

**Cook, Jackie**

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**From:** Cook, Jackie  
**Sent:** Wednesday, January 17, 2018 4:54 PM  
**To:** 'Ronald Frick'  
**Subject:** RE: Re: REQUEST FOR ADDITIONAL INFORMATION FOR EYE SURGERY CENTER OF HAWAII DOCKET # 030-39085; CONTROL # 601824

**Importance:** High

Aloha Ron: I will attempt to respond to your questions below in bolded blue text.

Please do not hesitate to contact me if additional information or clarification is needed.

Warmest Regards,

*Ms. Jacqueline "Jackie" D. Cook*  
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US Nuclear Regulatory Commission Region IV  
Division of Nuclear Materials Safety  
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**From:** Ronald Frick [mailto:rfrick@gammacorp.com]  
**Sent:** Tuesday, January 16, 2018 7:36 PM  
**To:** Cook, Jackie <Jackie.Cook@nrc.gov>  
**Subject:** [External\_Sender] Re: REQUEST FOR ADDITIONAL INFORMATION FOR EYE SURGERY CENTER OF HAWAII DOCKET # 030-39085; CONTROL # 601824

Hi Jackie,

Could you please provide some clarification on item #2? As it is written, it appears that it isn't an option for the retinal surgeon to use the device under the supervision of the Authorized User. The surgeon is not one of the proposed authorized users, and we are not planning to list him as an authorized user. The AU (radiation oncologist) will be present for each procedure, and the surgeon will be under his supervision. Can we make this statement in the response, or will this be a problem? **Yes, you may confirm this statement in your response.**

Also, regarding the training for the medical physicists, for 35.400 ophthalmic use, form 313A(AMP) only requests information on the device, who provided the training and the training dates in table 3.c. Would it be sufficient to provide documentation of the manufacturer's training which has been completed? **Please include the actual training received.** I believe it would be difficult to find a medical physicist with experience with this new device to sign the preceptor statements. According to Part II Fourth Section of NRC Form 313(AMP), the preceptor must affirm by checking the applicable box, **signing, providing their phone number and dating this section of the form that they meet the requirements in 10 CFR 35.51 or equivalent Agreement State requirements for AMP for the following:**

Thank you,  
Ron Frick

**PUBLIC**  
☐ Immediate Release  
☒ Normal Release  
**NON-PUBLIC**  
☐ A.3 Sensitive-Security Related  
☐ A.7 Sensitive Internal  
☐ Other:

Reviewer: JPC Date: 1/17/18