

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

NO.: CA0471D101B

DATE: February 6, 2006

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SEALED SOURCE TYPE: Thickness Gauge

MODEL: 105, 107

MANUFACTURER/DISTRIBUTOR:

NDC Infrared Engineering, Inc.
5314 North Irwindale Avenue
Irwindale, CA 91706

SEALED SOURCE MODEL DESIGNATION:

Amersham Model CLCL,
Amersham AMC.D3 (was Model AMC.66)
Amersham Model AMCL

ISOTOPE:

Curium 244 (Model CLCL)
Americium 241 (Model AMC.D3)
Americium 241 (Model AMCL)

MAXIMUM ACTIVITY:

250 millicuries
150 millicuries
100 millicuries

LEAK TEST FREQUENCY:

Six (6) months for Cm-244 sources
Three (3) years for Am-241 (AMC.D3)
Six (6) months for Am-241 (AMCL)

PRINCIPAL USE: X-ray Fluorescence (U)

CUSTOM SOURCE: _____ YES NO

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DESCRIPTION:

The Models 105 and 107 detector/source housings are the scintillation detector and source housing parts of the NDC X-ray Fluorescence Gauge System. The radioactive source is enclosed in a tungsten holder and locked into the holder by both epoxy cement and a pin that permanently locks a tungsten holder plug to the tungsten body.

The tungsten collimator together with the source is held in position by a steel rod that has been brazed onto the collimator, and similarly brazed to a threaded stainless steel ring that holds the crystal detector.

This assembly screws onto the probe body into contact with the photomultiplier tube. A special tool is required to screw this component in and out. A special head screw threaded through the probe body is tightened against this assembly so that the source/detector is locked in. This screw access is hidden by the final assembly steps of the shutter. The shutter actuator arm threads into the assembly covering up access to this locking screw. A special tool is needed to unscrew the actuator arm.

The manual shutter is a tungsten blade that pivots across the front of the source. This is accomplished by the manual movement of a positioning arm from one indent position to another indent position. The positioning arm is well below the plane of the source, and there is no detectable radiation at that location. When the shutter is open, a red warning strip is visible.

As an option, the manufacturer can provide compressed air actuated automatic shutter assemblies that contain a "spring activated close on loss of air" feature as a safety device. These shutters are equivalent to the manually operated shutter in attenuation and do not affect the ANSI classification.

The Model 105 can contain either Cm-244 in Model CLCL or Am-241 in the Model AMCL source capsule and the Model 107 contains Am-241 in the Model AMC.D3 source capsule. Other differences include sensitivity, type of substrate measured or application in industry.

LABELING:

The Models 105 and 107 are labeled in accordance with Title 17, California Code of Regulations Section 30192.1 (equivalent to 10 CFR 32.51) for General Licensees, and 10 CFR 20.1901.

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DIAGRAM:

Attachment 1: XRF Probe Assembly with Manual Shutter
Attachment 2: XRF Probe Assembly with Auto Shutter
Attachment 3: Radiation Profile 105 with Cm-244 (CLCL)/107 with Am-241 (AMC.D3)
Attachment 4: Radiation Profile 105 with Am-241 (AMCL)

CONDITIONS OF NORMAL USE:

These devices are intended to measure the amount of coating laid down on a substrate. The following conditions apply:

Temperature: 15 degrees C to 25 degrees C

Pressure: Atmospheric

Vibration: Essentially zero

Corrosion: Essentially zero

Dust: Essentially zero

The gauges are on-line devices, making measurements either just after the coating is applied, or after the coating has been dried. Manufacturers of magnetic tape products are the most likely users. The maintenance of a high benign atmosphere is essential to the manufacturing process.

Other possible industrial users would be photographic paper manufacturers, manufacturers of metallic coated plastics or other manufacturers measuring specialized coatings. The plant conditions would be no different than described above.

The detector/source housing will be installed by the manufacturer at a fixed location and, aside from opening and closing the shutter, will not be a line component requiring operator manipulation.

