

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE.

NO.: CA0471D107B

DATE: January 27, 1998

PAGE: 1 of 6

DEVICE TYPE: Thickness Gauges

MODEL: 101X, 102X and 103X

DISTRIBUTOR/MANUFACTURER:

NDC Systems
5314 North Irwindale Avenue
Irwindale, CA 91706
(818) 960-3300 (voice)
(818) 939-3870 (fax)

SEALED SOURCE MODEL DESIGNATION:

Amersham Model AMC.P1
Amersham Model AMC.P6

ISOTOPE:

Americium 241

MAXIMUM ACTIVITY:

150 millicuries

LEAK TEST FREQUENCY:

Three (3) years

PRINCIPAL USE: (D) Gamma Gauges

CUSTOM SOURCE: _____ YES NO

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DESCRIPTION:

The Models 101X, 102X, 103X are the scintillation detector and source housing part of NDC gamma backscatter gauging systems. The Models 101X, 102X and 103X differ with respect to the external electronics. The radioactive source, crystal, and detection assembly consist of one unit (Attachment 1). The radioactive source is epoxied into a tungsten collimator which is epoxied into the crystal well. A 0.001 stainless steel cover is attached across the probe face providing further closure.

The sensor for the Models 101X, 102X and 103X is similar to the Models 101, 102 and 103. It is approximately the same length but is about two times the diameter of the Models 101, 102 and 103 (Registration Certificate CA0471D102B). The main change is a larger detector area. The shutter for the Models 101X, 102X and 103X is also similar to the Models 101, 102 and 103. It is a single piece of stainless steel while the 101, 102 and 103 models use a thinner piece of tungsten inserted into a casting holder. The radiation profile of the Models 101X, 102X and 103X both with the shutter open and closed is less than the Models 101, 102 and 103.

The crystal head containing the source screws on to the probe body and a hidden screw locks the head to the probe body. Short of total destruction of the probe, the source and its housing cannot be separated from the probe body.

The shutter is a mechanical type and is shown in Attachment 1. Shielding is provided by a 0.550" thick stainless steel disc. The underside of the shutter is red, indicating the open position when it is opened, and the upper surface shows green when the shutter is closed.

As an option, the manufacturer can provide compressed air actuated automatic shutter assemblies (Attachment 2). This shutter contains a "spring-activated close on loss of air" feature as a safety device. This shutter is equivalent to the manually operated shutter in attenuation and should not affect the ANSI classification.

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LABELING:

The device is labeled in accordance with 10 CFR 20.1901. The labels contain the radiation symbol, isotope, activity, model number, serial number, name of distributor and the words "Caution- Radioactive Material".

When distributed to persons generally licensed, the device is additionally labeled in accordance with CCR Title 17, Section 30192.1 (equivalent to 10 CFR 32.51).

DIAGRAM: (See Attachments)

Attachment 1: Model 10XX Probe Assembly (Dwg. 680600)

Attachment 2: Model 10XX Probe Assembly with Auto Shutter (Dwg. 680650)

Attachment 3: Safety Labels

Attachment 4: Radiation Profile NDC Model 10XX with Shutter Open

Attachment 5: Radiation Profile NDC Model 10XX with Shutter Closed

CONDITIONS OF NORMAL USE:

The devices are intended for use in industrial gauging applications. The devices are typically used in industrial process control environments for the measurement of properties of various low atomic number materials. The devices are designed for the following environments:

Temperature: 15°C to 50°C

Pressure: Atmospheric

Vibration: Normal plant machinery vibration

Corrosion: Essentially zero

Dust: From zero to moderate

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PROTOTYPE TESTING:

A prototype of the Models 101X, 102X and 103X has been tested in accordance with ANSI standard N538-1979 and has achieved a classification of ANSI 43-254-985-R2. The device passed the tests in accordance with the acceptance criteria included in the standard.

The ANSI classification for the Amersham Model AMC.P1 and Model AMC.P6 is C64444.

EXTERNAL RADIATION LEVELS:

The radiation profile with the shutter in both the open and closed positions was taken with a Victoreen Panoramic Meter and is shown in Attachments 4 and 5. 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 assurance and control program 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 an Agreement State.
2. Initial installation, initial training, service and repair shall be performed by NDC or by persons specifically licensed by the NRC or Agreement States.
3. 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.
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.

