From: Seeley, Shawn
To: ksciole@nemours.org
Cc: Lanzisera, Penny
Subject: Nemours Amendment request dated 3/14/18 MC602753
Date: Wednesday, May 16, 2018 12:52:00 PM

Ms. Sciole,

We are in receipt of your amendment request to add Yttrium-90 SirTex Sir-spheres to license number 07-16199-02. In order to continue our review, we need the following additional information.

1. You have requested Yttrium-90 Sir-Spheres in 189 mCi per vial quantities. The sealed source and device sheet allows up to 296 mCi per vial. Please confirm which amount you would like for your license limit.

2. Please commit to establishing procedures for administration and to following the manufacturer's procedures for calculating and documenting the dose or activity to the treatment site; preparing the dose for administration; determining shunting to non-treatment sites; and performing pre- and post-vial dose measurements; or submit alternative methods. Additionally, administration of Y-90 microspheres must be performed in accordance with the written directive. The licensee shall record the dose or activity delivered to the treatment site. The record should be prepared within 24 hours after the completion or termination of the administration and must include the name of the individual who determined the administered dose or activity and the date.

3. Please commit to establishing a record for the Termination of Treatment Due to Stasis in accordance with the guidance dated February 12, 2016, revision 9. If the administration was terminated because of stasis, then the total dose or activity to the treatment site is the value of the total dose or activity administered when stasis occurred and the administration was terminated. The record should be prepared within 24 hours after the completion or termination of the administration and must include the name of the individual who determined the administered dose or activity, the date, and the signature of an AU for Y-90 microspheres.

4. Please commit to establishing a procedure for the modifying the written directive to account for Emergent Patient Conditions, in accordance with the guidance dated February 12, 2016, revision 9. If the procedure must be modified due to emergent patient conditions that prevent administration in accordance with the written directive (e.g., artery spasm or sudden change in blood pressure), the AU should document such changes in the written directive within 24 hours after the completion or termination of the administration. The modification to the written directive should include the reason for not administering the intended dose or activity, the date, and the signature of an AU for Y-90 microspheres.

5. Please confirm that you are requesting authorization to conform with the current revision of the guidance to incorporate into your license a change process similar to 10 CFR 35.26. Such a change process will allow some future changes to radiation safety programs provided that the change process in accordance with the criteria

established in the guidance dated February 12, 2016, revision 9.

Please remember to have your response signed by a member of management before submission to the Agency.

We will continue our review upon receipt of the information. If we do not receive a response within 30 days, we will assume you no longer wish to continue with your request.

Please let me know if you have any questions.

Shawn

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