

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

NO.: CA0471D103B

DATE: April 29, 1998

PAGE: 1 of 6

DEVICE TYPE: Portable Mass Gauge

MODEL: 104P/104PD

DISTRIBUTOR/MANUFACTURER:

NDC SYSTEMS  
5314 North Irwindale Avenue  
Irwindale, CA 91706  
(626) 960-3300 (voice)  
(626) 939-3870 (fax)

SEALED SOURCE MODEL DESIGNATION:

Amersham Model AMCP1  
Isotope Products Model GFS  
**BEBIG Model Am 1.PO8**  
Amersham Model AMCP6

ISOTOPE:

Americium 241

MAXIMUM ACTIVITY:

150 millicuries

LEAK TEST FREQUENCY: Six (6) Months

PRINCIPAL USE: Gamma Gauge (D)

CUSTOM SOURCE: \_\_\_\_\_ YES ☒ NO

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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 (Attachments 1&3). The radioactive source is epoxied into a tungsten collimator which is epoxied into the crystal 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 shutters are of a mechanical type. Shielding is provided by a 0.125" thick tungsten disc. The Model 104P shutter has a small handle which extends at a right angle from the shutter. By using this handle the shutter can be flipped back and turned out of the way of the face of the probe without the fingers getting into the radiation beam. The shutter assembly is supplied with a hole for a padlock. (See Attachments 2 & 4). Model 104PD shutter has a knob which must be manually pushed up and turned to move the shutter to the side of the probe face. (See Attachments 3 & 5).

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LABELING:

The device is labeled in accordance with Sections 30192.1 of the California Radiation Control Regulations (equivalent to 10 CFR 32.51) and 10 CFR 20.1901. See Safety Labels, Attachment 8.

DIAGRAM: (see Attachments)

- Attachment 1---NDC Model 104P and 104PD Sensor Probe, Side and Top View.
- Attachment 2---NDC Model 104P Sensor Probe with Locking Shutter.
- Attachment 3---NDC Model 104PD Sensor Probe with Locking Shutter.
- Attachment 4---NDC Model 104P Probe with Shutter Opened and Closed.
- Attachment 5---NDC Model 104PD Probe with Shutter Opened and Closed.
- Attachment 6---NDC Models 104P and 104PD Radiation Profile with Shutter Open.
- Attachment 7---NDC Models 104P and 104PD Radiation Profile with Shutter Closed.
- Attachment 8---Safety Labels

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.

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**DEVICE TYPE:** Portable Mass Gauge

**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 operate in excess of 500 open-close cycles. The ANSI classification assigned by the manufacturer is 43-254-985-R2. This is based on tests in accordance with NBS 129, the ANSI classification of the Amersham source of C64444, the ANSI classification of the Isotope Products source of C64545, the ANSI classification of the BEBIG source of C64444 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 Attachment 6. With the source in the closed position, the radiation field is less than 1mr/hour on any surface (See Attachment 7).

**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.

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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/185 bequerels of removable contamination.
6. General licensees are provided with instructions on calibration and shutter manipulation. The requirement of specific licensure for leak tests, 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. Generally Licensed users are authorized to check the proper functioning of the shutter at intervals not to exceed six months, using instructions provided by the manufacturer. This check must be documented.
9. This registration sheet and the information continued within the references shall not be changed without the written consent of the California Department of Health Services.

SAFETY ANALYSIS SUMMARY:

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

**Furthermore, we continue to conclude that the source 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.**

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REFERENCES:

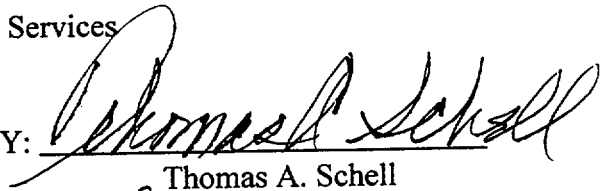
The following supporting documents for the NDC Model 104P/104PD gauge are hereby incorporated by reference and are made part of the registry document.

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 letter with attachments dated October 11 and 12, 1993.
6. NDC Systems letters dated November 17, 1994, December 7, 1994 and March 17, 1995.
7. NDC Systems letters dated January 15, 1997, September 5, 1997, December 17, 1997 and April 29, 1998 with attachments thereto.

