Radioactive Materials Unit
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Date: March 23, 2007

To: Medical-Use Licensees

From: Radioactive Materials Unit

Subject: Yttrium-90 SIRSpheres and TheraSpheres Impurities

Information Notice 2007-06

The Minnesota Department of Health (MDH) is issuing this Information Notice to alert addresses to the presence of radioactive contaminants in two variations of commercially available Yttrium-90 (Y-90) labeled microspheres, "SIRSpheres®" and "TheraSpheres®," manufactured by Sirtex Medical, Inc. and MDS Nordion, respectively, and the possible problems with their disposal in accordance with Chapter 4731.4429. Recipients should review the information, contained in this Notice, for applicability to their facilities, and consider actions, as appropriate.

SIRSpheres® and TheraSpheres® are therapeutic devices that deliver radiation directly to tumors in the liver, using glass or resin microspheres. Y-90 is either integrated into the glass matrix or attached to the resin beads with diameters from 15 to 35 microns. Millions of these microspheres are injected into the hepatic artery, the liver's main blood vessel, in a manner that preferentially traps them in the capillary bed feeding the tumor, and not the larger blood vessels feeding healthy tissues. The SIRSpheres® and TheraSpheres® are designed to deliver radiation directly to tumors, while sparing healthy tissues.

Samples of TheraSpheres®, held for decay-in-storage, appeared to be radioactive for much longer than would have been expected, because of the presence of Yttrium-88 (Y-88) and other contaminants. The Y-90 SIRSpheres® sample contained detectable amounts of Y-88 and the TheraSpheres® sample had measurable amounts of the following radionuclides:

- Y-88 (half-life of 106.6 days);
- Europium-154 (half-life 8.8 years);
- Europium-152 (half-life 13.6 years);
- Cobalt-57 (half-life 270-9 days); and
- Cobalt-60 (half-life 5.27 years).

It is important to note that only one sample from each device was analyzed. Further characterization of radioactive levels in more samples may yield more accurate results.

A preliminary evaluation of the radiation dose that might be delivered to the liver of an adult, assuming 100 percent of the activity of the microspheres containing contaminants was distributed uniformly in the liver and was removed only by physical decay, indicated that the dose to the liver did not exceed the medical event limit (i.e., the dose delivered did not differ from the prescribed dose by 20 percent or more), and did not differ form the prescribed dose by more than 0.5 Sv (50 rem) to an organ.

Licensees should be concerned with disposal of microspheres. Depending on the contaminants, licensees may need to:

- hold the remaining microspheres longer in decay-in-storage, in accordance with Chapter 4731.4429;
- return the microspheres to the manufacturer; or
- transfer to an authorized recipient according to Chapter 4731.2450.