PROTOTYPE TESTING:

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One device has been tested by the manufacturer for effects of 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 degrees 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 for all models except for the **Model 105 containing a AMCL source for which the classification is 84-233-985-R3.** This is based on tests in accordance with NBS Handbook No. 129, the ANSI classification of the Amersham source and the 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 3. A profile for the AMCL source taken with a Victoreen 450B is also provided as Attachment 4. With the source in the closed position, the radiation field is less than 2 mrem/hour on any surface. The Radiation levels for Cm-244 and Am-241 were reported as identical except as noted. **The main difference when the AMCL source is used is that the radiation field is more collimated by the probe construction yielding nearly identical forward radiation values with less stray radiation perpendicular to the primary beam.**

QUALITY ASSURANCE AND CONTROL:

There is 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.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

1. The device may be used by specific or general licensees of the NRC or Agreement States.
2. Installation, initial testing, training, relocation, maintenance, tests or other service involving the radioactive material, its shielding and containment shall be performed by NDC or by persons holding a specific radioactive materials license to provide those services.

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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 proper functioning or the on/off mechanism or indicator at intervals not to exceed six months.
6. The device shall be tested for radioactive leakage by NDC at time of installation and at intervals thereafter of not longer than six months for Curium 244 sources and not longer than three years for Americium 241 sources. The leak test shall be capable of detecting 0.005 microcuries of removable contamination. Generally licensed users may collect the sample from the Model 105 and 107 using the instructions provided by the manufacturer in the Radiation Safety Section of the Users Manual.
7. This registration 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 manufacturer states that the Models 105 and 107 are comparable to the generally licensed Model 103, and can be safely operated by persons having no previous training in its use.

Under the conditions of use specified above, its housing cannot be removed inadvertently during routine or extreme conditions of use. It is unlikely that any person would receive external radiation doses in excess of 10 percent of the limits specified in 10 CFR 20. 1201 (a).

Under accident conditions associated with handling, storage and use of the Model 105/107 Device, it is unlikely that any person would receive an external 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 THE BODY

DOSE

**Whole body; head and trunk; active blood forming organs
Gonads; or lens of eye**

0.15 Sv (15 rem)

**Hands and forearms; feet and ankles; localized areas of
Skin averaged over areas no larger than 1 cm² (.15 in²)**

2.0 Sv (200 rem)

Other organs

0.50 Sv (50 rem)

Based on review of the Model 105/107, and the information and data provided, we conclude that this device is safe for industry use and is acceptable for licensing and distribution. Furthermore, we conclude that the device would be expected to maintain containment integrity for normal conditions of use and accidental conditions that might occur during uses specified in this certificate.

REFERENCES:

This certificate of registration is based on information and test data contained in the following supporting documents which are hereby incorporated by reference and made part of this registry document:

1. NDC Systems letter with enclosures (quality assurance included) dated April 20, 1983.
2. NDC Systems letters with enclosure dated June 6, 1983, and the letter dated November 13, 1984.
3. NDC Systems letter with enclosure dated June 12, 1985 (addition of Model 107).
4. NDC Systems application dated November 15, 1985 (addition of Model 106).
5. NDC Systems letters (with attachments) dated July 30, 1986 and December 29, 1986.
6. NDC Systems letter (with attachments) dated February 24, 1988 and May 4, 1988.
7. NDC Systems letter (with attachments) dated March 17, 1995 and May 10, 1995.

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8. NDC Systems letter dated October 4, 1995, with attachments thereto.
9. NDC Systems letter dated May 9, 1997, with attachments thereto.
10. NDC Infrared Engineering letter dated January 8, 1999, with attachments thereto.
11. NDC Infrared Engineering letter dated April 13, 1999, with attachments thereto.
12. NDC Infrared Engineering letter dated March 7, 2005, with attachments thereto.

