

**From:** [Gallagher, Robert](mailto:Gallagher.Robert)  
**To:** [douglas.d.barrickman.mil@mail.mil](mailto:douglas.d.barrickman.mil@mail.mil)  
**Subject:** Request for Additional Information - Control No. 590661  
**Date:** Wednesday, May 18, 2016 8:04:00 AM  
**Attachments:** [image001.png](#)

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PLEASE CONFIRM RECEIPT OF THIS REQUEST FOR ADDITIONAL INFORMATION BY RETURN EMAIL

License No. 10-12044-03  
Docket No. 03011936  
Control No. 590661

Dear Major Barrickman;

This letter refers to your request to amend byproduct materials License Number 10-12044-03 issued to the Dwight David Eisenhower Army Medical Center (DDEAMC) to change the Radiation Safety Officer and to add authorization to use iodine-125 seeds for radioactive seed localization (RSL). In order to continue with your request more information is necessary.

1. Please confirm that the DDEAMC Radiation Safety Committee (RSC) uses the guidance developed for licensing of emerging technologies and 10 CFR 35.1000 titled "Iodine-125 and Palladium-103 Low Dose Rate Brachytherapy Seeds Used for Localization of Non-Palpable Lesions" regarding: (1) proposed authorized user's training and experience in the use of iodine-125 and palladium-103 seeds for the RSL procedure; (2) written directives; and (3) safety precautions and instructions. This guidance may be found in the Medical Uses Licensee Toolkit located at <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.
2. Item 5 of your request (Page 9 of 64) discusses your intent to use iodine-125 sealed sources manufactured by Best Medical International (Model 2301) and that the actual delivered activity will be based on the device manufacturer's attestation of activity, corrected for decay from the source calibration date. Please confirm that Best Medical International determines the activity of 100% of all sources manufactured and distributed for medical use.
3. Please confirm that you will use the guidance developed for licensing of emerging technologies and 10 CFR 35.1000 for any future approvals for 10 CFR 35.1000 materials.

Please respond to this request for additional information by letter signed by Colonel Weber. You may then send a pdf of the letter to me at [Robert.gallagher@nrc.gov](mailto:Robert.gallagher@nrc.gov).

In addition, please note that for 10 CFR 35.100 your RSC can approve these new uses as long as you are licensed for the byproduct material in the broad listing.

Regards,

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NRC Seal