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5. The device shall be tested for radioactive leakage at intervals of not longer than three years. The leak test shall be capable of detecting 0.005 microcuries (185 Bq) of removable contamination.
6. The proper functioning of the shutter mechanism shall be checked at intervals not to exceed six months.
7. The generally licensed user is authorized to perform certain maintenance on the device. These services include calibration, shutter manipulation, shutter testing, collection of leak test samples, and transportation within the general licensee's registered location of use.
8. Specific licensees of these devices are expected to seek authorization for leak testing, shutter checks, and relocation. Such procedures are provided upon installation by NDC.
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.

SAFETY ANALYSIS SUMMARY:

The distributor has submitted sufficient information to provide reasonable assurance that:

1. The device can be safely operated by persons not having training in radiological protection.
2. 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 any period of one year a dose in excess of 10 percent of the limits specified in Section 20.1201 (a), 10 CFR Part 20.
3. 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:

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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 cm² (0.15 in²).

200 rem (2.0 Sv)

Other organs

50 rem (0.50Sv)

Based on review of the Models 101X, 102X and 103X, and the information and test data cited below, we conclude that the device is acceptable for licensing purposes.

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

REFERENCES:

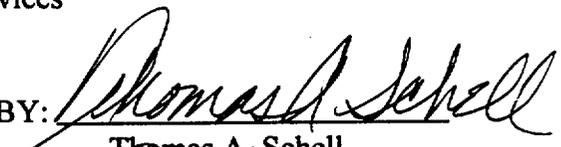
The following supporting documents for the Models 101X, 102X and 103X gauges are hereby incorporated by reference and made part of this registry document:

1. NDC Systems letters dated July 2, 1996, November 13, 1997 and December 17, 1997, with attachments thereto.

ISSUING AGENCY: California Department of Health Services

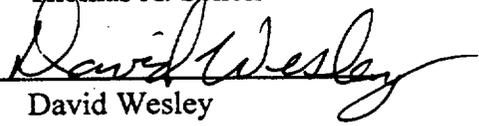
DATE: January 27, 1998

REVIEWED BY:


