

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: MA-0219-S-112-S

DATE: 10/23/95

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SEALED SOURCE TYPE: Dose Calibrator Reference Source (DCRS)

MODEL: Manufacturer's Type EGCI:

Manufacturer's Model

Distributor's Product No.

CO57-EGAG65

6112

CO57-EGAG80

6113

CO57-EGAG90

6114

MANUFACTURER: Commissariat à l'Energie Atomique (CEA)
Département des Applications et de la Métrologie des
Rayonnements Ionisants (DAMRI)
et Laboratoire de Mesure des Rayonnements Ionisants (LMRI)
BP 52
91193 Gif-Sur-Yvette CEDEX FRANCE

DISTRIBUTOR: CIS-US, Inc.
10 DeAngelo Drive
Bedford, MA 01730

SEALED SOURCE MODEL DESIGNATION:

ISOTOPE:

MAXIMUM ACTIVITY:

Cobalt-57 (Model EGAG65)

1.2 mCi/44.4 MBq

Cobalt-57 (Model EGAG80)

3.6 mCi/133.2 MBq

Cobalt-57 (Model EGAG90)

6.0 mCi/222.0 MBq

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: (X) Medical Reference Source

CUSTOM DEVICE: _____ YES X NO

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DEVICE TYPE: Dose Calibrator Reference Source (DCRS)

DESCRIPTION:

The Type EGCI Dose Calibrator Reference Source (DCRS) is used for nuclear medicine quality control procedures prescribed by 105 CMR 120.515 and equivalent requirements of other Agreement and Licensing States. Such procedures are performed frequently, and involve removing the calibrated vial source from its storage shield, placing it into the dose calibrator to obtain a measurement, then returning it to the storage shield.

The sealed source consists of a uniformity radioactive, 20 ml solid thermoplastic casting within a 27 ml shatterproof polyethylene vial having a sealed-on polypropylene nipple-style cap. The source is supplied with an enameled lead storage shield of 10 mm thickness surrounding the active volume and 6 mm thickness over the cap section.

Safety performance classifications ISO 2919/C 22212, and AFNOR M61 002/C 22212, equivalent to ANSI 77C 22212, have been established for the manufacturer's Type EGCI Sources by the French national testing laboratory, Laboratoire National D'Essais (LNE).

Models of the Type EGCI source which contain Byproduct Material nuclides have been evaluated and listed by the U.S. Nuclear Regulatory Commission under NR-219-S-104-S. The subject Cobalt-57 models were approved by the California Dept. of Health Services under CA-621-S-103-S for distribution by Syncor International, the previous U.S. distributor for CEA/DAMRI.

LABELING:

The Type EGCI source and storage shield bear identical 1.5" x 4" paper self adhesive identification and warning labels showing: Manufacturer and distributor identification, isotope, activity, calibration date, manufacturer's model number, serial number, the trefoil radiation symbol and the words "CAUTION RADIOACTIVE MATERIAL", and the statement "This sealed source is licensed for distribution to persons licensed pursuant to the Code of Massachusetts Regulations, 105 CMR 120.500, or equivalent licenses of the U.S. Nuclear Regulatory Commission (NRC), an Agreement State or a Licensing State."

DRAWING:

See attachment 1

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DEVICE TYPE: Dose Calibrator Reference Source (DCRS)

CONDITIONS OF NORMAL USE:

Dose Calibrator Reference Sources are used by trained personnel in hospital or clinic nuclear medicine departments to perform quality control tests on radionuclide dose calibrators. The Type EEGCI DCRS has been assigned safety Performance Classification C22212, as prescribed by Standards ISO 2919 and ANSI N542-1977 for instrument calibration sources.

The product information supplied with this source states that it should be used and stored under the following conditions and restrictions:

Temperature: 0-30° C. Humidity: 5-90% RH (non-condensing)

External Pressure: Ambient atmosphere, 700-1300 millibars

Avoid contact with: concentrated acids, oxidants, ketones,

Do not: abraided, cut, puncture or autoclave, place source on a hot surface, or immerse it in any liquid.

PROTOTYPE TESTING:

Safety performance classifications ISO/C 22212 (International) and AFNOR C22212 (French) have been established for the Type EGCI sealed source, upon testing of manufacturer's prototypes by the French national testing laboratory, Laboratoire National D'Essais (LNE).

The respective ANSI, ISO (International) and AFNOR (French) standards for "Classification of Sealed Radioactive Sources" are essentially equivalent, and prescribe a minimum test classification of 22212 for calibration sources with applications and conditions of use exemplified by the Type EGCI Dose Calibrator Reference Source

EXTERNAL RADIATION LEVELS: Radiation levels by CIS-US:

mR/h/mCi Co-57 content at distance:	<u>5 cm</u>	<u>30 cm</u>
unshielded source	17	0.9
source in storage shield*	0.26	0.012

* Co-56+58 gamma radioimpurity 0.15% at measurement.

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DEVICE TYPE: Dose Calibrator Reference Source (DCRS)

QUALITY ASSURANCE AND CONTROL:

CEA/DAMRI has in place a quality assurance and control program for manufacture, testing and certification of sealed calibration sources in conformance with ISO 1677-197 (E), Sealed radioactive sources-General.

LMRI is the radioactivity measurement laboratory of the French Bureau de Métrologie (BNM), and is bilaterally recognized equivalent to the U.S. National Institute of Standards and Technology (NIST) for measurement of Cobalt-57 and many other radionuclides. LMRI certifies the following measurements for each Type EGCI Dose Calibrator Reference Source:

- Cobalt-57 activity calibration
- Radionuclide impurities present and relative percent activities
- Freedom from leakage and contamination by Wipe Test method ISO/TR 4826, 2.1.1/ANSI N542 A2.1.1

The type EGCI Dose Calibrator Reference Source is a USFDA Medical Device (21 CFR 892.1400 - Nuclear sealed calibration source, (Class I generic, 510(k) exempt), manufactured under FDA Good Manufacturing Practice (GMP) for Medical Devices (21 CFR 820) requirements pursuant to a Device Master Record (820.181) at USFDA Registered Medical Device Establishment No. 8010111, The Center for Nuclear Studies at Saclay. CIS-US, Inc. is the FDA registered initial distributor in the U.S.

