectively.

It has been concluded, from the testing performed and the years of use, that the device will withstand the abuse it may receive during its useful life.

EXTERNAL RADIATION LEVELS:

The Swedish National Institute of Radiation Protection performed a radiation survey on the unit containing two (2) 30 mCi sealed sources and found the maximum dose rate at the surface of the device to be less than 0.1 mrem/hr (1.0 uSv/hr).

QUALITY ASSURANCE AND CONTROL:

Vidar will be contracted to perform the quality control functions on behalf of the U.S. distributor, Provalid Corp. The contractor receives completed analyzers from Provalid and removes the outer covers from the devices and inspects the units to ensure that all

DEVICE TYPE: X-ray Fluorescence Analyzer

QUALITY ASSURANCE AND CONTROL (Cont.):

the components are assembled correctly. The contractor performs a radiation survey and leak test on each unit to ensure its proper assembly.

Vidar has submitted a copy of their quality assurance and control program. The program has been deemed acceptable for licensing purposes and is on file with the Source Containment and Devices Branch.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The device may be distributed to specific or general licensees of NRC or an Agreement State.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority or as required by 10 CFR 31.5 or Agreement State equivalent.
- The device shall be leak tested at intervals not to exceed 36 months using techniques capable of detecting 0.005 mCi (185 Bq) of removable contamination.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

SAFETY ANALYSIS SUMMARY:

Provalid has submitted sufficient information to provide reasonable assurance that:

- The device can be safely operated by persons not having training in radiological protection.

DEVICE TYPE: X-ray Fluorescence Analyzer

SAFETY ANALYSIS SUMMARY SECTION (Cont.):

- Under ordinary conditions of handling, storage, and use of the device, the byproduct material contained in the device will not be released or inadvertently removed from the source housing, and it is unlikely that any person will receive in one year a dose in excess of 10 percent of the limits specified in Section 20.1201(a), 10 CFR Part 20.

- Under accident conditions associated with handling, storage, and use of the source housing, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in the following chart:

PART OF BODY	DOSE
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	15 rem (0.15 Sv)
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	200 rem (2.0 Sv)
Other organs	50 rem (0.50 Sv)

Based on review of Provalid's Renalyzer PRX90 Model 615 00 00, and the information and test data cited below, we continue to conclude that the device is acceptable for general licensing purposes.

Furthermore, we continue to conclude that the device would be expected to maintain it's containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: NR-794-D-101-B DATE: January 7, 1994

DEVICE TYPE: X-ray Fluorescence Analyzer

REFERENCES:

The following supporting documents for the Renalyzer PRX90 Model 615 00 00 are hereby incorporated by reference and are made a part of this registry document.

- Vidar's application dated March 2, 1990, with enclosures thereto.
- Vidar's letters dated October 22, 1990, and August 17, 1993.
- Package received from Vidar on November 13, 1990, including Renalyzer Library 1 & 2, User Manual, and IEC Test Report.
- Provalid Corporation's letters dated August 17, 1993, and December 20, 1993.
- Provalid AB's letter dated April 8, 1993, with enclosures thereto and facsimiles dated July 13, 1993, August 19, 1993, August 24, 1993, August 30, 1993, September 28, 1993, and December 13, 1993.

ISSUING AGENCY:

