

From: [Elliott, Robin](#)
To: [Oskin, Christine R](#); [Lowe, Kim](#)
Cc: [Artz, Steven, M.D.](#); lsphysics@att.net
Subject: Y-90 amendment: Request for additional information
Date: Monday, November 15, 2021 11:19:00 AM

License No.: 47-15473-0

Docket No: 030-09164

Licensee Name: Charleston Area Medical Center

This refers to your request to amend your license dated September 1, 2021. In order to continue our review of your request, the following additional information is needed:

All the following information is based on the Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres Licensing Guidance, April 20, 2021, Revision 10.2 which can found at the following link: <https://www.nrc.gov/materials/miau/med-use-toolkit/emerg-licensed-med-tech.html>

1. Provide documentation to support Amy Deipolyi, M.D. as an authorized user. Reference section 5.1 of above document.
2. Confirm that the materials requested will only be used at the 3200 MacCorkle Avenue, S.E., Charleston, WV, or provide the other addresses where this material will be used.
3. Provide documentation to support Steven A. Artz, M.D. as Radiation Safety Officer as indicated in section 5.2 of the above document. If you request this authorization for your ARSO as well, please provide documentation to support that as well.
4. Commit to provide training in your procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed. This training must be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres.

Your reply must be an originally signed and dated letter. The letter may be scanned and submitted as a pdf document attached to an email (preferred method); or it may be transmitted by facsimile to (610) 337-5269; or it may be sent by regular mail. If we do not receive a reply from you within 30 calendar days from the date of this e-mail, we will assume that you do not wish to pursue your amendment request.

Please respond by e-mail to acknowledge that you have received the e-mail request for additional information.

Regards,

Robin L. Elliott

(Pronouns: she/her/hers)

Health Physicist

Medical & Licensing Assistance Branch

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