



MARYLAND DEPARTMENT OF THE ENVIRONMENT

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Governor

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Acting Secretary

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Deputy Secretary

APR 10 2003

Traci Kime, Sealed Source Device Assistant
U.S. Nuclear Regulatory Commission
Mail Stop T:8F5
Washington DC 20555-0001

RE: SEALED SOURCE & DEVICE REGISTRY

Dear Ms. Kime:

Please find enclosed a copy of the Maryland Department of the Environment's (MDE) Radiological Health Program's (RHP) Shimadzu Scientific, Inc. sealed source and device sheet MD-0600-D-101-B (amended in its entirety). If you have any questions, please feel free to contact Mr. Ray Manley at (410) 537-3301. You may also reach our office toll-free (in Maryland only) by dialing 1-800-633-6101 and requesting extension 3301. Also, you may contact this office via facsimile at (410) 537-3198.

Sincerely,

Roland G. Fletcher, Program Manager III
Radiological Health Program

Enclosure: SS&D Sheet MD-0600-D-101-B (amended in its entirety)

RGF/rem

"Together We Can Clean Up"

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

No: MD-0600-D-101-B

DATE: April 9, 2003

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DEVICE TYPE: Electron Capture Detector

MODELS: ECD-8, ECD-9/14/17 (aka ECD-9, ECD-14, ECD-17), ECD-14C
and ECD-2010

MANUFACTURER/DISTRIBUTOR: Shimadzu Scientific Instruments, Inc.
7102 Riverwood Road
Columbia, Maryland 21046
(410) 381-1227 1-800-477-1227

SEALED SOURCE MODEL DESIGNATION: Isotope Products Laboratory NER 004
(formerly New England Nuclear NER 004)

ISOTOPE: Nickel-63 **MAXIMUM ACTIVITY:** 10 millicuries (370 MBq)

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: (N) Ion generators, chromatography

CUSTOM DEVICE: _____YES ☒X_____NO

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DESCRIPTION:

The manufacturer is distributing electron capture cells Model's ECD-8, ECD-9/14/17 (aka ECD-9, ECD-14, ECD-17), ECD-14C and ECD-2010 in gas chromatograph instrumentation designated as series: GC-8XXX, GC-9XXX, GC-14XXX, GC-17XXX and GC-2010XXX. The XXX signifies cosmetic designators that do not reflect major physical or safety changes in the chromatograph (i.e. color or power supply vendor). The manufacturer has stated that the cells and devices are distributed in accordance with the following matrix:

GAS CHROMATOGRAPH MODEL	DETECTOR CELL MODEL
GC-8 Series	ECD-8
GC-9 Series	ECD-9/14/17
GC-14 Series	ECD-9/14/17 & ECD-C14
GC-17 Series	ECD-9/14/17
GC-2010 Series	ECD 9/14/17 & ECD-2010

A 10.0-millicurie (370 MBq) nickel-63 source is inserted into a stainless steel detector vessel (cell body). The radiation source is composed of a gold, platinum, nickel or copper foil evenly plated with nickel-63 on one side. The foil is curled into a cylindrical shape and inserted into the cell body so the plated surface is facing the inside. The detector vessel is sealed within a ceramic cylinder and an electrode assembly. Basic operation entails beta radiation from the nickel-63 (sealed within the cell) ionizing an inert gas. The sample (electrophillic molecules) is sent through the cell causing the electron density and number of electronic pulses to drop. The variation in the number of pulses is proportional to the density of the sample. The cells defined in this sheet are similar in construction and use. Those differences in the construction of the Models ECD-8, ECD-9/14/17, ECD-14C and ECD-2010 can be seen in the diagrams on pages 7 and 8.

LABELING:

Each detector cell is tagged (by wire) with a 1.625 inch by .375 inch (4.1 centimeter by 1 centimeter) aluminum label indicating source serial number and radionuclide. The gas chromatograph also carries a 3.1 inch by 2.4 inch (8 centimeter by 6 centimeter) "Caution-Radioactive Material" label with radiation symbol, radionuclide, and activity. This label is made of aluminum, rectangular in shape, attached by adhesive and is located on the upper left hand corner of the device door.

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LABELING (cont.):

When distributed to persons generally licensed the devices are additionally labeled in accordance with COMAR 26.12.01.01 Section C.22. A copy of the cell label and the two gas chromatograph labels can be found on page 11.

