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Department of Public Health  
Center for Environmental Health  
Radiation Control Program  
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January 4, 2008

John Jankovich  
SS&D Team Leader  
Division of Industrial & Medical Nuclear Safety  
Mailstop T-8F5  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555

**RE: New Sealed Source and Device  
Registration Number: MA-1059-S-185-S**

Dear Dr. Jankovich:

We have completed action on a Sealed Source and Device (SSD) registration certificate for the QSA Global, Inc. Models NBC and NBCD electron capture detector sources. The number for this sheet is MA-1059-S-185-S. Please find enclosed a copy of this sheet. This registration supersedes # NR-136-S-185-S which should be deleted from the National Registry.

If you have any questions please contact me at (617) 242-3035.

Sincerely,

A handwritten signature in cursive script that reads "John Sumares".

John Sumares  
Radiation Control Officer  
Radiation Control Program

JES/jes

Enclosure: (1)

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF SEALED SOURCE

NO: MA-1059-S-185-S  
(Supersedes NR-136-S-185-S)

DATE: December 26, 2007

PAGE 1 OF 6

SOURCE TYPE: Electron Capture Detector Source

MODEL: NBC; NBCD

DISTRIBUTOR: QSA Global, Inc.  
40 North Avenue  
Burlington, MA 01803

MANUFACTURER: QSA Global GmbH  
Gieselweg I  
38110 Braunschweig  
Germany

ISOTOPE: Nickel-63      MAXIMUM ACTIVITY: 1,110 megabequerels (30 mCi)

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: (N) Ion Generators, Chromatography  
(S) Foil Sources

CUSTOM SOURCE: YES \_\_\_ NO X

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PAGE 2 OF 6

SOURCE TYPE: Electron Capture Detector Source

DESCRIPTION:

The Model NBC source consists of nickel-63 electroplated on the base of a thin nickel or nickel alloy foil. The active, electroplated Ni-63 is covered by an inactive electroplated nickel coating at a nominal thickness of 0.1 microns. The source foil is 0.05 millimeters (0.002 in.) thick. The source foil size ranges from a minimum 3 millimeters (0.12 in.) x 10 millimeters (0.39 in.) to a maximum of 30 millimeters (1.18 in.) x 50 millimeters (1.97 in.). The active Ni-63 is loaded to a maximum concentration of 10 millicuries per square centimeter (370 MBq / cm<sup>2</sup>).

The Model NBCD consists of Ni-63 electroplated on a base of thin inactive nickel coating onto the inside surface of a detector housing. The detector housing is fabricated from stainless steel. The active, electroplated Ni-63 surface is covered by an inactive nickel coating. The maximum concentration of active Ni-63 is 10 millicuries per square centimeter (370 MBq / cm<sup>2</sup>).

LABELING:

The non-active side of the NBC foil is engraved with a unique serial number. When space permits, the non-active area of the NBCD source is engraved with a unique serial number, Ni-63, a trefoil symbol or the word "Radioactive", and the manufacturer's logo.

The following information is provided on a label affixed to the primary container for the NBC and NBCD sources: 'Ni-63, a trefoil symbol or the word "Radioactive", and the manufacturer's logo'.

Each source shipment is accompanied with a Test Report listing the model number, nuclide, activity assay results, a reference date, serial number, leak test results, and other pertinent information. The sources are distributed with 'Handling Instructions for Radiation Sources'.

DIAGRAM: No diagrams are attached.

CONDITIONS OF NORMAL USE:

These sources are typically used as beta ionizing sources and are routinely used in gas chromatography (GC) or ion mobility spectrometry (IMS) devices where the nickel-63 source is further encapsulated within a detector cell / module that is installed into a GC or IMS instrument. The nickel-63 source should be rolled on its length and inserted into the detector cell / module having a minimum inside diameter of 4 millimeters (0.16 in.).

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PAGE 3 OF 6

SOURCE TYPE: Electron Capture Detector Source

CONDITIONS OF NORMAL USE (Cont'd.):

These sources should not be subjected to temperatures which exceed 400° C (752° F).

The recommended working life of the NBC and NBCD sources is 15 years, after which the user should arrange for the source to be inspected and assessed by a qualified authority (eg. The manufacturer or other persons specifically licensed to perform such service) to extend its working life, or dispose of the product through a suitable disposal route.

PROTOTYPE TESTING:

ANSI classifications are based on test data and the source achieved an ANSI rating of 77C4X212. (Pressure test for classification X was performed at 5 kPa absolute). In addition, prototype sources were subjected to 400° C (752° F) in air for one hour followed by a thermal shock down to 20° C (68° F). Wipes of the inactive side of the sources after the test revealed no removable contamination above 0.005 microcuries (185 Bq).

