

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

NO: CA0471D108B
(supersedes OH1033D101B)

DATE: April 9, 2012

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DEVICE TYPE: Gauging system

MODEL: TG-2

**MANUFACTURER/
DISTRIBUTOR**

NDC Infrared Engineering, Inc.
5314 North Irwindale Avenue
Irwindale, CA 91706
Phone: (626) 960-3300
FAX: (626) 939-3862

**SEALED SOURCE
MODEL DESIGNATION:**

ABB Inc Models S-16, S-18

Eckert & Ziegler Isotope Products Models
AM1.G55, SIFQ 2820, SIFQ 6494, SIFW 517,
SIFV 328, SIFQ 8213, SIFK 6108

QSA Global (AEA Technology) Models CLC.D1,
AMC.30

ISOTOPE:

Strontium-90

Curium-244

Americium-241

MAXIMUM ACTIVITY:

(b)(7)(F)

LEAK TEST FREQUENCY:

6 months

PRINCIPAL USE:

(D) Gamma Gauge
(E) Beta Gauge

CUSTOM DEVICE: _____ YES X NO

B/1

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DEVICE TYPE: Gauging system

DESCRIPTION:

The NDC Model TG-2 gauging device is designed for gauging physical characteristics of processed materials such as the thickness, density, weight per unit area or length, or composition of the measured material. The device is always mounted in a fixed geometry with the detector housing. The detector housing is mounted in front of the beam port of the device. Either the material being measured is passed between the device and the detector, or the device and the detector are moved simultaneously maintaining their geometrical relationship over the material to be measured. The air gap between the source housing and the detector ranges from 0.5 cm (0.2 inches) to 10 cm (4 inches) for beta emitting sources and up to 70 cm (30.3 inches) for gamma emitting and bremsstrahlung sources.

Installation

The device is installed at fixed locations by the manufacturer or another specific licensee of the NRC or an Agreement State that is licensed to do so. The device may be installed into existing manufacturing equipment or onto a frame or scanner that is incorporated into the process. The device may be mounted in laboratories or similar locations.

Size/Dimensions

The dimensions of the device range from 130 to 210 mm (5.12 to 8.27 inches) wide by 140 to 230 mm (5.51 to 9.06 inches) high by 400 or 820 mm (15.75 or 32.28 inches) long. The device consists of an outer shell, the sealed source, source holder, shutter mechanism, source holder adaptor, and various electronic components. A drawing of the device is shown in Attachment 1.

Construction

(b)(7)(F)

reduced

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DESCRIPTION: continued

Linear drive shutter and source holder

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Rotary shutter and source holder

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Mode of operation and safety features

The shutter mechanism is operated by an air or electric actuator. The actuator is equipped with a fail-safe spring mechanism that will automatically return the shutter to the closed position if there is a power failure.

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The device is operated as part of a larger measurement and control system that is computer controlled. The computer control system may be located in a remote location. The system software and logic determines if the conditions are appropriate (material to measured is present, line is moving, etc.) for the shutter to open. However, the operator at the computer can close the shutter by executing a command such as "off sheet" which will automatically close the shutter. The device may also be equipped with a mechanism that allows the shutter to be closed by executing a lockout control at the operator's station or at the scanner.

In devices manufactured by ABB, a firelock was generally added to the shutter mechanism to hold the shutter in the closed position under extreme accident temperatures. The firelock operates by melting the lead solder holding a spring mechanism in place, and when the spring is released, it holds the shutter in the closed position. It is not a user serviceable part and is released at temperatures that would have destroyed the device electronics.

Modifications

The device is designed to withstand the environmental conditions listed in this document. If more extreme conditions are expected or realized, the manufacturer may substitute different materials for the source base plate, source head, and side covers and/or may plate, coat or treat these components to achieve higher performance after prior written approval by the Department.