DIAGRAM:

Diagrams of Model ECD-8, ECD-9/14/17, ECD-14C and ECD-2010 cells are found on pages 7 and 8. Photographs of Gas Chromatographs Series GC-8, GC-9, GC-14, GC-17 and GC-2010 can be found on pages 9 and 10.

CONDITIONS OF NORMAL USE:

The ECDs are designed to be used in conjunction with gas chromatographs in analytical situations. The devices are expected to be subjected to environments typically found in laboratories occupied by humans. The manufacturer states that the useful lifetime of the devices is approximately 5-10 years. The lifetime is dependent on how often the cell is cleaned, the usefulness of the gas chromatograph and the requirements of the using laboratory. The manufacturer also states that a temperature to the cell greater than 350 degrees Celsius may cause damage. Even though the cell can be programmed by the user to heat greater than 350 degrees Celsius, all the gas chromatographs have overheat protection devices that prohibit the detector from reaching above that temperature. In addition, the GC-14 series and GC-17 series both have visible and audible warnings if the cell attempts to exceed the 350 degree Celsius limit. Due to the physical location of the detector cell that contains the source within the gas chromatograph, the effect of adverse conditions including accidents and fires are minimal. Access to the source for unauthorized use is both difficult and unlikely.

PROTOTYPE TESTING:

The manufacturer has submitted device prototype testing data including results from the "shielding test", "sealing test", "heat resistance test" and "impact test". The tests were conducted in accordance with Japanese testing protocol Article 5 of the Science and Technology Office Notification Number 9 (1981) "Notification Providing the Technological Standard for Prevention of Radiation Hazard Related to the Gas Chromatograph Electron Capture Detector."

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EXTERNAL RADIATION LEVELS:

The manufacturer reports that the radiation levels from the device are not discernable from background.

QUALITY ASSURANCE AND CONTROL:

The effective activity of the deposited Nickel-63 sources is calibrated by Isotope Products Laboratories. The sources are cleaned in both the flat and rolled positions and tested to yield 0.005 microcurie or less. Source foils are viewed under a minimum 30x magnification and inspected for flaking, cracking or peeling of the Nickel-63 plate. The manufacturer has a quality assurance program that is comparable to ANSI ASQ ISO 9002:1994 and was ISO 9000 certified until January 2001. The manufacturer's "*Standing Operating Procedure Systems and Integration & Test*" was reviewed and found adequate.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

1. Shimadzu ECD Cells ECD-8, ECD-9/14/17, ECD-14C and ECD-2010 may be distributed to specific or general licensees of an Agreement State or NRC.
2. The devices shall be leak tested at intervals not to exceed six (6) months using techniques capable of detecting 0.005 microcurie (185 Bq) of removable contamination.
3. Defective cells may be returned to the device manufacturer for testing (or other persons specifically licensed to conduct such activities) while any disassembly of the source from the cell may only be done by the source manufacturer (or other persons specifically licensed to conduct such activities). Cleaning of the ECD cell should be conducted by the manufacturer (or other persons specifically licensed to conduct such activities).

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LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE(cont.):

4. A general licensed detector cell may only be transferred from the general licensee to an authorized recipient.
5. This registration sheet and the information contained within the references shall not be changed without the written consent of the Maryland Radiological Health Program.

SAFETY ANALYSIS SUMMARY:

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

1. Models ECD-8, ECD-9/14/17, ECD-14C and ECD-2010 can be safely operated by persons not having training in radiological protection.
2. Under ordinary conditions of handling, storage, and use of the devices, the byproduct material contained in Models ECD-8, ECD-9/14/17, ECD-14C and ECD-2010 will not be released or inadvertently removed from the cell 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 COMAR 26.12.01.01 201(a)(i) (10 CFR 20.1201(a)).
3. Personnel operating the devices will not in the period of one (1) year receive a dose in excess of ten (10) Percent of the values in COMAR 26.12.01.01 Section D.201 (a)(i) (10CFR 20.1201(a)).
4. In the event of an accident, personnel will not receive radiation exposure or organ dose in excess of the limits in COMAR 26.12.01.01 Section D.201 (a)(ii).

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REFERENCES:

This Certification of Registration is based on information and test data contained in:

1. Application for a General License and Radioactive Source Registration dated October 9, 1986,
2. Letter dated March 11, 1988
3. Letter dated November 9, 1989
4. Letters with attachments dated December 1, 2001, August 1, 2002, August 7, 2002, August 9, 2002, August 12, 2002, August 19, 2002, August 20, 2002, October 25, 2002, March 10, 2003, facsimile dated March 12, 2003 and facsimile dated March 19, 2003.