Performance of the nickel foil sources as related to loss of emission (ionization current) with time when used in a 500° C (932° F) environment was shown in Amersham Corporation Technical Bulletin 79/2. Based on information originally provided by Amersham, loss of emission was due to diffusion of Ni-63 into the substrate and not leakage of the Ni-63.

The distributor states that no specific bending tests have been performed on these sources, however, QSA Global GmbH has provided these sources rolled to a minimum diameter of 4 millimeters since 2001 with no problems or customer complaints related to foil damage due to the rolling / bending process.

EXTERNAL RADIATION LEVELS:

The following dose rates were measured from a Model NBC source using a MAB 500 instrument with a SZS 0500 detector. This instrument is manufactured by Munchener Apparatebau GmbH, has a dose rate measurement range of 50 nSv / hr (0.005 mrem / hr) to 100 mSv / hr (10 mrem / hr) and is sensitive over the energy range of 33 keV to 7.5 MeV. Survey results were based on measurements taken from a 600 MBq (16 mCi) source measuring 24 millimeters (0.94 in.) long x 7 millimeters (0.28 in.) wide. Dose rate results shown below are extrapolated to the maximum source activity of 1,110 MBq (30 mCi).

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PAGE 4 OF 6

SOURCE TYPE: Electron Capture Detector Source

EXTERNAL RADIATION LEVELS (Cont'd.):

Distance from Source	Nearly on Contact (< 5 mm) with Active Side	Contact with Non-active Side
Dose Rate	< 11 $\mu$ Sv / hr (< 1.1 mrem / hr)	< 0.25 $\mu$ Sv / hr (< 0.025 mrem / hr)

QUALITY ASSURANCE AND CONTROL:

Sources are manufactured and distributed in accordance with the Quality Assurance program of QSA Global, Inc. which is in compliance with the requirements of ISO9001:2000. In addition, the Quality Assurance program of QSA Global, Inc. is compliant with Subpart H of 10 CFR Part 71 (Quality Assurance Program Approval for Radioactive Material Packages, certificate number 0040). For operations performed by vendors, these actions are controlled to QSA Global, Inc. specifications through the Quality Assurance program. The program has been deemed acceptable for licensing purposes by the Agency and a copy of the program is on file with the Agency.

The following tests are performed on all sources:

- Leak Test in accordance with ISO9978:1992(E) (or more recent editions). The removable contamination from the inactive side of the source shall not exceed 0.005 microcuries (185 Bq) and removable contamination from the active side shall not exceed 0.5 microcuries (18.5 kBq).
- Source activity is determined by Liquid Scintillation Counting assay technique. The nominal activity tolerances are  $\pm 30\%$  at time of manufacture.
- Sources are visually inspected, under a minimum of 4X magnification, for defects such as cracking peeling, or flaking of the Ni-63 plate and any physical damage after manufacture.

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PAGE 5 OF 6

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LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The sources shall only be distributed to persons specifically licensed by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State and is limited to manufacturers of gas chromatography (GC) or ion mobility spectrometry (IMS) devices where the nickel-63 source is further encapsulated within a detector cell / module that is installed into a GC or IMS instrument.
- These sources, once installed into a detector cell / module, shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 185 Bequerels (0.005  $\mu\text{Ci}$ ) of removable contamination. Removable contamination from the detector cell / module shall not exceed 0.005 microcuries (185 Bq).
- *REVIEWER NOTE:* Sources contained in a detector cell / module device may have longer leak test intervals. Consult the appropriate registration sheet for leak test intervals of a specific detector cell / module device.
- Handling, storage, use, transfer, and disposal: to be determined by the licensing authority. In view of active surface contamination levels of up to 0.5  $\mu\text{Ci}$ , source foils should not be handled with the bare hand.
- The sources shall not be exposed to environments which exceed their ANSI classification nor to temperatures which exceed 400° C (752° F).
- This registration certificate and the information contained within the references shall not be changed without the written consent of the Commonwealth of Massachusetts, Radiation Control Program.

SAFETY ANALYSIS SUMMARY:

Based on our review of the Models NBC and NBCD sources, their ANSI classification, and the information and test data cited below, we conclude that the electron capture detector sources are acceptable for licensing purposes.

Furthermore, we conclude that these sealed sources would be expected to maintain their containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

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PAGE 6 OF 6

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REFERENCES:

The following supporting documents for the models NBC and NBCD sealed sources are hereby incorporated by reference and are made part of this registry document.

- QSA Global, Inc. letters dated February 21, 2006, January 17, 2007, October 29, 2007, November 2, 2007, and December 11, 2007 with enclosures thereto.

ISSUING AGENCY: Massachusetts Department of Public Health Radiation Control Program

Date 12/26/07

Reviewer John Sumares  
John Sumares

Date 12/26/07

Concurrence J. E. Daehler  
Joshua E. Daehler