Each source is received, inspected and prepared for distribution as follows:

- Inspection for conformity of documents enclosed.
- A CIS-US Product Information Pamphlet is added to the document folio.
- Each Type A packaged source is prepared for transport per USDOT and IATA requirements. A distribution record is comprised of a shipping paper and manufacturers certifications.

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DEVICE TYPE: Dose Calibrator Reference Source (DCRS)

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

These sources should not be subjected to environmental conditions which exceed its ANSI performance classification. Normal use precludes abrasion, corrosion, impact, puncture and avoided exposure to hot surfaces, concentrated acids, oxidants and ketones.

These sources shall be distributed only to persons specifically licensed by the NRC, an Agreement State, or a Licensing State. These dose calibrator reference sources shall be leak tested at intervals not to exceed six months using techniques sufficiently sensitive to detect 0.005 microcurie of contamination.

Handling, storage, use, transfer and disposal to be determined by the licensing authority but should be, at a minimum, in accordance with the product information pamphlet provided by the distributor.

SAFETY ANALYSIS SUMMARY:

Based on our review of the manufacturer's information and test data, it is concluded that subject dose calibrator reference sources are acceptable for specific licensing purposes and may be used safely by appropriately trained individuals. We have concluded that these sources are designed and manufactured in a manner to provide adequate assurance that no part of the radioactive content will be released during normal use, nor as the result of any credible adverse situation which might occur attendant to normal use.

We conclude that the type EGCI sources are acceptable for specific licensing purposes.

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REFERENCES:

This Certificate of Registration is based on information and test data for Models EGAG65, EGAG80 and EGAG90 reference contained in the following supporting documents which are hereby incorporated by reference and made part of this registry document.

- CIS-US application dated September 27, 1995
- CIS-US letter dated October 5, 1995

DATE: 10/23/95

REVIEWED BY: Agostino Savastano

Agostino Savastano

DATE: 10/23/95

CONCURRENCE: Thomas F. O'Connell

Thomas F. O'Connell

ISSUING AGENCY:

Massachusetts Department of Public Health, Radiation Control Program

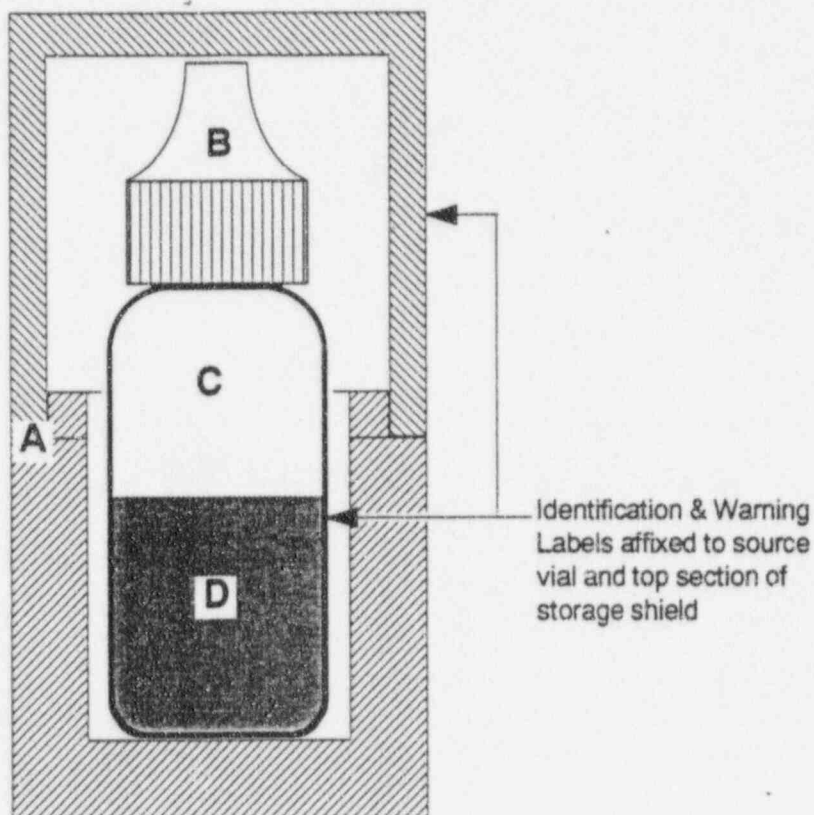
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ATTACHMENT 1

TYPE EGCI DOSE CALIBRATOR REFERENCE SOURCE, Cobalt-57



KEY	DESCRIPTION	MATERIAL - DIMENSIONS - FINISH
A	Storage Shield	Sb hard lead, med. blue enamel exterior finish, 55 mm \varnothing x 102 mm, 10 mm shielding in base, 6 mm in cover. Assembled weight 1.4 Kgm
B	Sealed Source Cap	Polypropylene, med. blue resin, nipple-style, 24 mm \varnothing - 28 mm h. 8 mm \varnothing nipple at top. Threaded on with sealant.
C	Sealed Source Vial	Low density polyethylene, 27 ml Boston round, 0.8 mm nominal wall. 30 mm O.D. x 70 mm. Assembled height nom. 85 mm
D	Source Matrix, Co-57	Chloride /chloro-cobalamine uniformly distributed in epoxy thermo-plastic resin; 20 ml rigid casting.