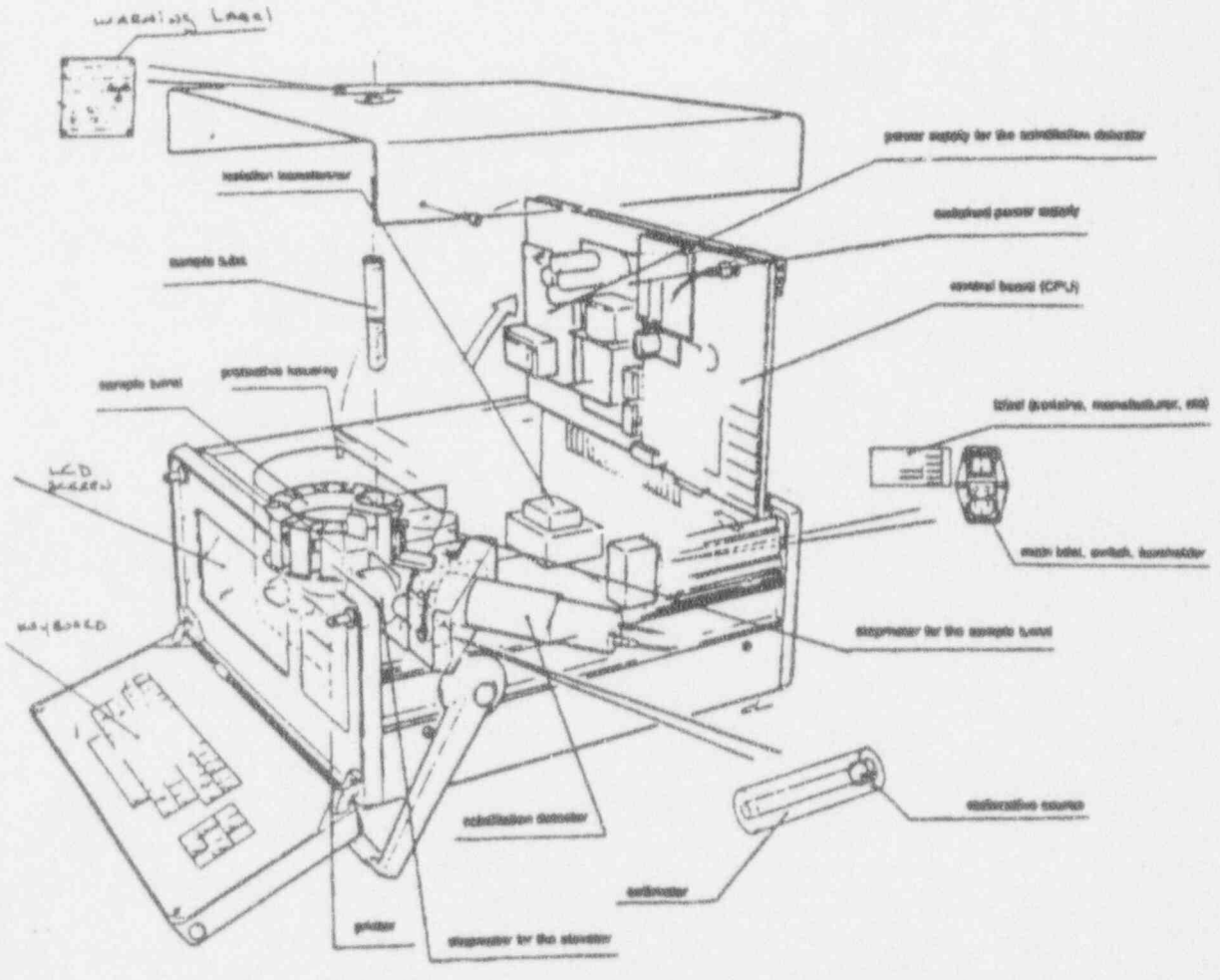
U.S. Nuclear Regulatory Commission

Date: January 7, 1994 Reviewer: John W. Lubinski

Date: January 7, 1994 Concurrence: Steven L. Baggett

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

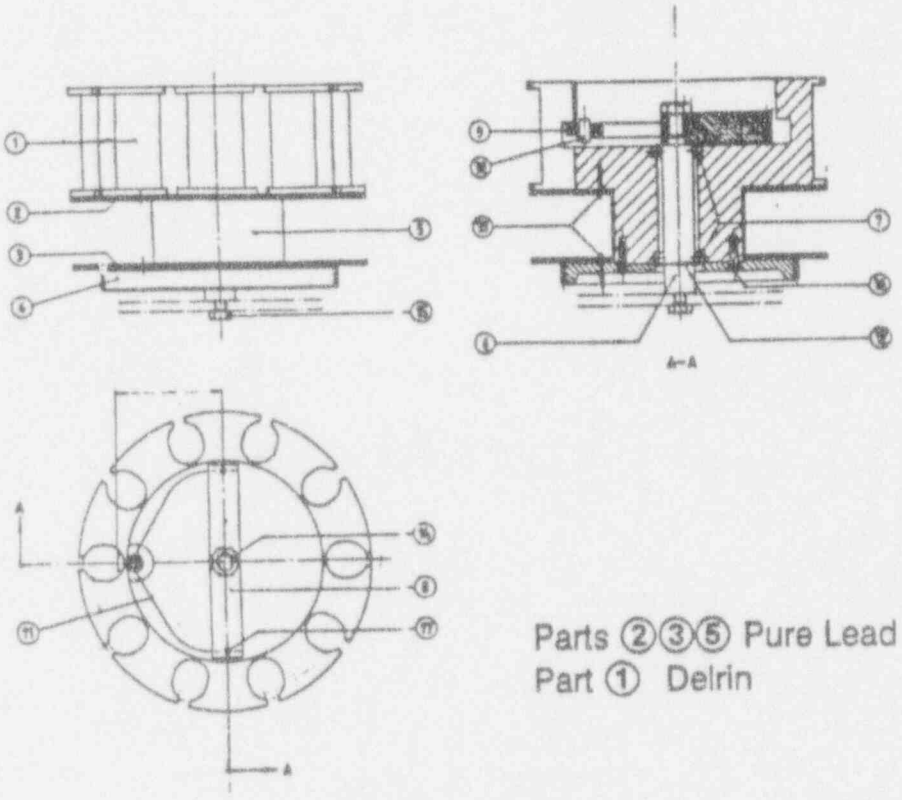
NO.: NR-794-D-101-B DATE: January 7, 1994 Attachment 1



Renalyzer PRX90
Model 615 00 00

