



International Isotopes Inc.

May 03, 2013

John P. Jankovich, Ph.D.
U.S. NRC
FSME/DMSSA/LISD/LB
11545 Rockville Pike
MS TWFN 8E24
Rockville, MD 20852

Subject: Request to Amend NR-1235-S-101-S.

Dear Dr. Jankovich,

International Isotopes Inc. has been manufacturing Co-60 sealed source as described in Registry NR-1235-S-101-S for the last eight years. These sources have been utilized as replacement sources in numerous devices both domestically and internationally. In some cases our source model, while equivalent to the original source provided with the device, was not authorized for use as an aftermarket source by an Agreement State regulator. I believe the March 12, 2013 NRC Regulatory Issue Summary 2013-01 Use of Aftermarket Sealed Source Registered Under 10 CFR 32.210, (RIS 2013-01) provides the guidance necessary for NRC and Agreement State regulators to evaluate the suitability of an aftermarket sealed source for use in a device.

As explained in RIS 2013-01, the equivalency determination includes confirming "The registration certificate of the aftermarket source must state which other sources the aftermarket source can be substituted for." This being the case I am requesting an amendment to Registry of Sealed Sources and Devices Safety Evaluation of Sealed Source number NR-1235-S-101-S to incorporate a list of sealed sources that the Model INIS-SF- XX-YY-Z can replace.

I believe this information is best suited in the Limitations sections of NR-1235-S-101-S and are provided on Page 2 of this letter.

Should you have any questions, please contact me by phone at (208) 524-5300 or by email at jjmiller@intisoid.com.

Sincerely,

John J. Miller, CHP
Radiation Safety Officer
JJM-2013-19

Requested Revisions to NR-1235-S-101

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Revisions, annotated with underlined text, to the Limitations and/or Other Conditions of Use section on Page 6 of 7 of NR-1235-S-101-S are suggested as follows:

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The sources shall be distributed only to persons specifically licensed by the NRC or an Agreement State.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority. In view that these sources exhibit high dose rates, the sources should be handled only by properly qualified personnel using adequate remote handling equipment and procedures.
- The sources shall be leak tested at intervals not to exceed 6 months using techniques and equipment capable of detecting 185 Bq (0.005 uCi) of removable contamination.
- The source assemblies shall not be subjected to conditions that exceed its ANSI N43.6-2007 classification, 07E53524 (5).
- The physical, chemical and radiological properties of the INIS-SF-X.X-YY-Z series source have been evaluated and found to be equivalent and acceptable for use as aftermarket sources in devices designed to utilize the sources listed in the table below:

Source Make	Source Model	Registration Number:
MDS Nordion	C-146	NR-220-S-116-S
MDS Nordion	C-151	NR-0220-S-115-S
MDS Nordion	C-188	NR-0220-S-103-S
MDS Nordion	C-198	NR-169-S-151-S
Neutron Products	NPTT - Series	MD-474-S-109-S
J.L Shepherd	JLS - 7810	CA-598-S-122-S

Note: The above source models are have an authorized range of geometries. The Model INIS-SF-X.X-YY-Z series replacement will be sized to meet the dimensions of the original source.

- When an INIS-SF-X.X-YY-Z source is distributed as an aftermarket replacement source, a metal name plate that lists the Radionuclide, Source Model, Serial Number, Source Activity and Reference Date along with the phrase, “Caution Radioactive Material” with the radioactive trefoil symbol is provided with the source to be affixed onto the device. The original label, if still attached to the device shall remain on the device.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.