

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

NO.: CA0471D102B

DATE: 08/23/00

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DEVICE TYPE: Thickness Gauges

MODEL: 101, 102, 103, 104, 108, 200, 210, 220

DISTRIBUTOR/MANUFACTURER: NDC Systems
5314 N Irwindale Avenue
Irwindale, CA 91706

SEALED SOURCE MODEL DESIGNATION: Amersham Model AMC.P1
Amersham Model AMC.P6
Isotopes Products Laboratories Model GFS
BEBIG Model Am1.PO8

ISOTOPE: Americium 241

MAXIMUM ACTIVITY: 150 millicuries

LEAK TEST FREQUENCY: Not to exceed 3 years

PRINCIPAL USE: Gamma Gauges (D)

CUSTOM DEVICE: _____ YES X NO

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DESCRIPTION:

The Models 101, 102, 103, 104, 108, 200, 210 and 220 are the scintillation detector and source housing part of the NDC gamma backscatter gauging systems. The radioactive source, crystal and detection assembly consist of one unit (Figure 2). The Model 104 is shown in Figure 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 **0.002" titanium** cover is attached across the probe face providing further closure.

The crystal head containing the source screws onto the probe body. Short of total destruction of the probe, the source and its housing cannot be separated from the probe body.

There are two types of mechanical shutters (Drawings 300078 & 580014, as shown in Figures 1 & 10). Shielding is provided by a 0.125" thick tungsten disc. The shutters can be held shut by padlock, pin or by spring tension so that they can not be accidentally opened. The Model 580014 incorporates a knob while the Model 300078 uses the end of the shutter extending past the probe surface to move the shutter without the fingers getting directly into the radiation beam. The underside of each shutter is red, indicating the open position when it is opened and the upper surface shows green when the shutter is closed.

The model 104 can be supplied with a shutter that 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 (See Figures 3 & 4).

As an option, the manufacturer can provide compressed air actuated automatic shutter assemblies for all device models except the 104. These automatic shutter assemblies are available in two versions, the NDC model 300138 and the NDC model 621710. Both contain a "spring-activated close on loss of air" feature as a safety device. Their shutters are equivalent to the manually operated shutter in density thickness and should not affect the ANSI classification. (See Figures 5 & 6).

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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 20.1901, respectively. See Figure 7).

DIAGRAM:

Figure 1---Model 10X Probe Head Assembly (Dwg. 300078)
Figure 2---Model 10X Probe Assembly (Dwg 300002)
Figure 3---Model 104 Sideview Probe Assembly (Dwg. 631528)
Figure 4---Model 104 Probe Head Assembly (Dwg. 631515)
Figure 5---Auto Shutter Assembly (Rotating) (Dwg. 300138)
Figure 6---Auto Shutter Assembly (Dwg 621710)
Figure 7---Safety Labels (Dwg. 631544-1)
Figure 8---Radiation Profile NDC Model 10X with Shutter Open
Figure 9---Radiation Profile NDC Model 10X with Shutter Closed.
Figure 10--- Manual Shutter, GBS, PICA (Drawing 580014)

CONDITIONS OF NORMAL USE:

The device is intended to measure the thickness or mass of various low atomic number materials. The following conditions apply:

Temperature: 15°C to 40°C

Pressure: Atmospheric

Vibration: Normal plant machinery vibration

Corrosion: Essentially zero

Dust: From zero to moderate

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CONDITIONS OF NORMAL USE:(Continued)

The detector/source housing will be initially installed by the manufacturer at a fixed location. See "Limitations" for restrictions on general licensees.

PROTOTYPE TESTING:

The units have been tested by the manufacturer for severe vibration and at temperatures up to 60°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 (based on ANSI classification of both Amersham sources and the BEBIG source of 77C64444, the ANSI classification of the Isotope Products source of 77C64545, and materials of construction).

EXTERNAL RADIATION LEVELS:

The radiation profiles with the shutter in both the open and closed positions were measured by a Lansverk R Meter and are included in Figures 8 and 9. With the **shutter** in the closed position, the radiation field is less than 1 mr/hour on any surface.

QUALITY ASSURANCE AND CONTROL:

There is a quality control program for 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.