ISSUING AGENCY: California Department of Health Services

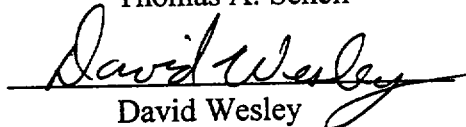
DATE: April 29, 1998

AMENDED BY:

  
Thomas A. Schell

DATE: April 29, 1998

CONCURRED BY:

  
David Wesley

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ATTACHMENT: 1

SEALED DEVICE TYPE: Portable Mass Gauge

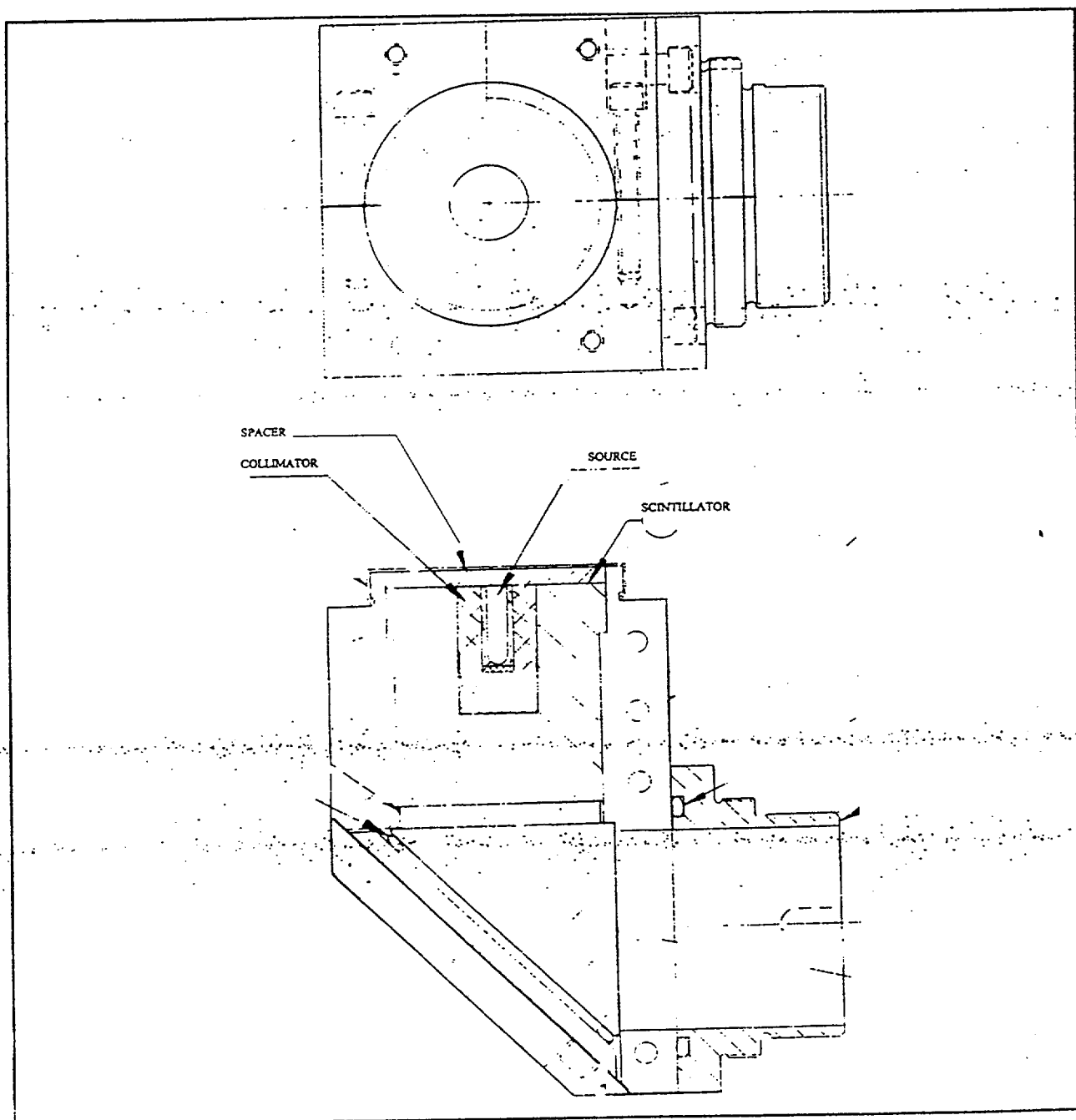


Figure 1: NDC Model 104P and 104PD Sensor Probe, Side and Top View

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ATTACHMENT: 2

SEALED DEVICE TYPE: Portable Mass Gauge

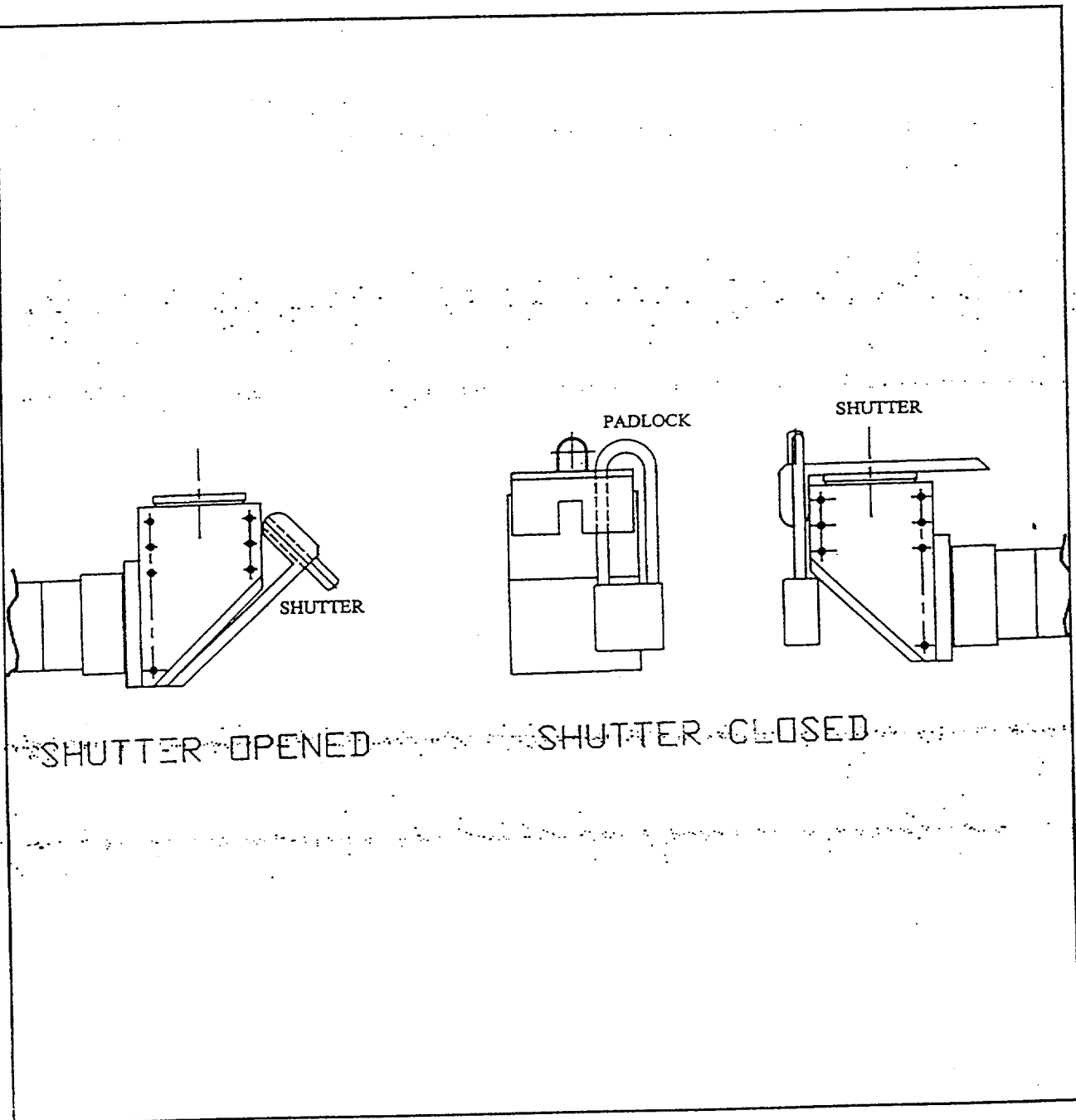


Figure 2: NDC Model 104P Sensor Probe with Locking Shutter