On/Off indicators

The shutter position is indicated by lights in the immediate vicinity of the device. The lights are red **when** shutter open, and green **when** shutter closed. Large indicator lights are mounted to U – or C – frame applications. The lights are mounted so they are readily visible to anyone working in the area near the device. Additional indicator lights may be located throughout associated areas. This could include lights or video displays at the operators monitoring and control stations.

Model name changes/replacement

The model TG-2 incorporates three alternative shutter designs and replaces the earlier ABB models M-3, M-3D, U-6, U-6D, U-8, and U-8D. The model TG-2 uses the same

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source housing which was used in these other devices. The primary change is that the model TG-2 is the source housing which was used in the models and this change allows the device to be mounted to various types of frames or existing process machinery.

Sealed source model name changes

The ABB sealed source S-18 includes several model numbers currently manufactured by Eckert and Ziegler Nuclitec and distributed under Eckert and Ziegler Isotope Products. These sources were formerly manufactured by QSA Global. These model numbers are currently:

SIFQ 2820
SIFV 328
SIFQ 6494
SIFQ 8213
SIFW 517
SIFK 6108

Prior Device Registrations:

- December 13, 2004 – Add source housing and conversion to Ohio SS&D registration. The TG-2 was previously registered under NR-1033-D-101-B.
- February 25, 2005 – Correct cover page to reflect company name change.
- November 1, 2010 – Add source model numbers. The ABB S-18 sources currently include several model numbers manufactured by Eckert and Ziegler. These sources were added to the SS&D registration.
- April 9, 2012 – Transfer of Ohio SS&D registration OH1033D101B to California SS&D registration CA0471D108B.

Transportation

The sealed sources are submitted, and maintained by their individual manufacturers for certifications as special form sources.

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LABELING:

The devices are labeled in accordance with **10 CFR Part 20 and 10 CFR 31 and 32, or equivalent Agreement State regulations**. The labels contain the radiation symbol, isotopes, activity, model number, serial number, name of the manufacturer, and the word "CAUTION – RADIOACTIVE MATERIAL".

When distributed as a generally licensed device, the device is additionally labeled in accordance with **10 CFR 31.5 or equivalent Agreement State regulation**.

The "Caution, Radioactive Material" label is attached to the end of the device and to the outer shroud, carriage, frame, or mounting assembly containing the device so that it is clearly visible after the device is installed. Label is either self-adhesive with the added information (isotope, activity, date of assay, serial number, model number) entered by typing and covered by a clear laminate or is fabricated from anodized aluminum, attached with screws, and the information die stamped. NDC will choose a label sufficient to withstand the environment in which the device is installed. The label has a yellow background and a magenta trefoil symbol.

Additionally, a general license label will be attached to the end of the devices distributed to the general licensees. The label will be attached to the device and to the outer shroud, carriage, frame, or mounting assembly containing the device so that it is clearly visible after the device is installed. The label is either self-adhesive or is fabricated from anodized aluminum, attached with screws. NDC will choose a label sufficient to withstand the environment in which the device is installed. The label has a **grey** background with black lettering.

The manufacturer's name is displayed on other labels and emblems attached to the supporting structures of the device. Copies of the labels are shown in Attachment 2.

DIAGRAMS:

There are two attachments.

Attachment 1: Diagram of TG-2 device

Attachment 2: Device labels

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CONDITIONS OF NORMAL USE:

The device is intended for use in industrial gauging applications. Typical environments are those associated with measurement and control applications such as paper machines, metals rolling mills, plastic extrusion lines, fiberglass mat lines, or tire fabric calendars. Operating temperatures may vary from 0°C to 200°C (32°F to 392°F). The temperatures will typically not exceed 125°C (257°F). The device will withstand humidity up to 100% RH. Vibration, shock, and corrosion will be typical of those associated with applications listed above.

In operation the source housing is typically sealed. Purging and temperature control may be included if the application requires it to prevent condensation and corrosive conditions that might adversely affect shutter operation.

If the source housing is to be subjected to more extreme environments that would require different materials of constructions, coatings or treatments of the materials, the manufacturer shall make the substitution only after prior approval by the **California Department of Public Health**.