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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 installation, initial testing, training and repair shall be performed by NDC or by person 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 three years. The leak test shall be capable of detecting 0.005 microcuries of removable contamination. The proper functioning of the shutter mechanism shall be checked at intervals not to exceed six months.
6. General licensees are provided with instruction on calibration and shutter manipulation and shutter testing. The requirement of specific licensure for leak tests, relocation outside the registered facility, 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 sample must be tested 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.

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SAFETY ANALYSIS SUMMARY:

Based on our review of the information referenced below we conclude that the Models 101, 102, 103, 104, 108, 200, 210 and 220 gauges are acceptable for licensing purposes.

The distributor has provided sufficient information to provide reasonable assurance of the following:

The device can be safely operated by persons without training in radiological protection.

It is highly unlikely that even specific licensees would receive doses in excess of those specified in section 30268 of the California Radiation Control Regulations (equivalent to 10 CFR 20.1201).

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 in the following table:

| <u>PART OF BODY</u> | <u>DOSE</u> |
|---|-------------|
| Whole body; hand and trunk; active blood-forming organs; gonads, or lens of eye | 15 rem |
| Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter | 200 rem |
| Other organs | 50 rem |

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REFERENCES:

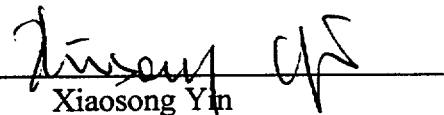
The following supporting documents for the NDC Systems gauges are hereby incorporated by reference and are made part of this registry document:

1. NDC Systems applications dated November 15, 1985, with attached drawings and quality control procedures.
2. NDC Systems letters dated July 30, 1986 and December 29, 1986, with attached "User Manuals".
3. NDC Systems letters, with attachments, dated February 24 and May 4, 1988.
4. NDC Systems letter dated March 4, 1992, with attached drawings.
5. NDC Systems letters, with attachments, dated April 18, June 3 and June 24, 1994.
6. NDC Systems letters, with attachments, dated December 15, 1994, February 14, 1995 and March 17, 1995.
7. NDC Systems letter dated January 15, 1997, with attachment dated December 16, 1996.
8. **NDC Systems letters, with attachments, dated August 5, 1998, and August 21, 2000.**

ISSUING AGENCY: California Department of Health Services

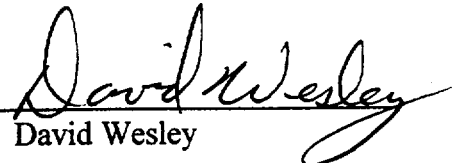
DATE: August 23, 2000

AMENDED BY:


Xiaosong Yin

DATE: August 23, 2000

CONCURRED BY:


