

Electron Capture Detector (ECD) Licensing - Scion 436/456

by Randall Bramston-Cook, Lotus Consulting, July 13, 2018

Disclaimer – This discussion is based on information from the US Nuclear Regulatory Commission (NRC.gov) and the California Department of Public Health, Radiologic Health Section (CDPH.ca.gov). This discourse is only intended to be guidelines to regulations pertaining to possession of radioactive material in electron capture detectors. Full details are available through contact with relevant State and Federal regulations, i.e., Title 17, California Code of Regulations, and Title 10, Code of Federal Regulations.

Radioisotope nickel-63 (^{63}Ni) is treated as a hazardous material, with special protocols involving ownership and operations. The decay of ^{63}Ni generates low-energy beta-electrons that are used to create the electron cloud inside the electron capture detector. A typical source has 15 millicuries (mCi), or 555 megabecquerel (MBq) plated on a foil. The US Nuclear Regulatory Commission classifies radiation sources inside electron capture detectors in a gas chromatograph into three categories:

Specific License – This license mandates that the end user's facility receives a "material license" from the relevant regulatory agency for a permit for the ownership and handling of the radioactive material. The USNRC and Agreement States classify some sources and devices as generally-licensable, and others as specifically-licensable, and that this distinction is provided in the Sealed Source and Device Registry information for the device/source in question. Requirements for a specific license involves designation of a responsible safety officer, development and implementation of a radiation safety program, development of operating and emergency procedures and other details. The application and annual fees are dependent on the regulatory agency and activity of the source.

General License – This class can be assigned to detectors that are sealed and the radioactive foil is not accessible to the user. No licensing is required as the manufacturer, with a distribution license, can ship the detector to the end user. Some states may need to have the end user register the source. Details can be found at www.nrc.gov/materials/miau/licensing.html#gl.

Exempt Quantity – This level is a special exclusion of the source from any regulation based on the registration of the device with regulators by the manufacturer. Wipe tests, restrictions of transfer and special disposal rules do NOT apply. Pertinent regulations can be found at www.nrc.gov/materials/miau/consumer-pdts.html#quantity.

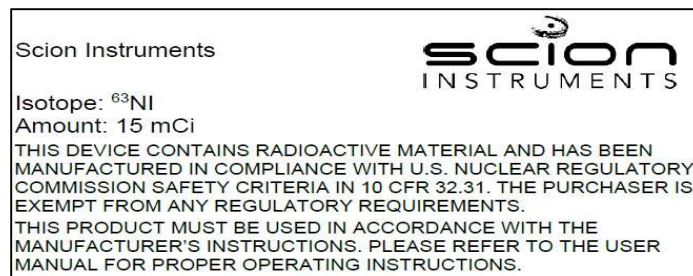
Other countries will have other regulations and registration mandates, and will not likely honor US categories of general licensing and exempt status.

Wipe Test – Specific and general licenses require regular wipe tests to determine whether radioactive material has leaked from the source. This task involves purchase of a wipe test kit (Scion part number 394904100), using the provided Q-tips pre-moistened with alcohol, and wiping prescribed areas around the detector as directed in the supplied instructions. The Q-tips are reinserted into the sealed vial and sent to the processing location. Maintenance of the wipe test records is the responsibility of the end user. Failure to keep these would constitute a violation and could result in forfeiture of the materials possessed. **EXEMPT** devices have **NO** requirements for wipe tests.

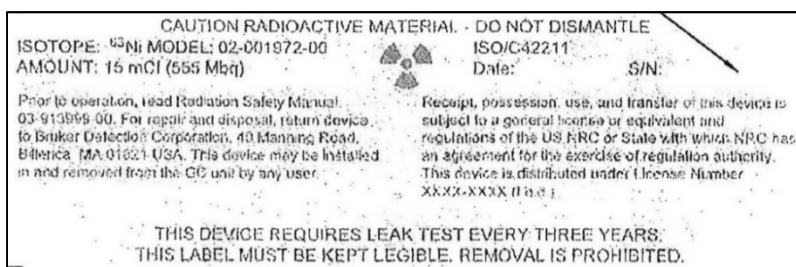
Shipments by Common Carrier – Devices covered under specific and general licenses can only be shipped to a consignee that has a specific license covering the isotope and its activity. Electron capture detectors can be shipped with Label UN2911¹ – “Radioactive Material, Excepted Package”, that exempts the package from special handling and labeling. Reference to shipping regulations is 49 Code of Federal Regulations 173.421. If transported by FedEx Ground, the package must be picked up from the shipper’s location by a FedEx truck. **EXEMPT** devices have no shipping restrictions and no special labeling.

Disposal of Source – Once a detector is beyond its serviceable life, specific and general licensed devices must be returned to a specific licensee, usually the manufacturer, for disposal. An exempt device can be disposed of through the regular trash, provided that all radioactive labels be removed beforehand.

Electron Capture Detectors in Scion 456/436 – Customer purchases of an electron capture detector after March 2015, with a detector part number of 02-001972-02 (aka 200197202) are **EXEMPT** from any regulations applied to end users in the US. The exempt Nuclear Regulatory Commission registration is NR-1385-D101-E. **NO WIPE TESTS** are required. The ECD device will normally be operated or stored in an analytical laboratory, with a rated maximum temperature of 400°C and the Ni-63 foil would be exposed to is 185°C maximum when in place. The detector will have this label attached to the tower:



Detectors for the Scion 456/436 shipped prior to March 2015 will have a part number as 02-001972-00 (aka 2001972-00). This source is covered as a **GENERAL** license device with license registry MA-1101-D-103-B. The end user is not required to possess a license. Wipe tests are mandated once every three years. The detector will have this label attached to the tower:



While this discussion can be used as a guideline, ultimately it is the responsibility of the licensee to know and follow the pertinent regulations.

¹ www.elementalcontrols.com/en/pdf/UN2911%20Label.pdf

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