Thomas A. Schell

DATE: January 27, 1998

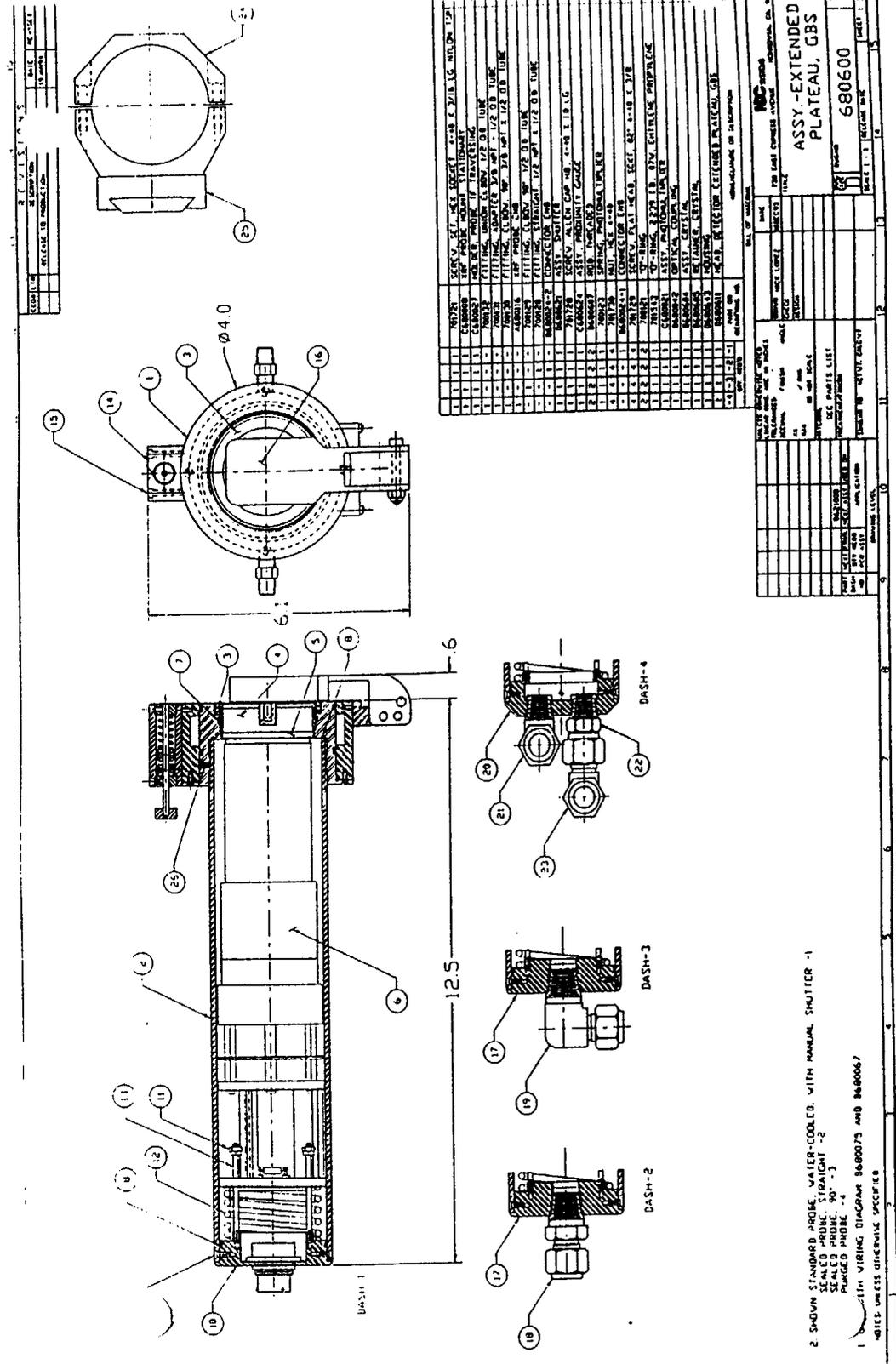
CONCURRED BY:


David Wesley

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES SAFETY EVALUATION OF DEVICE

NO.: CA0471D107B DATE: January 27, 1998 ATTACHMENT: 1

DEVICE TYPE: Thickness Gauge



2 SHOW STANDARD PROBE, WATER-COOLED, WITH MANUAL SHUTTER -1
 SEALED PROBE, STRAIGHT -2
 SEALED PROBE, 90° -3
 PURGED PROBE -4
 WITH WIRING DIAGRAM 8690075 AND 8690067
 *NOTICE UNLESS OTHERWISE SPECIFIED

FIGURE 1 - MODEL 101X, 102X, 103X

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ATTACHMENT: 3

DEVICE TYPE: Thickness Gauge

 CAUTION: RADIOACTIVE MATERIAL SOLD UNDER CALIF. GENERAL LIC. GL-1933-70 NDC SYSTEMS - IRWINDALE, CA
MODEL: S/N: SOURCE: STRENGTH: DATE:
DO NOT REMOVE LABEL MADE IN U.S.A.

NDC SYSTEMS - IRWINDALE, CALIFORNIA 91706 - 818-960-3300 - Model 100K Series

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.

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 shutter mechanism or indicator.

This device shall be tested for proper operation of the on-off mechanism or indicator at intervals not to exceed 12 months. Generally licensed users may perform the shutter check using instructions provided by the manufacturer in the Radiation Safety Section of the Users Manual.

The sealed radioactive source contained in this device shall be tested at installation and every three years thereafter for leakage of radioactive material. Generally licensed users may collect the sample using the instructions provided by the manufacturer in the Radiation Safety Section of the Users Manual. NDC or other specifically licensed persons must perform the test.

Maintenance, tests or other service involving the radioactive material, its shielding and containment shall be performed by persons holding a specific radioactive materials license to provide these services.

Initial installation and radiation survey, maintenance, repair and relocation outside the general licensee's facility of this device and leak testing, installation, replacement, and disposal of sealed sources containing radioactive material used in this device shall be performed only by persons holding a specific radioactive materials license to provide these services.

This device shall not be transferred, abandoned or disposed of except by transfer to a person holding a specific radioactive materials license to receive this device.