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ATTACHMENT: 3

SEALED DEVICE TYPE: Portable Mass Gauge

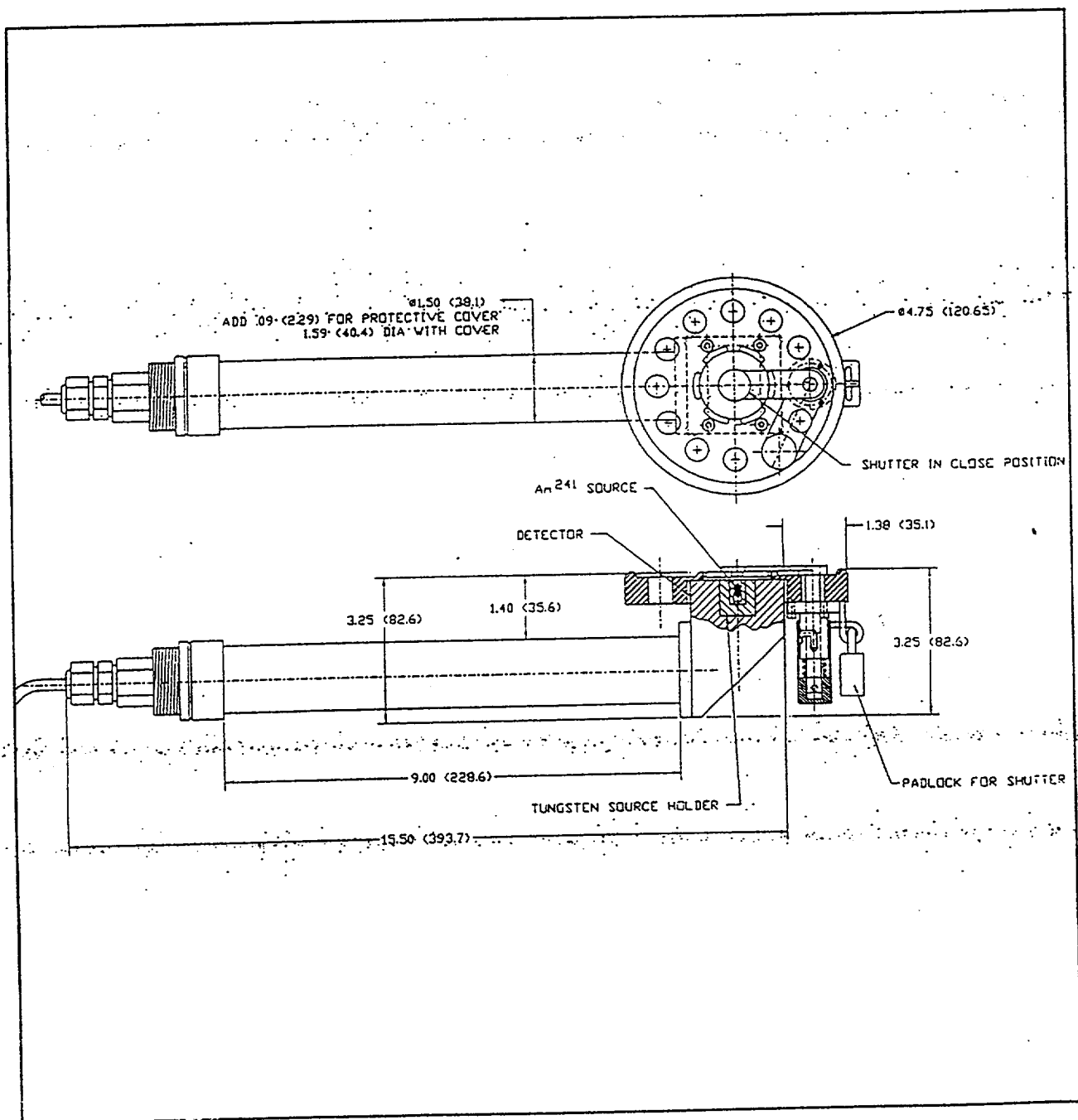


Figure 3: NDC Model 104PD Sensor Probe with Locking Shutter

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ATTACHMENT: 4

SEALED DEVICE TYPE: Portable Mass Gauge