PROTOTYPE TESTING:

According to the manufacturer, the expected useful life of the linear shutter design is 200,000 cycles. This represents the typical number of shutter operations a device may encounter during 10 years of use.

A prototype of the linear shutter mechanism (source, source holder and complete shutter mechanism) similar in design to Model TG-2 shutter mechanism was subjected to the Underwriters Laboratories four-hour fire test. The test consisted of the device being subjected to a temperature of 2000°F (1093°C) for four hours followed by being dropped six feet while incandescent.

The shutter mechanism was then immediately quenched in water at 68°F (20°C) and then dropped fifteen feet on each of its three major axes. After the test, the source remained in the device and leak tests indicated no leakage of byproduct material. A prototype of the rotary shutter was subjected to similar testing with similar results.

As stated, the model TG-2 had been manufactured and distributed by ABB Industrial Systems, Inc. as part of the Models M-3, M-3D, U-6, U-6D, U-8 and U-8D. The device

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has demonstrated the capability to withstand the typical shock, vibration and corrosion expected in typical operating environments.

EXTERNAL RADIATION LEVELS:

The following is the maximum external radiation levels from the device when mounted with a detector unit. These levels were taken from iso-distance radiation patterns submitted by the manufacturer.

The manufacturer states that the patterns were prepared using the procedures specified in ANSI N538-1979 and represent the worst case situations as determined from data of actual measurements of all of the geometric combinations envisioned.

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As stated, the above levels represent the worst case mounting configurations. However, once installed the external radiation levels may be lower because of external shielding. In addition, because these housings are usually mounted within a frame or existing machinery, the workers will usually not be able to get within 30 cm (11.8 inches) of the device.

When installed at a general licensee's facility the radiation level will be controlled with external shielding, barrier, and location such that dose rate at continuously occupied workstations will not exceed 2.5 uSv/hr (0.25 mR/hr). In addition, maximum radiation levels on the surface of the application will not exceed 500 uSv/hr (50 mR/hr) when the shutter is in the closed position.

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QUALITY ASSURANCE AND CONTROL:

The manufacturer maintains a quality assurance and control program that has been deemed acceptable for licensing purposes by the Department.

Manufacturer has committed to performing the following and other additional checks on each device prior to distribution:

- All designs conform to information submitted in support of individual applications to include materials, dimensions, within stated tolerance, manufacturing methods, and assembly methods.
- All units are leak tested to less than 185 Bq (5 nCi, 0.005 uCi).
- All units are tested for proper operation of all safety features.
- All units are verified that radiation levels do not exceed the maximum limits stated in each device application.
- Tamper resistant hardware is applied as required in the device.
- All units have the correct labeling on the device and inclusion of appropriate user manuals.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

Licensing requirements – The device can be distributed to specific or persons generally licensed by the California **Department of Public Health, or another Agreement State, or NRC.**

Leak testing – These devices must be leak tested by a specific licensed person at intervals not to exceed six months, using techniques capable of detecting 185 Bq (0.005 uCi) of removable contamination.

Shutter tests – Must be performed at least once every six months.

Servicing – Servicing of the device is to be performed only by the manufacturer or other specifically licensed persons who have been trained by the manufacturer. Installation, removal from installation, and maintenance of the device involving the source, its container, or shielding shall only be performed by the manufacturer or other persons specifically licensed by the **licensing state, or another Agreement State or NRC** to perform such services.

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Installation – Installation of the device may be performed only by a specific licensee.

Transfer and disposal – The device containing the sealed source may be transferred only to a specifically licensed person, or transferred to another general licensee in accordance with 10 CFR 31 & 32, or by an Agreement State equivalent regulations, or disposed of at a specifically licensed disposal facility.

Physical inspections of the device and its labeling must be conducted at least once every six months for corrosion prevention and maintenance in accordance with the manufacturer's instructions.

