

Gryglak, Magdalena

From: Gryglak, Magdalena
Sent: Monday, November 18, 2019 8:05 AM
To: Ed Kline
Subject: RE: Additional Information

Mr. Kline,

Thank you for the additional info.

I am reviewing all of the information provided. I realize that you may or may not have a dose calibrator. However, if you decide to use a dose calibrator, you will need to get check sources and perform leak tests. When you submitted your response dated 10/28/19, the 'Leak Tests' commitment was marked NA. However, I am thinking that we need to add this commitment, "We have developed and will implement and maintain written procedures for sealed sources leak testing that meet the requirements of 10 CFR 35.67". I am excluding the procedures that you provided in the tie down documents since you may need to make changes. Therefore, please submit a short letter signed by Dr. Bryan with the commitment and email it to me.

I am in the process of reviewing and documenting the case. I should be able to issue the license by the end of the month.

Magdalena

From: Ed Kline <ed@uscancertherapies.com>
Sent: Sunday, November 17, 2019 9:15 AM
To: Gryglak, Magdalena <Magdalena.Gryglak@nrc.gov>
Subject: [External_Sender] Additional Information - ARSO

Hi Magdalena:

I forgot to mention that the manufacturer of Xofigo (Bayer HealthCare) provides training and support in radiopharmaceutical therapy. Bayer provides onsite, hands-on training for Xofigo. And Bayer provides continued support in QA, radiation safety, and other aspects of Xofigo usage on a per need basis. Once the NRC license is issued, Bayer plans to be onsite at Arch Cancer Care to provide hands-on training and calibration of the dose calibrator/well counter system. The training involves the entire therapeutic treatment process using Xofigo from handling, preparing, measuring, administering, recording, disposing, manufacturer's recommended policies and procedures, and practical radiation safety aspects. Radiation safety topics to be covered include use of the equipment such as the dose calibrator (QA and dosage), well counter (wipes/contamination), radiation survey meter (ambient dose rate measurement techniques), and various documentation requirements (receipt, usage, disposal). When at Arch Cancer Care, Bayer will use radioactive materials to calibrate the dose calibrator/well counter system. I will be handling this material with the trainer. The trainer from Bayer will be James Alton, RT(N)(ARRT), Radiotherapy Specialist/Gulfcoast:

Email: james.alton@bayer.com



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I thought this information might be useful for you regarding the ARSO review.

Lastly, the physicians asked when the license might be issued.

Thank you,
Ed

Ed Kline
Partner – Clinical Operations/Physics



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