ISSUING AGENCY: California Department of Health Services

DATE: 2/16/06

REVIEWED BY: Bonnie Bessemer
Bonnie Bessemer

DATE: 2/16/06

CONCURRED BY: John A Fassell
John Fassell, CHP

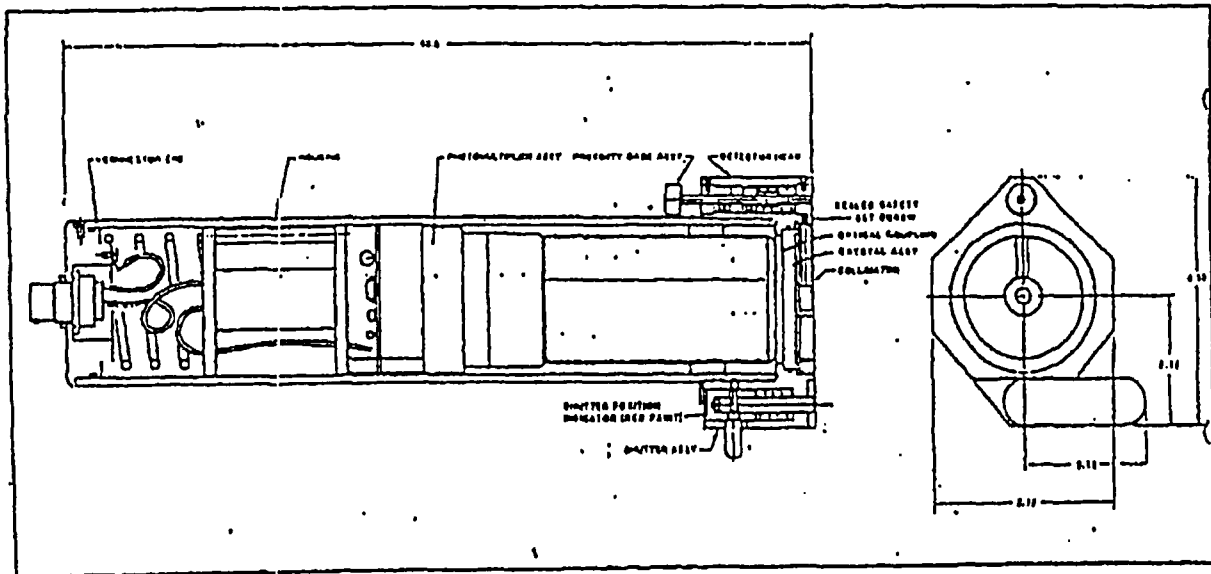
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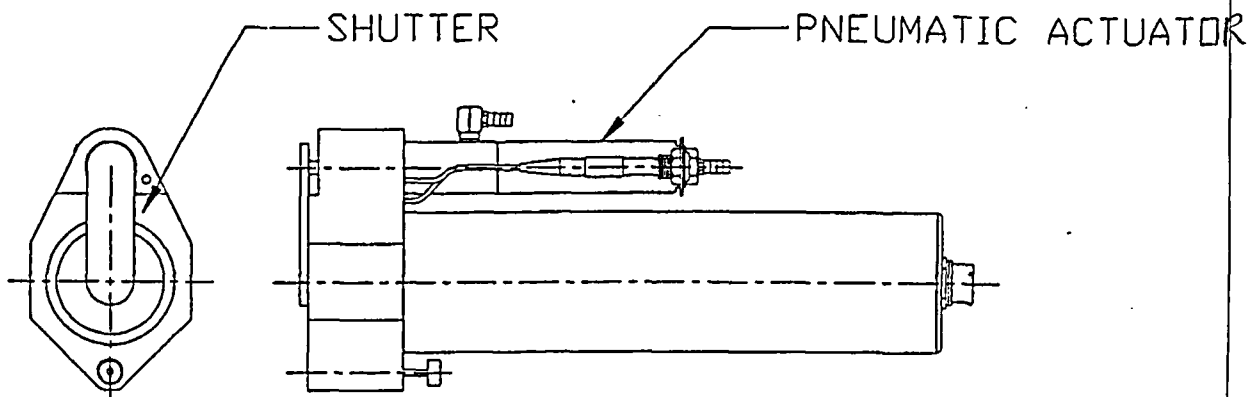
DATE: February 6, 2006

ATTACHMENT: 1

SEALED SOURCE TYPE: Thickness Gauge



XRF Probe Assembly



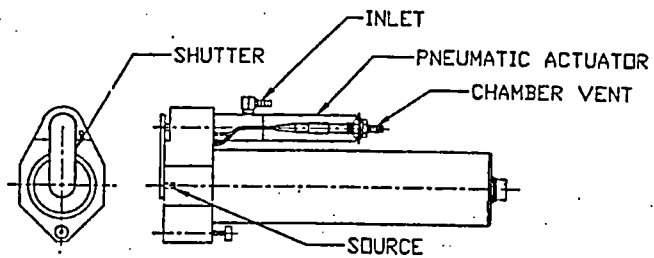
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ATTACHMENT: 2