David Wesley

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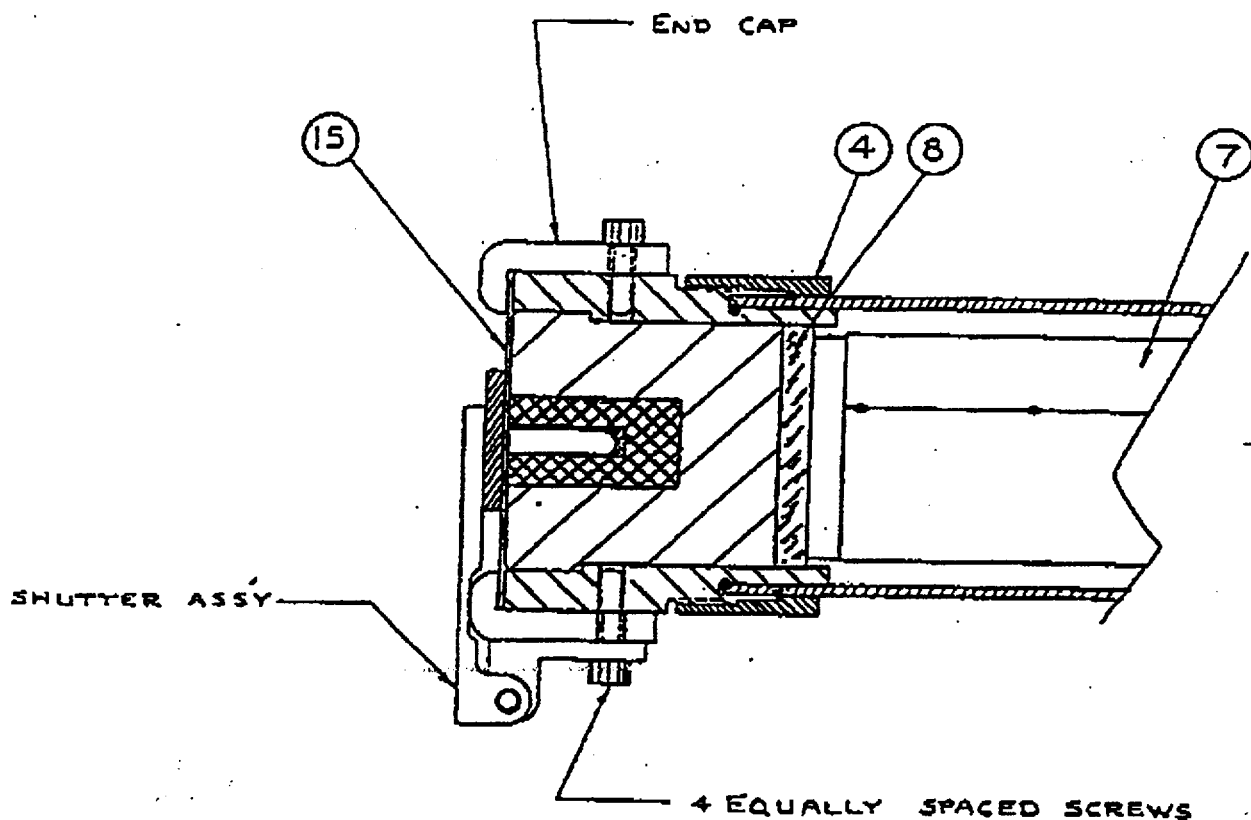


Figure 1: Model 10 X Probe Head Assembly (Drawing 300078)

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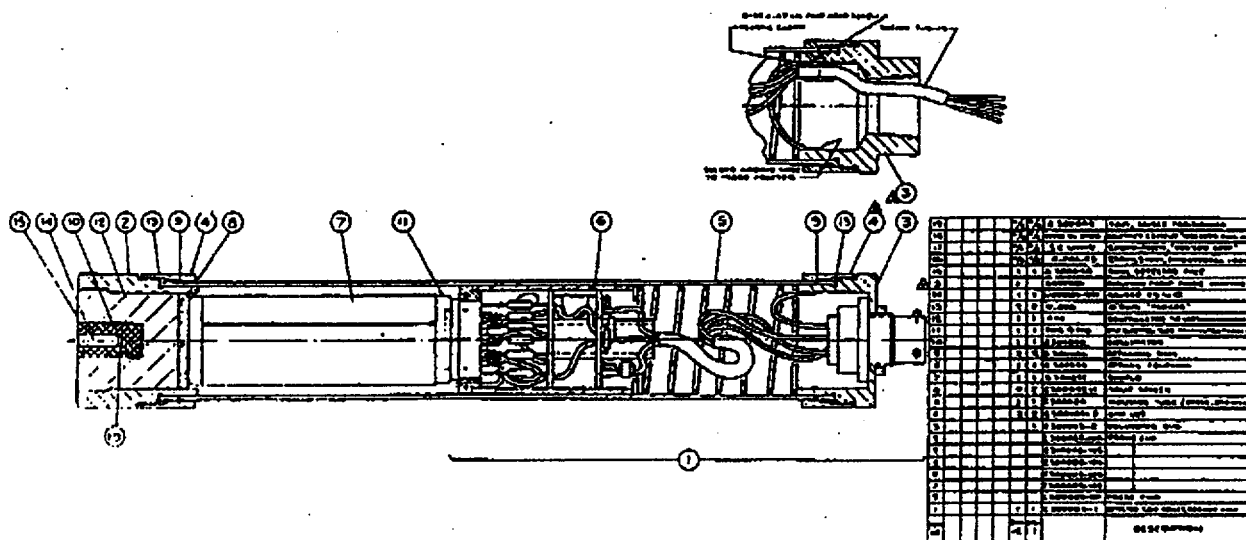