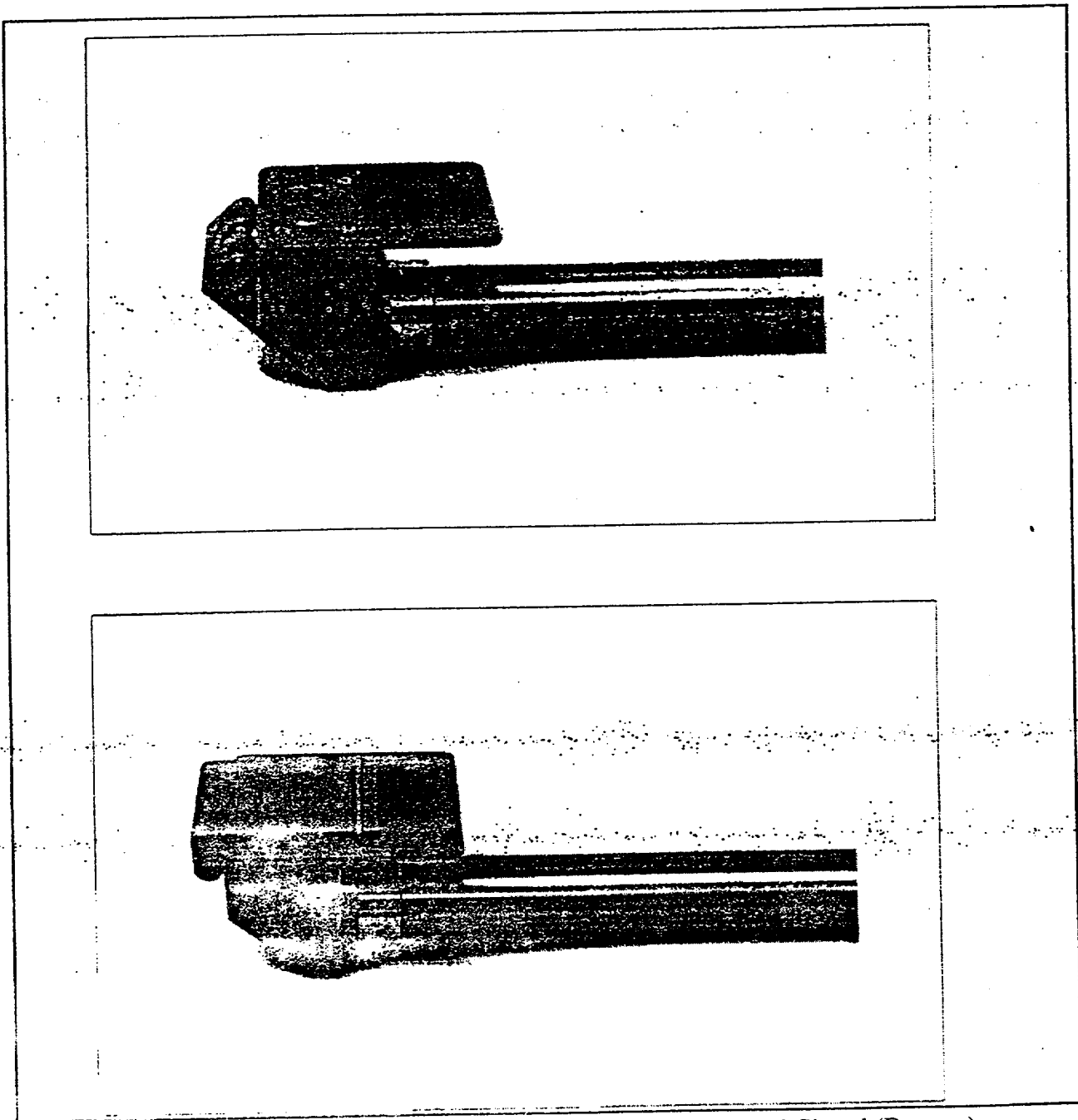


Figure 4: NDC Model 104P Probe with Shutter Opened (Top) and Closed (Bottom)

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ATTACHMENT: 5

SEALED DEVICE TYPE: Portable Mass Gauge

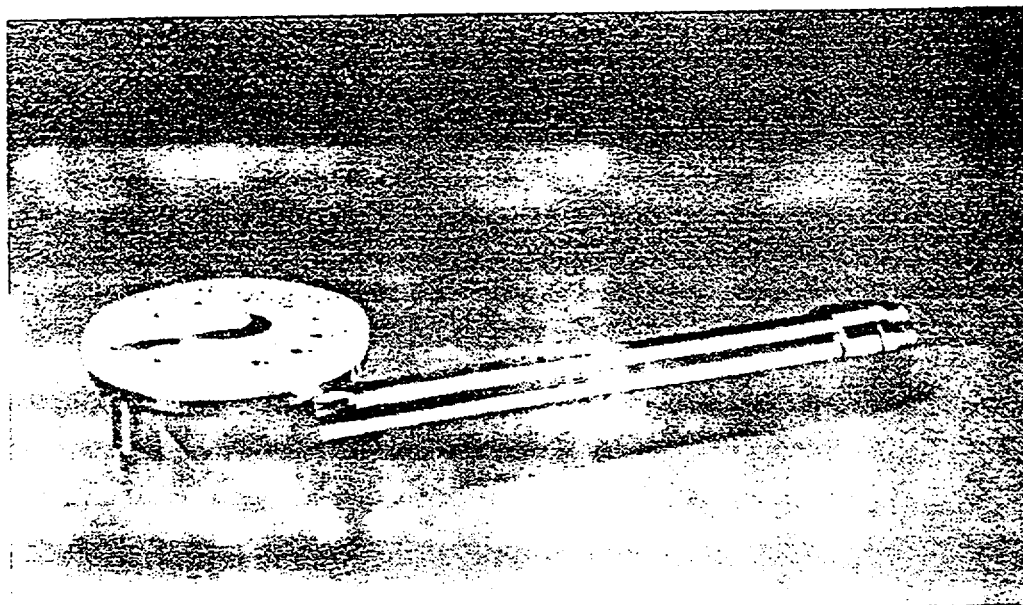
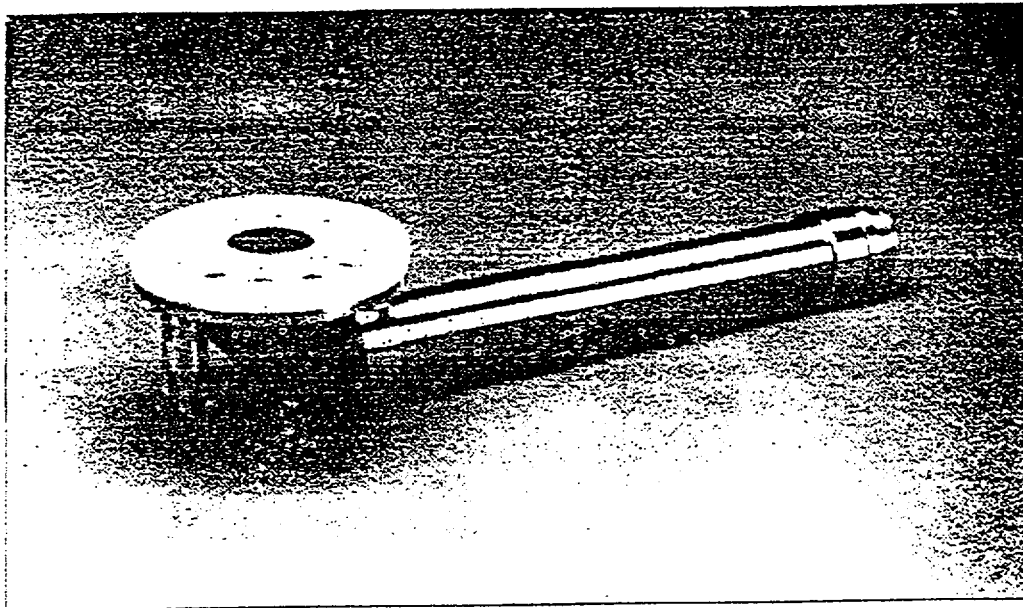


