

From: Demaris, Curt (DOH)
To: [Dimmick, Lisa](#)
Cc: [Matthews, Steve \(DOH\)](#); [Hay, Tristan \(DOH\)](#)
Subject: [External_Sender] STC-17-078 Opportunity For Comment
Date: Thursday, November 16, 2017 5:25:59 PM

Lisa:

We have reviewed the subject document, **Draft Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance, October 30, 2017, Revision 10**, and offer the following:

- A. Overall, this document is a serious improvement over Revision 9.
- B. We like the additional information contained in the SSD and Autopsy & Cremation sections.
- C. The two footnotes, one regarding compatibility category and the other explaining that the “AU Eligible” does not need to be on the relevant board-certificate are most useful information.
- D. There was no explanation why the total limit was raised to 3 Ci from the 2 Ci in Revision 9.
- E. The additional requirement regarding Written Directives in the training portion is an improvement.
- F. We agree with the deletion of the semi-annual inventory, for the reasons stated in Revision 10.
- G. The requirement to submit documentation of the three completed patient cases is an improvement.
- H. Page 18 refers to “...continuing review” by the IRB of the initial approval from the IRB. It would be clearer here if you simply put in the “12 months” requirement for additional periodic IRB review so that reviewers (and inspectors) know the actual timeframe.
- I.

Two other points:

- A. Revision 9 has duplicate headings/paragraphs at the end, the “Waste Disposal Issues” section and the “TheraSphere Use Outside Humanitarian Device (HDE) Restrictions” section. A moot point now, with the imminent distribution of proposed Revision 10.
- B. It would be most helpful when sending these things out for comment to actually include the draft revision itself for perusal. This particular notice did not come with the draft revision. It did say the revision was available on the medical toolbox website but we could not find it

there, and it was cumbersome tracking the actual document down in ADAMS.

Thank you for the opportunity to comment.

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