From: "John J. Miller" <jjmiller@intisoid.com>
To: "John Jankovich" <JPJ2@nrc.gov>
Date: 01/25/2007 5:03:28 PM
Subject: International Isotopes Inc. Co-60 Source SS&D NR-1235-S-101-S

John,

I am attempting to address a question raised by the State of Wisconsin in regards to the use of our Co-60 sources in a Theratron 780. Below I have drafted an email but I want you to read it before I send it out with the folks form Wisconsin, (regulators and customer) cc'ed. I didn't want to send it out everybody and put you on the spot. If you don't think my proposed email adequately addresses the concern then please let me know and I will attempt a different route.

John

Dr. Jankovich,

The State of Wisconsin has raised a question regarding the use of our Co-60 sealed source (SS&D NR-1235-S-101-S) in an MDS Nordian Theratron 780. We have been asked to provide a source for this device however the SS&D for the Theratron 780 (NR-220-D-117-S) specifies the MDS Nordian C-146 or C-151 as the Sealed Source Model Designation. Because the SS&D for the Theratron 780 fails to mention the International Isotopes Inc Co-60 source design and NR-1235-S-101-S doesn't specifically list the Theratron 780 the question the State of Wisconsin raises is: Is the International Isotopes Inc. Model INIS-SF-X.X.-YY-Z Co-60 sealed source manufactured in accordance with NR-1235-S-101-S authorized for use in the Theratron 780?

There appears to be an expectation that the SS&D for a sealed source should include a list of devices in which the source may be used. A good example of this is in the NPI SS&D MD 0474S109S which includes a 4 page table that lists devices in which their source design may be used, which I suspect is a list of all units with drawers that could accommodate their source design at the time of the SS&D submittal or revision. When I see such a list I instinctively question what it may imply? Has the manufacturer installed one of their sources in each device listed? Does the manufacturer maintain updated SS&Ds for each device on the list? Does the manufacturer only provide a source for a device that is on the list? And did the source manufacturer receive approval from the manufacturers of the devices listed to specifically name their device? It is interesting to note that while the SS&D for the Theratron 780 lists the C-146 or C-151 sealed sources, the SS&Ds for the C-146 and C-151 fail to mention the Theratron 780 or any other teletherapy device for that matter.

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As I prepared the application for Safety Evaluation for our Co-60 irradiator and teletherapy source, now covered by NR-1235-S-101-S, I deliberately left such a list out of the application. I feel such a list goes beyond the intent of the National Sealed Source and Device Registry (NSSDR) and including such a list would then raise the aforementioned questions. And if the questions regarding the list are not raised then what is the point of a list of devices to begin with? The physical source dimensions and radioactivity content would limit what device a source could be used in.

If one where to review the regulations, Title 10, §32.210 Registration of product information, and for this specific instance in regards to the use of a Theratron 780, Title 10, §32.210, Use of a sealed source in a remote after loader unit, teletherapy unit, or gamma stereotactic radiosurgery unit, as well as the guidance provided by NUREG-1556 Vol. 3 Rev.1, Applications for Sealed Source and Device Evaluation and Registration, there is nothing in the regulations or the guide that suggests the device or devices a source may be used in is included on the SS&D. Section 4.9 Sealed Sources and Devices for Medical Use includes the following statement: "Prior to evaluation of a sealed source or device for medical use, the applicant must provide proof of Federal Drug Administration (FDA) Approval. Sealed sources are evaluated either as part of a medical device or separately when they can be interchanged in several devices. FDA uses the term "device" for both sealed sources and devices." This paragraph acknowledges that sources may be interchanged among devices but there is nothing that suggests sources must be tied to specific devices. However the same isn't true for the devise, intuitively a devise would list a source or else there is no need for it to be evaluated. While the regulatory guide does not mention what class a teletherapy source falls into, it is important to note that 21 CFR § 892.5740 Radionuclide teletherapy source, categorizes medical teletherapy sources as a Class 1 device which are exempted from the FDA premarket notification procedures in Subpart E of part 807 of Title 21.

My interpretation of the regulations and guidance provided is that a source which is to be used in a medical teletherapy device or irradiator must be designed and successfully tested against criteria established in ISO 2919 and/or the ANSI N43.6-1997 for the given classification, that the source classification meets the minimum requirements for the device category (Category I, II, III, IV irradiator or medical teletherapy), that the device is manufactured by a licensee with an established quality control program, and that the source has been evaluated by the NRC or an Agreement State and is registered in the NSSDR.

I do not expect and will not request that the US NRC provide a statement that authorizes the use of the International Isotopes Inc. Model INIS-SF-X.X-YY-Z Co-60 source in the MDS Nordian Theratron 780. The NRC should not be expected to provide such a statement because it may be misinterpreted as recommending one manufacturer's product over another's. I would however request clarification as to whether an SS&D must specifically list devices a source may be used in or if it is generally accepted that sources must be used in devices for which the source is classified. In the

case of the Model INIS-SF-X.X-YY-Z, Category I, II, III, IV irradiators and Photon Emitting Teletherapy devices.

I appreciate your consideration on this matter.

John J. Miller, CHP

Radiation Safety Officer

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