Figure 5: NDC Model 104PD Probe with Shutter Opened (Top) and Closed (Bottom)

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ATTACHMENT: 6

SEALED DEVICE TYPE: Portable Mass Gauge

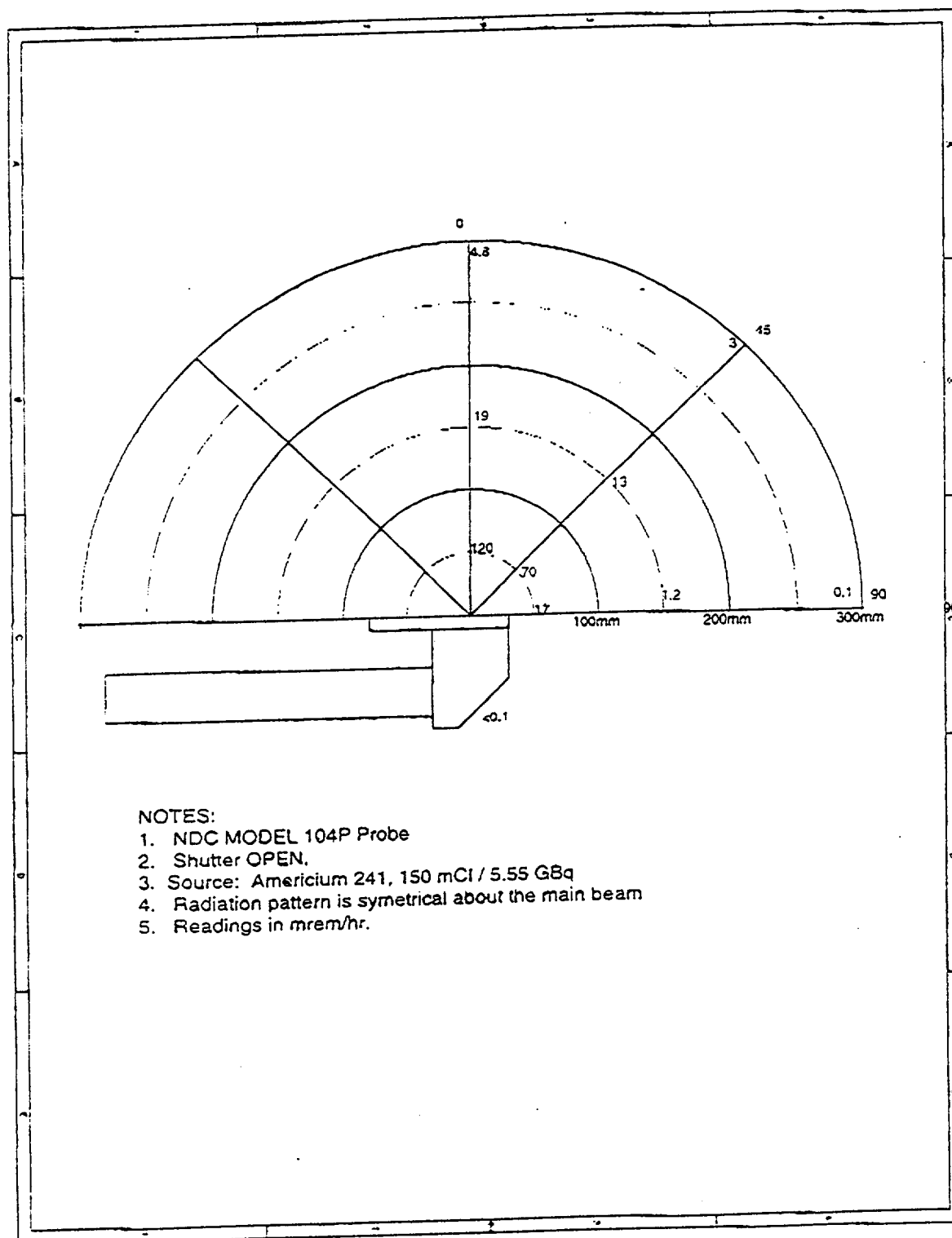