Figure 2: Model 10 X Probe Assembly (Drawing 300002)

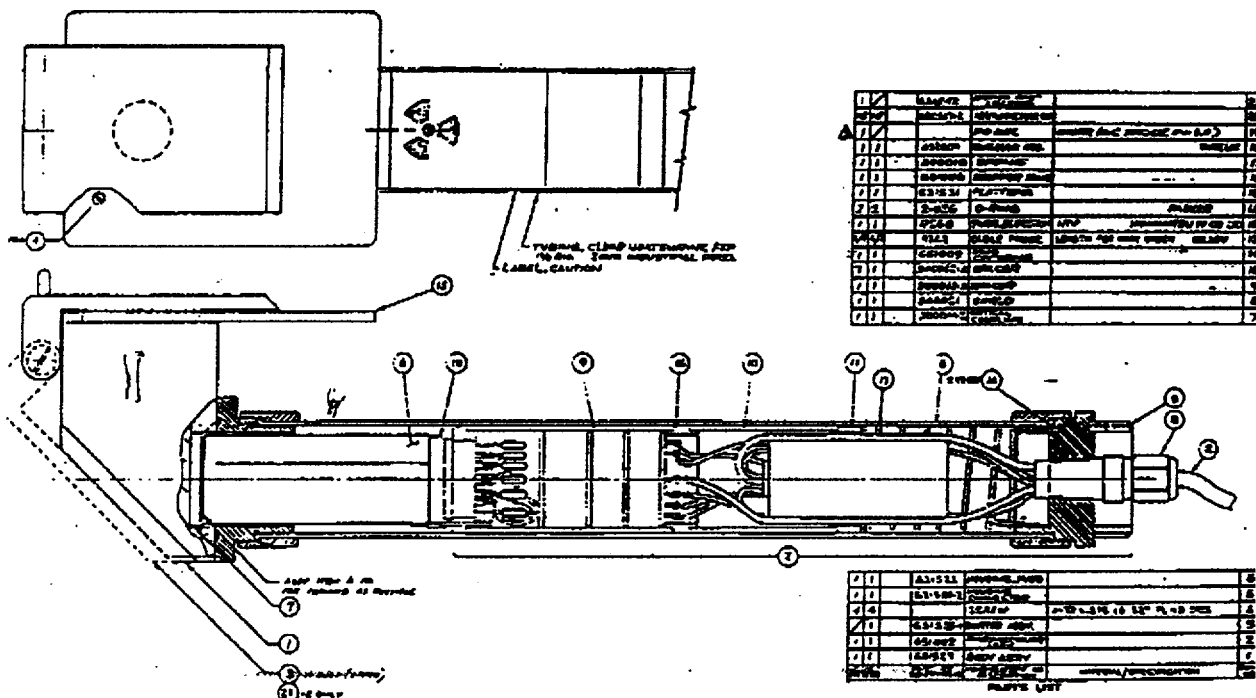
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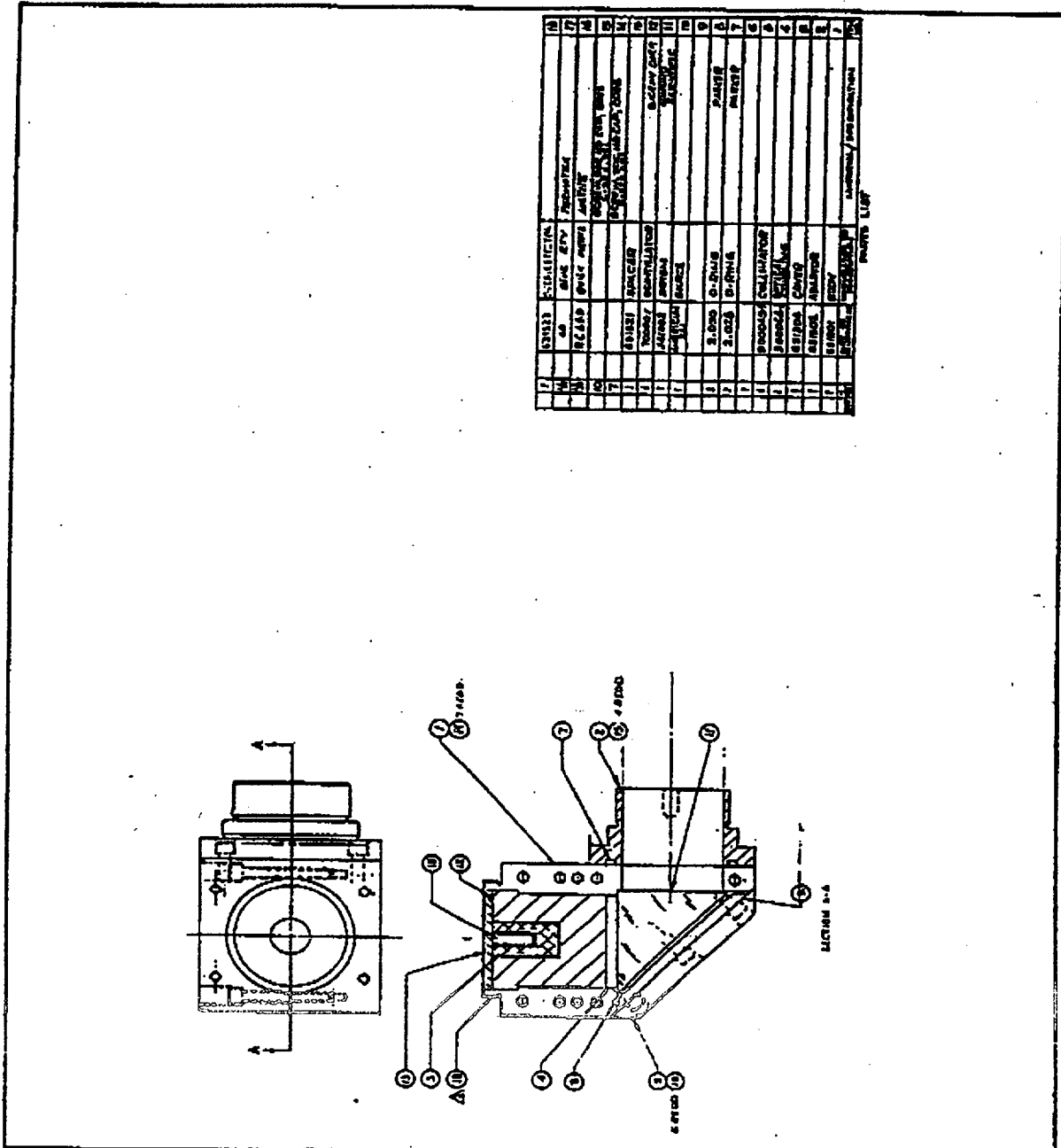