ISSUING AGENCY:

This document is not a license to receive, possess or distribute radioactive material. Receipt, possession and distribution of radioactive materials, source, and devices containing radioactive material are subject to terms and conditions of applicable regulations and license issued by NRC or Agreement States.

DATE April 9, 2003 REVIEWED BY: Kayla T. Hurling
DATE: April 9, 2003 CONCURRENCE: Barbara J. Park

ISSUING AGENCY
Maryland Department of the Environment
Radiological Health Program
1800 Washington Blvd.
Suite 705
Baltimore, Maryland 21230

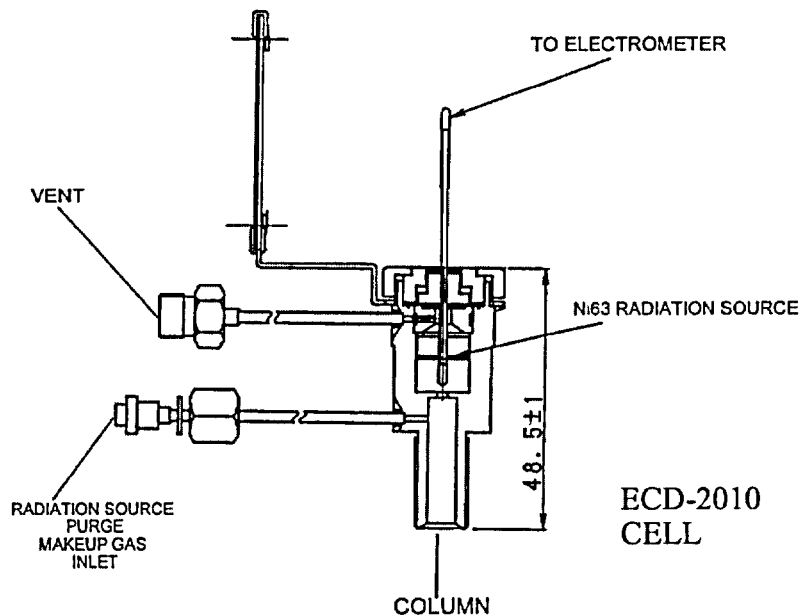
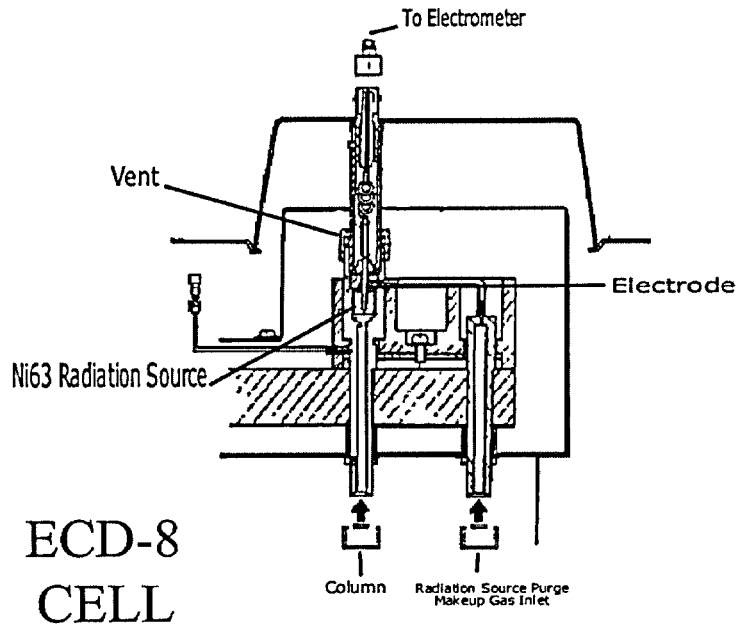
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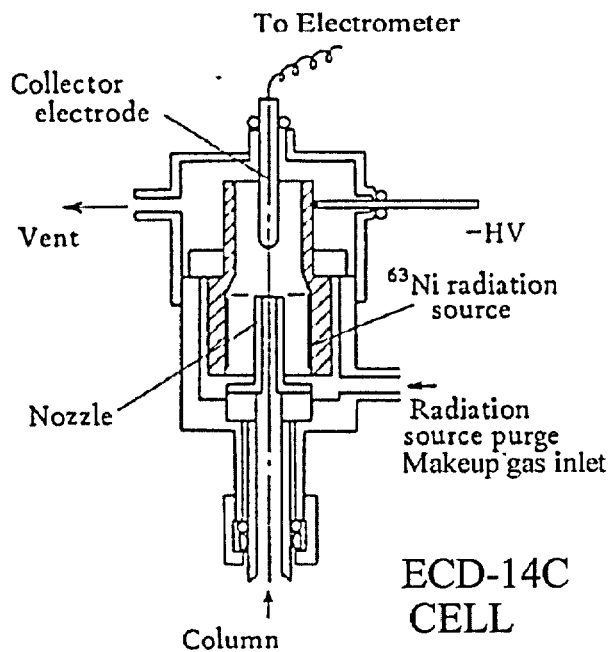
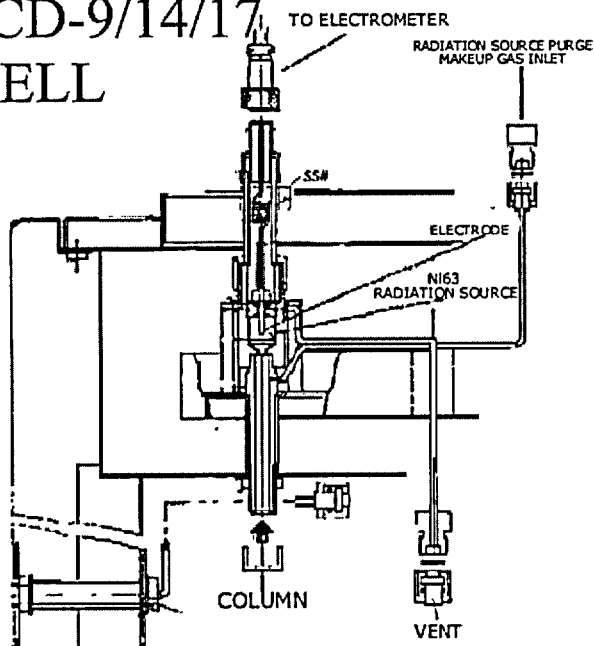
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ECD-9/14/17
CELL