The expected service life of the device is 10 years, after which it should be assessed for integrity and a determination made as to whether the source/device should continue to be used or replaced.

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

REVIEWER'S NOTE: The IRM Group of Ohio has been purchased by the NDC Infrared Engineering, Inc. of California. This SS&D amendment is a transfer of the Ohio sealed source & registration sheet for the TG-2 gauging system previously manufactured by IRM Group. The Ohio registration sheet OH-1033-D-101-B superseded the prior SS&D registration sheet NR-1033-D-101-B, and the latest amendment CA-0471-D-108-B supersedes the Ohio SS&D registration. The NDC QA program and all related prior correspondences from Ohio State are on file with the California Department of Public Health.

SAFETY ANALYSIS SUMMARY:

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

- The device can be safely operated by persons not having training in radiological protection.
- Under ordinary conditions it is unlikely that any person will receive in any one year period a dose in excess of:

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5 mSv (500 mRem) TEDE
50 mSv (5 Rem) DDE and CDE to any individual organ
15 mSv (1.5 Rem) LDE to the eye, or
50 mSv (5 Rem) SDE to the skin or extremity.

- 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.	0.15 Sv (15 rem)
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 cm ² (0.15 in ²).	2.0 Sv (200 rem)
Other organs.	0.50 Sv (50 rem)

Based upon review of the Model TG-2 device, and the information and test data cited below, and history, we continue to conclude that the device is acceptable for licensing purposes.

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

REFERENCES:

The following supporting documents for the Model TG-2 device are hereby incorporated by reference and are made a part of this registry document.

1. IRM's application dated January 24, 1997, with enclosures.
2. Duke Associates' facsimile dated August 8, 1997.
3. IRM's letter dated October 15, 2004, and November 16, 2004.

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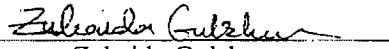
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4. IRM Group's letter dated October 12, 2010.
5. NDC Infrared Engineering letters, dated September 26, 2011, and January 10, 2012, and April 9, 2012, with attachments thereto.

ISSUING AGENCY:

California Department of Public Health

Date: April 9, 2012

Reviewer: 
Zubaida Gulshan

Date: April 9, 2012

Concurrence: 
Ronald Rogus

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ATTACHMENT 1

(supersedes OH1033D101B)

DEVICE TYPE:

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TG-2 Device

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ATTACHMENT 2

(supersedes OH1033D101B)

DEVICE TYPE:

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Labels

 CAUTION: RADIOACTIVE MATERIAL NDC, IRVINDALE, CA
<small>MODEL: S/N: SOURCE: STRENGTH: DATE: SOURCE S/N:</small>
<small>DO NOT REMOVE LABEL MADE IN U.S.A.</small>

Additional Label for General License

<p>NDC - IRVINDALE, CALIFORNIA 91706 - 626-960-3300 - Model TG-2 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 shutter mechanism or indicator.</p> <p>This device shall be tested for proper operation of the on-off mechanism and indicator at intervals not to exceed six months. Generally licensed users may perform the shutter check and change the dust cover using instructions provided by manufacturer in the Radiation Safety Section of the Users Manual.</p> <p>The sealed radioactive source (Americium-241, Strontium-90 or Curium-244) contained in this device shall be tested at installation and every six months thereafter for leakage of radioactive material. Generally licensed users may collect the sample using the instructions provided by the manufacturer in the leak test kit or in the Radiation Safety Section of the Users Manual. NDC or other specifically licensed persons must perform the test.</p> <p>Maintenance, test 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.</p> <p>Installation, relocation, maintenance, repair and initial radiation survey 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 material license to provide these services.</p> <p>This device shall not be transferred, abandoned or disposed of except by transfer to a person holding a specific radioactive material license to receive this device.</p> <p><u>Removal of this label is prohibited.</u></p> <p style="text-align: right;">SOLD UNDER CALIFORNIA GENERAL LICENSE GL-1933-19</p>
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Made in USA