Figure 4: Model 104 Probe Head Assembly (Drawing 631515)

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Figure 6: Auto Shutter Assembly (Drawing 621710)

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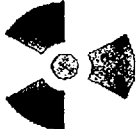
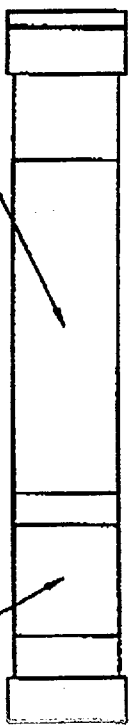
| | | |
|---|--|--|
|  <p>CAUTION: RADIOACTIVE MATERIAL</p> <p>SOLD UNDER CALIF. GENERAL LIC. TL-1933-70</p> <p>MRC SYSTEMS KIRKLAND, CA</p> <p>MODEL S/N SOURCE STRENGTH DATE</p> <p>DO NOT REMOVE LABEL MADE IN U.S.A.</p> | <p>NDO INSTRUMENTS - MONROVIA, CALIFORNIA 90818 - 618-386-1891 - Model 100 Series</p> <p>The receipt, possession, use and transfer of this device are subject to a general license or equivalent and the regulations of the U.S. NRC or of a state with which the NRC has entered into an agreement for the exercise of regulatory authority.</p> <p>Operation of this device shall be immediately suspended until any necessary repairs have been made if there is any indication of possible failure of or damage to the shielding or containment of radioactive material or to the detector mechanism or indicator.</p> <p>This device shall be used for proper operation of the on-off mechanism or indicator at intervals not to exceed six months. Generally licensed users may perform the shut-off check using instructions provided by the manufacturer in the Radiation Safety Section of the Users Manual.</p> <p>The sealed radioactive source contained in this device shall be tested at installation and every three years thereafter by the manufacturer. Generally licensed users may collect the sample using the instructions provided in the manufacturer's Radiation Safety Section of the Users Manual. NDO or other specially licensed persons must perform this test.</p> <p>Modifications, tests or other services involving the radioactive material, its shielding and containment shall be performed by persons holding a specific radioactive materials license to provide these services.</p> <p>Initial installation and radiation survey, maintenance, repair, and relocation outside the general licensed facility of this device and tank testing, inspection, replacement, and disposal of failed sources containing radioactive material used in this device shall be performed only by persons holding a specific radioactive materials license to provide these services.</p> <p>This device shall not be transferred, stored or disposed of except by transfer to a person holding a specific radioactive materials license to receive this device.</p> <p>Removal of this label is prohibited.</p> <p>NDO UNDER CALIFORNIA GENERAL LICENSE TL-1933-70</p> <p>Made in U.S.A.</p> |  |
|---|--|--|

