

March 15, 2007

Ohio Information Notice 2007-03:

YTTRIUM-90 THERASPHERES[®] AND SIRSPHERES[®] IMPURITIES

ADDRESSEES

All Applicable Medical Use Licensees

PURPOSE

The NRC has issued this Information Notice (IN) to alert addressees 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 OAC rule 3701:1-38-19. Recipients should review the information, contained in this IN, for applicability to their facilities, and consider actions, as appropriate. However, recommendations contained in this IN are not new Ohio requirements; therefore, no specific action nor written response is required.

NRC is providing this IN to the Agreement States for their information, and for distribution to their medical use licensees, as appropriate.

BACKGROUND

TheraSpheres[®] and SIRspheres[®] 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 (μ). 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.

DESCRIPTION OF CIRCUMSTANCES

On March 20, 2006, the staff at the Vanderbilt University, Department of Radiology and Radiological Science, informed NRC's Operation Center of its discovery of the presence of radioactive contaminants in SIRspheres and TheraSpheres. As a follow-up, on March 21, 2006, Vanderbilt University staff, in a letter to the Radiological Devices Branch of the U.S. Food and Drug Administration (FDA), explained that they detected contaminants in the samples by using a high-purity germanium detector.

The Y-90 SIRspheres[®] sample contained detectable amounts of Yttrium-88 (Y-88), with a half-life of 106.6 days and the TheraSpheres[®] sample had measurable amounts of the following radionuclides: Y-88; 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.

DISCUSSION

The main reason the Vanderbilt University, Department of Radiology and Radiological Science reported this issue, to both NRC and FDA, was because the 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 Y-88 and other contaminants.

The staff at the Vanderbilt University, Department of Radiology and Radiological Science performed 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. Based on this evaluation, the dose to the liver from the contaminants 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 from the prescribed dose by more than 0.5 Sv (50 rem) to an organ. However, licensees should be concerned with disposal of microspheres. Depending on the contaminants, licensees may need to: (1) hold the remaining microspheres longer in decay-in-storage, in accordance with OAC rule 3701:1-38-19; (2) return the microspheres to the manufacturer; or (3) transfer to an authorized recipient according to OAC rule 3701:1-38-19.

CONTACTS

This IN requires no specific action or written response. If you have any questions about the information in this notice, please contact Mark Light at 614-644-2727.