Figure 6: NDC Models 104P and 104PD Radiation Profile with Shutter Open

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ATTACHMENT: 7

SEALED DEVICE TYPE: Portable Mass Gauge

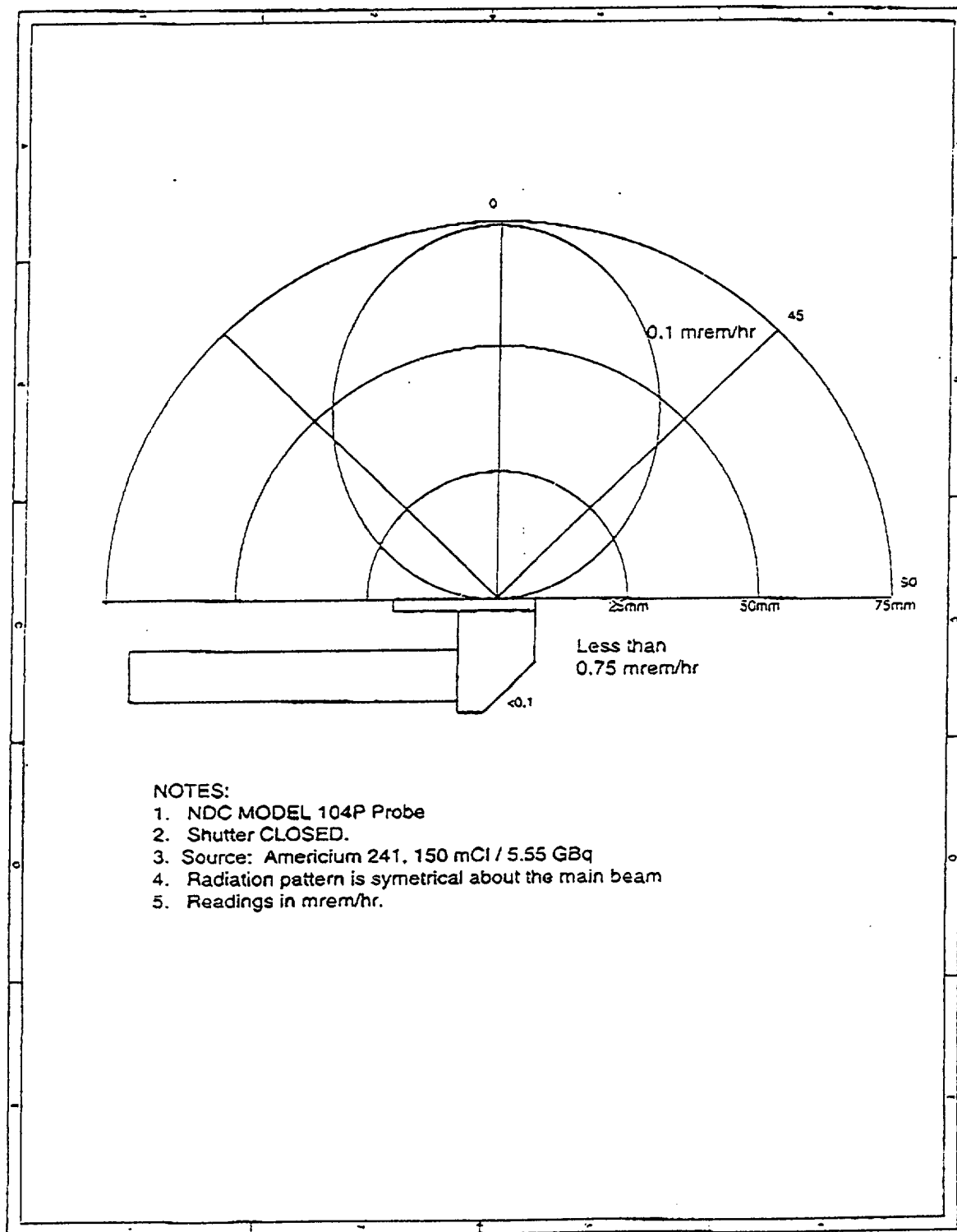


Figure 7: NDC Models 104P and 104PD Radiation Profile with Shutter Closed

