Nemours. Alfred I. duPont Hospital for Children

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J-3

August 30, 2017
Region I, Materials Licensing Assistance Branch
U.S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406-1415

Re: Request for additional clarification for Amendment
License No. 07-16199-02
Docket No. 03019939
Control No. 600553

Dear Mr. Gallaghar:

In response to your email, dated 8/29/2017, requesting additional information before considering the above Amendment request.

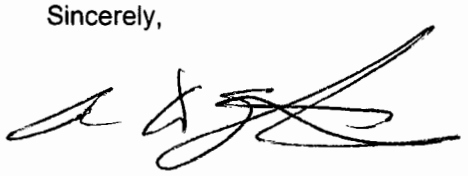
1. We commit to following the manufacturer's procedures for calculating and documenting the dose or activity to the treatment site; preparing the dose for administration; determining shunting to non-treatment sites; and performing pre- and post-vial dose measurements.
2. We confirm that the administration of y-90 microspheres will be performed in accordance with the written directive. We also confirm that we will record the dose or activity delivered to the treatment site. The record will be prepared within 24 hours after the completion or termination of the administration and will include the name of the individual who determined the administered dose or activity and the date.
3. We confirm that if prescribed activity is documented in lieu of prescribed dose, the prescribed activity will be used on all documentation and evaluations.
4. We confirm that in the event the administration is 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 will be prepared within 24 hours after the completion or termination of the administration and will include the name of the individual who determined the administered dose or activity, the date, and the signature of the authorized user for y-90 microspheres.
5. We confirm that, in the event a procedure must be modified due to emergent patient conditions that prevent administration in accordance with the written directive the authorized user will document such changes in the written directive within 24 hours after the completion or termination of the administration. The modification to the written directive will include the reason for not administering the intended dose or activity, the date, and the signature of the authorized user for y-90 microspheres.
6. We confirm that we will develop procedures that describe measures taken to ensure that radiation emissions, which may include bremsstrahlung, from each patient permits his or her release in accordance with 10 CFR 35.75.
7. We will receive the y-90 in the Nuclear Medicine Hot lab. We will use a Geiger-Muller counter to check in the receivable. We will assay it in the Atom lab 500 plus dose calibrator before administration to verify the activity. We will use an Ion counter to check for contamination at the end of the procedure. We will perform daily wipes and surveys of both the hot lab and the IR suite where the administration will occur. We will hold the remaining microspheres longer in

decay in our storage area in a Nalgene container in accordance with 10 CFR 35.92.

8. We confirm that following the license amendment that Allison Aguado, M.D., as an authorized user of y-90 Thera Spheres, the first three patients cases completed by her will be hands-on and supervised in the physical presence of a manufacturer representative.

Please contact Kelly Sciole, ksciole@nemours.org or 302-494-7229 for any additional information as needed.

Sincerely,



Paul Kempinski
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CC. Kelly Sciole, C.N.M.T., R.S.O. (Medical)