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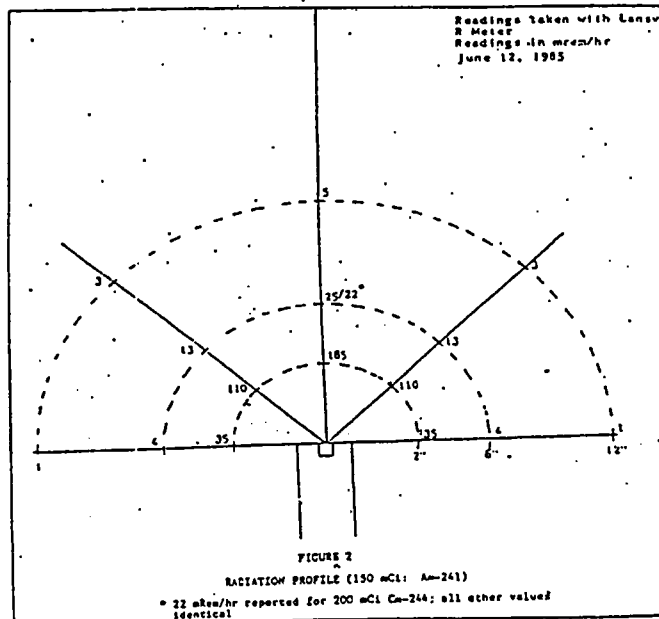
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ATTACHMENT: 3

SEALED SOURCE TYPE: Thickness Gauge



Radiation Profile

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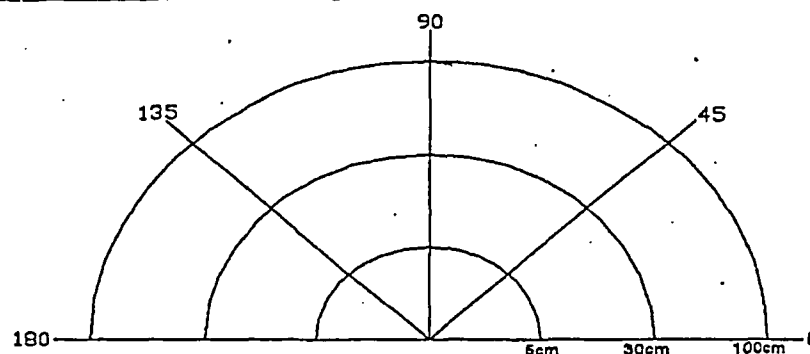
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SEALED SOURCE TYPE: Thickness Gauge

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Exposure Rate - mR/hr (7mg/cm ²)						
Position	Shutter Open			Shutter Closed		
	5 cm	30 cm	100 cm	5 cm	30 cm	100 cm
90	189.6	20.5	1.98	0.03	< 0.01	< 0.01
45	29.2	6.3	0.75	0.02	< 0.01	< 0.01
0	0.95	0.03	< 0.01	0.02	< 0.01	< 0.01
135	20.5	4.6	0.51	0.03	< 0.01	< 0.01
180	0.67	0.03	< 0.01	0.02	< 0.01	< 0.01

Exposure Rate - mR/hr (300mg/cm ²)						
Position	Shutter Open			Shutter Closed		
	5 cm	30 cm	100 cm	5 cm	30 cm	100 cm
90	182.6	16.6	1.66	0.03	< 0.01	< 0.01
45	29.1	3.9	0.5	0.03	< 0.01	< 0.01
0	0.31	0.03	< 0.01	0.03	< 0.01	< 0.01
135	19.1	3.3	0.46	0.03	< 0.01	< 0.01
180	0.3	0.03	< 0.01	0.03	< 0.01	< 0.01

Radioactive Sensor Model: 105 Source Serial Number: 2357CW (Capsule AMCL)

Isotope: Am-241 Activity: 100mCi (3.7 GBq) Date of assay: 11-Feb-05