Removal of this label is prohibited.

SOLO UNDER CALIFORNIA
GENERAL LICENSE GL-1933-19

Made in USA

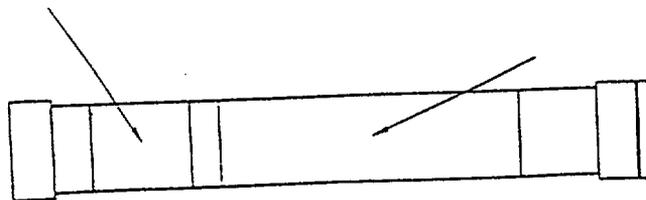


FIGURE 3 - SAFETY LABELS

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ATTACHMENT: 5

DEVICE TYPE: Thickness Gauge

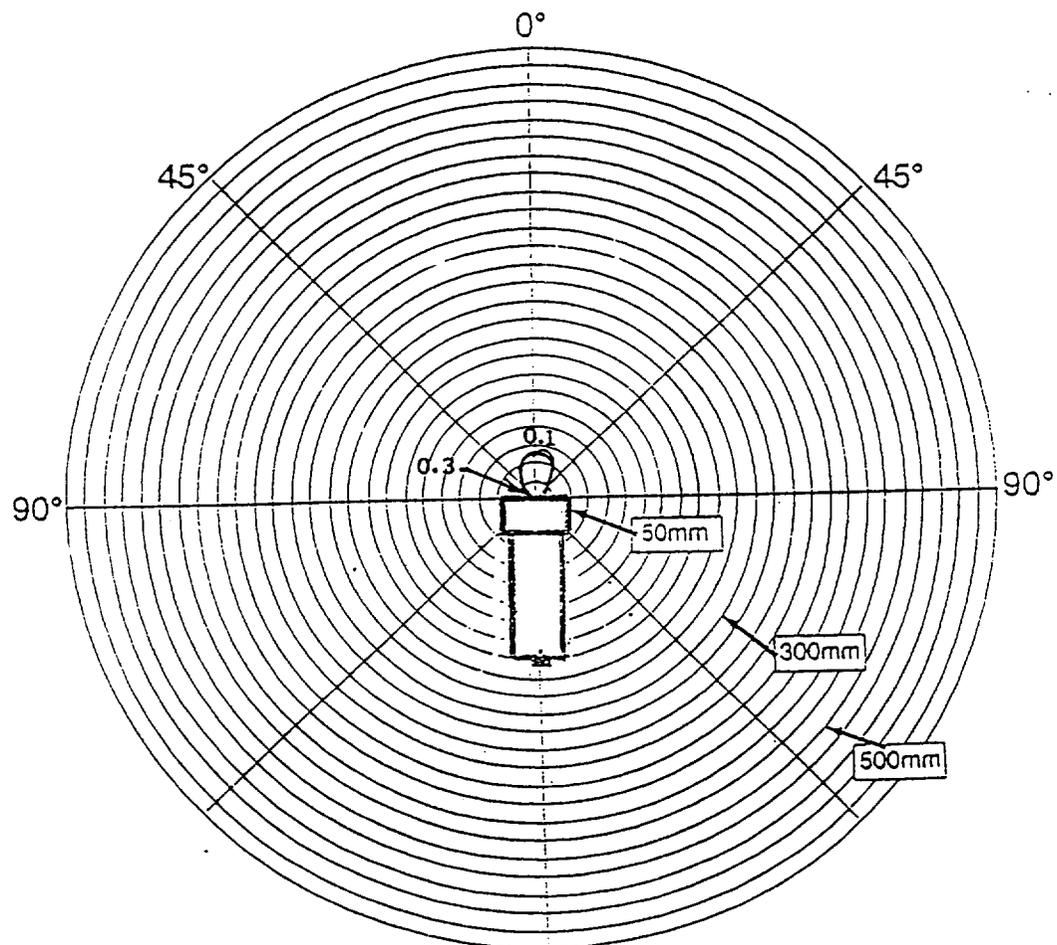


FIGURE 5 - NDC MODEL 100X SERIES PROBE
RADIATION PROFILE - SHUTTER CLOSED
Am-241 Source - 150 mCi

Readings are at mr/hr