Figure 7: Safety Labels (Drawing 631544-1)

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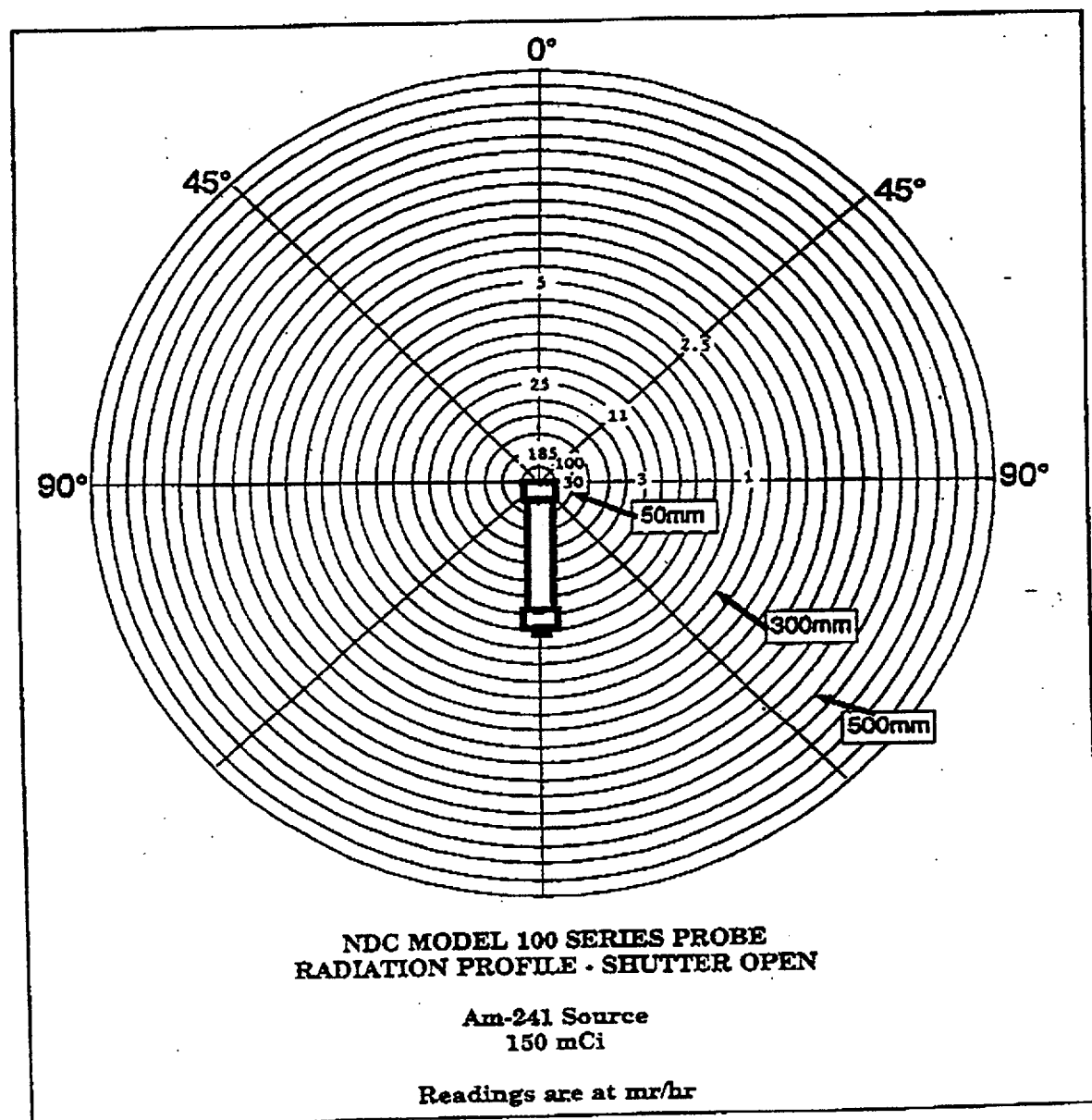