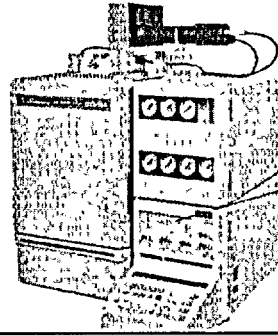
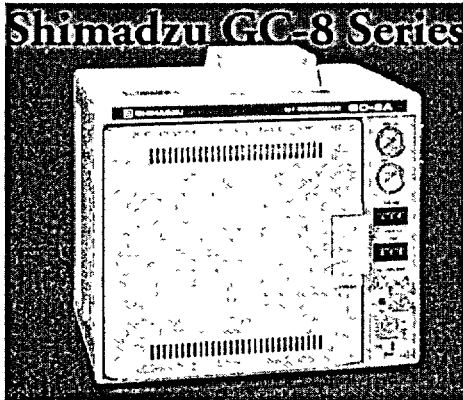
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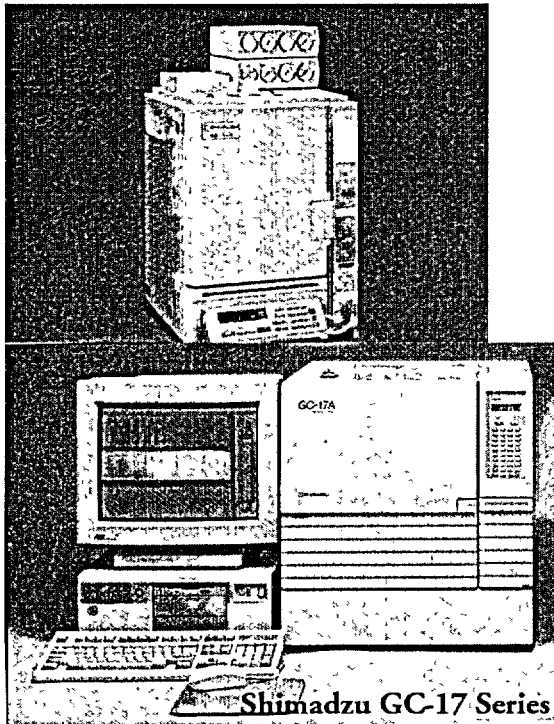
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Shimadzu GC-9 Series

