Memorandum

Date: January 5th, 2018

From: Jinsy Babu, RSO/Health Physicist, Hunter Holmes McGuire VA Medical Center, Richmond, VA

Subj: Public Comment - Docket ID NRC–2017–0215

To: Attn: Carol Gallagher
U.S. Nuclear Regulatory Commission,
Washington, DC 20555–0001

Ref: (a) Draft Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance, Oct 10th2017, Revision 10

In light of the popularity of promising outcomes utilizing Radio-embolization in the treatment of Hepatocellular carcinoma (HCC), many medical centers are now offering Yttrium 90 (Y90) treatment options, and would like add our experience with BTG/Nordian Therasphere and their medical event criteria. We feel there should be further standardization of survey instrumentation within the medical event portion of the licensing guide ref (a).

BTG TheraSphere uses a rather simple vendor provided written directive template that utilizes collected data, of importance in this discussion is: calculated shunt factor, calibrated unit dose, along with measurements of the source vial/waste pre and post-administration (to determine the dose administered, and residual waste). The medical event in this case is determined by the amount of residual waste measured. Because this measurement is so vital, it has come to our attention that there needs to be further standardization of appropriate instrumentation utilized in making the residual Y90 waste measurement.

Within the FDA approved Written directive document provided by the vendor, there is a clearly denoted "ion chamber" template measurement for unit dose/waste, yet there is leeway in utilizing an appropriate meter within the instruction and vendor training. Therefore, we have learned through multiple contacts with outside medical facilities using Theraspheres, there is a variety of instrumentation including using: GMs, scintillators, and ion chambers to make sure measurement; each of which has different meter sensitivities.

83 FR 159
1/2/2018

133

SUNSI Review Complete
Template = ADM – 013
E-RIDS= ADM -03
Add= Lisa Dimmick (lcd1)
Katherine Tuppe (kns1)

In fact, when our site received its' first proctored case, the vendor instructor recommended using an Ion chamber with a lower sensitivity (non-pressurized ion chamber instead of a pressurized Ion chamber). Therefore, our results of residual waste was far lower than facility that may have used a meter of greater sensitivity, thereby indirectly reducing the likely-hood of a medical event significantly; If this is of NRC interest, we can furnish a separate report that shows the differences in residual waste measurement readings using various instrumentation upon request.

We feel the manufacturer (BTG) or any Radio-embolization vendor must provide a list of approved instrumentation, and standardize how written directive measurements are made amongst its multiple client sites. We have informed BTG of this discrepancy along with the intention to include this topic during the open NRC inquiry period. It is our impression that the manufacturer is quite receptive, and would hope this consideration would be integrated into future vendor procedures, and into the NRC licensing guidance ref (a). Thank you.

Very Respectfully,

Jinsy Babu

Jinsy Babu (JB)

Radiation Safety Officer,

Hunter Holmes McGuire VA Medical Center

Richmond, VA