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: NR-794-D-101-B DATE: January 7, 1994 Attachment 2

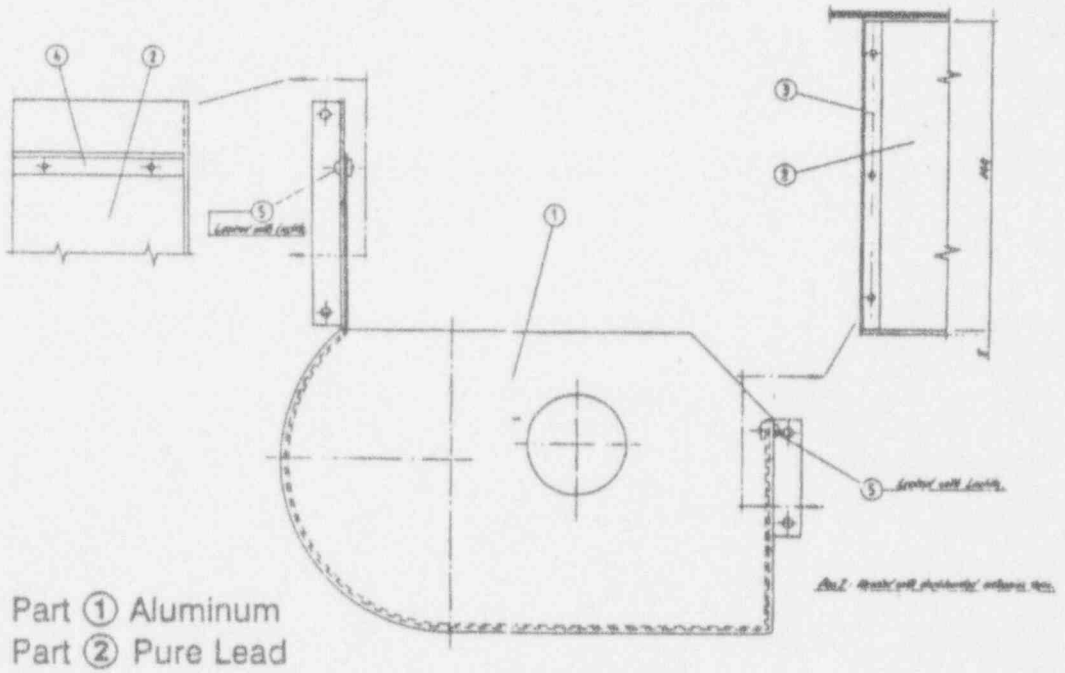


Parts ②③⑤ Pure Lead
Part ① Delrin

Sample Turret

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: NR-794-D-101-B DATE: January 7, 1994 Attachment 3



Part ① Aluminum
Part ② Pure Lead

Protective Housing