Shimadzu GC-14 Series



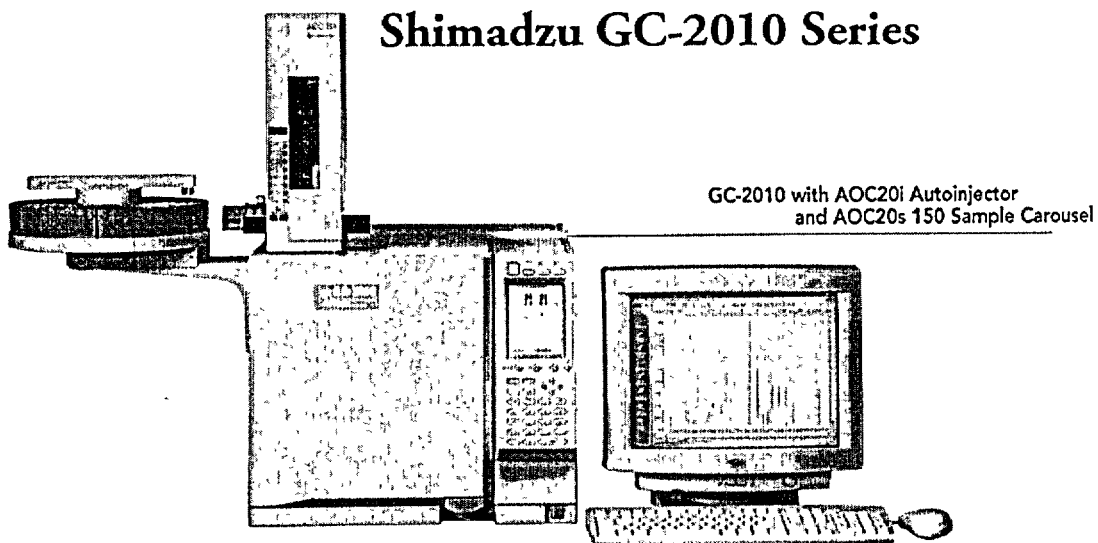
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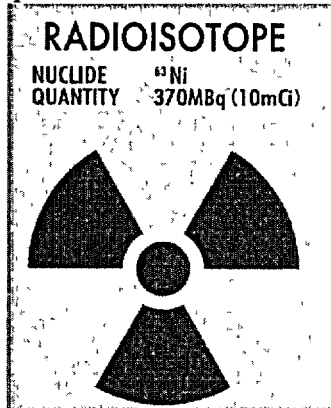
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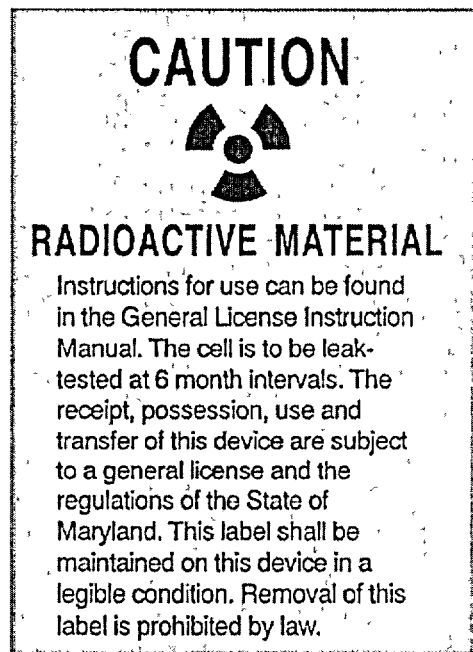
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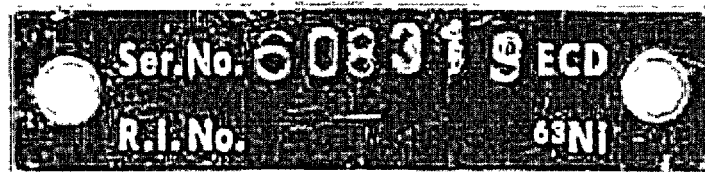
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GAS CHROMATOGRAPH LABEL



GENERAL LICENSE LABEL



CELL LABEL