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

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ATTACHMENT: 8

SEALED DEVICE TYPE: Portable Mass Gauge

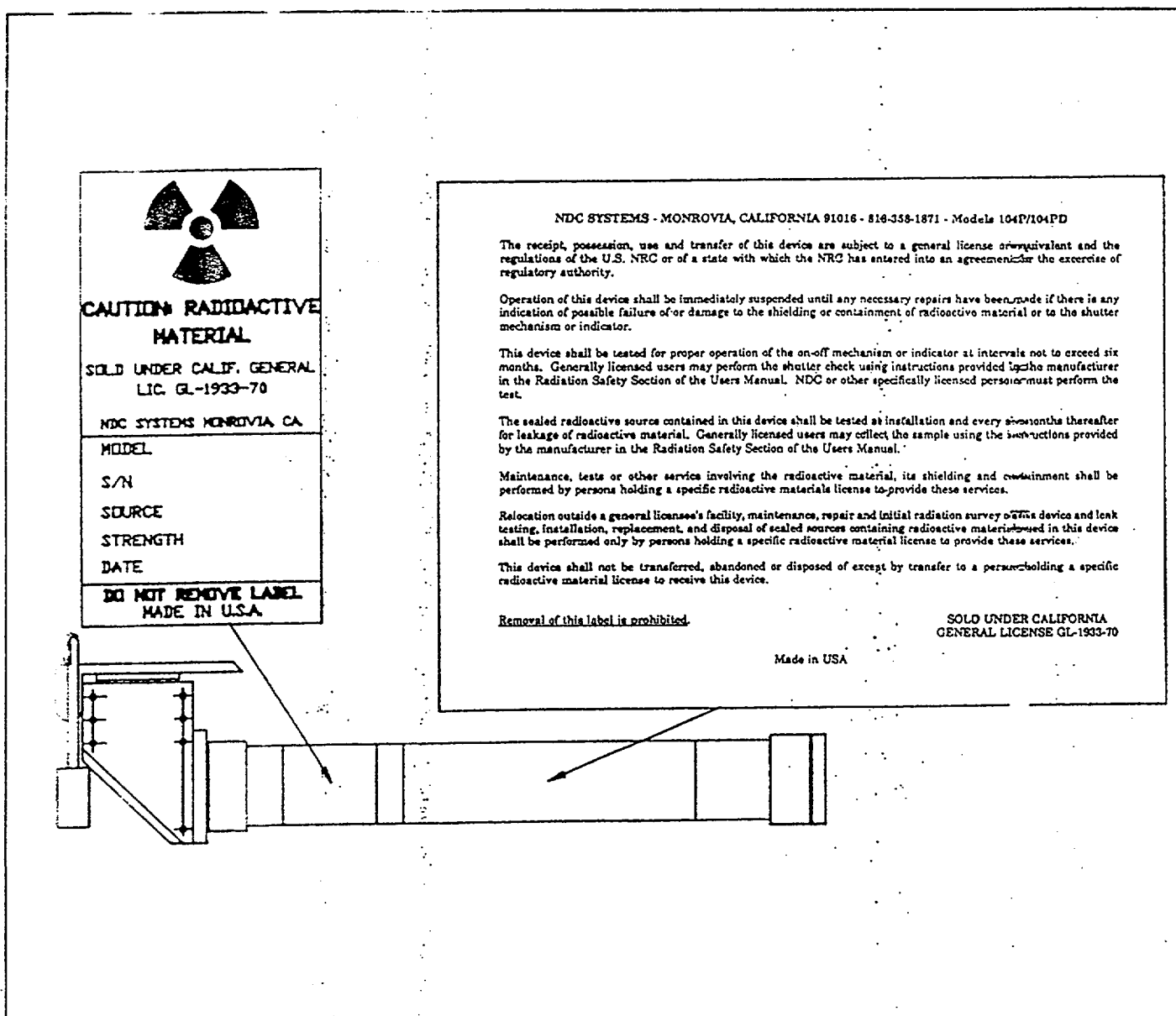


Figure 8: Safety Labels