Figure 8: Radiation Profile NDC Model 10X with Shutter Open

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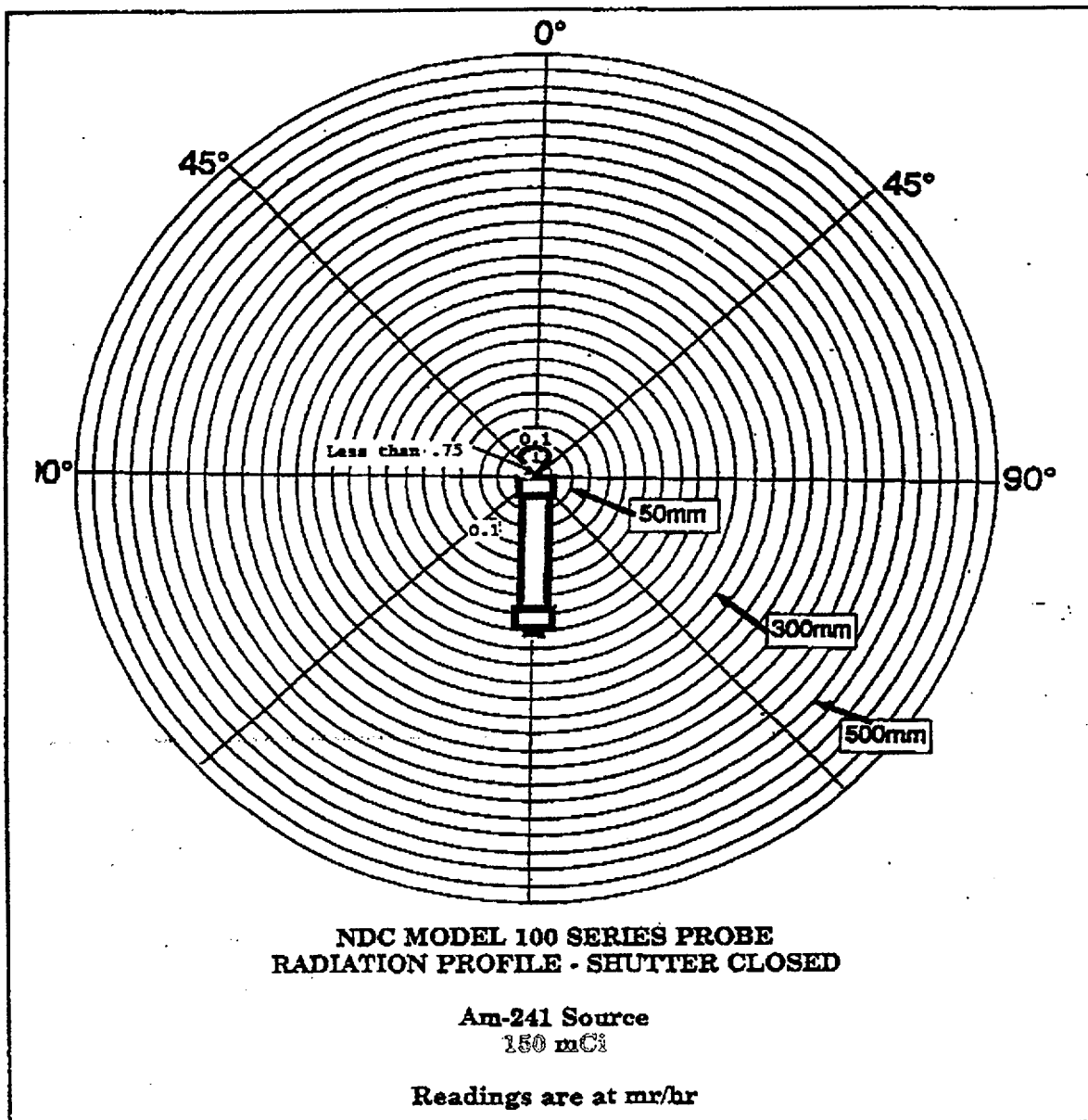


Figure 9: Radiation Profile NDC Model 10X with Shutter Closed

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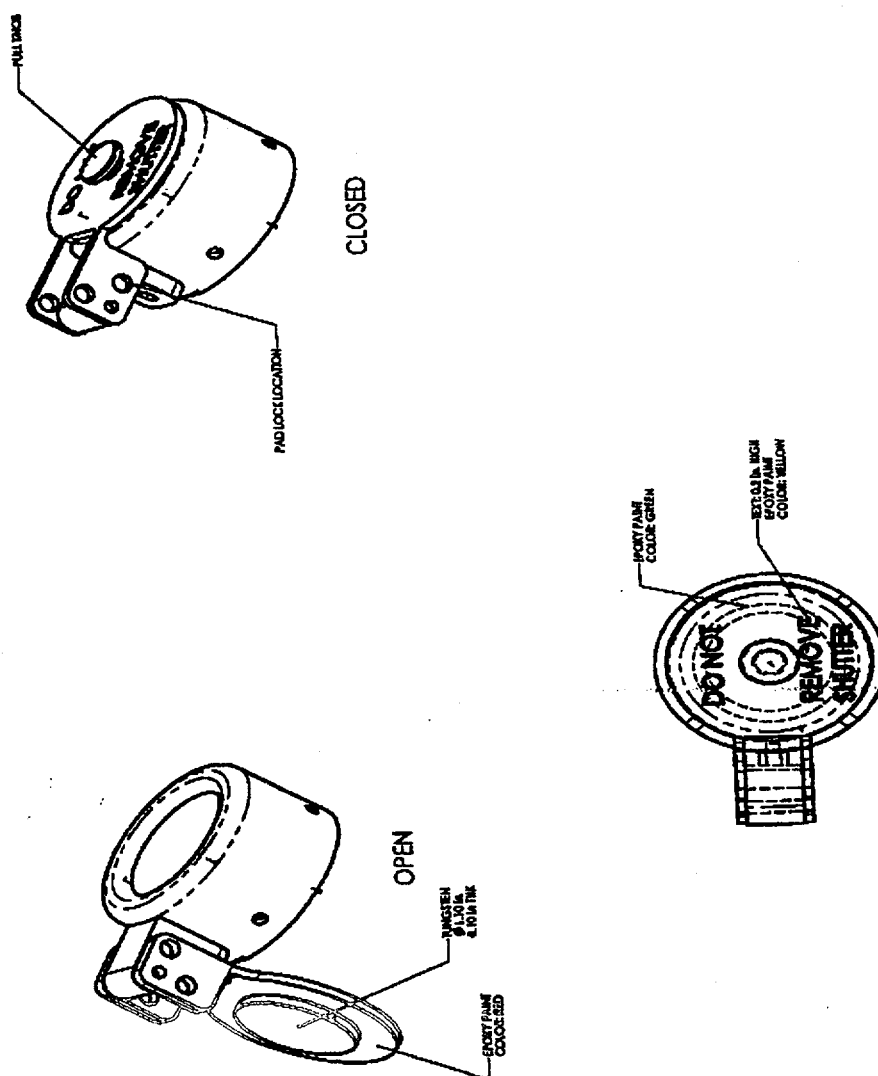


Figure 10: Manual Shutter, GBS, PICA (Drawing 580014)