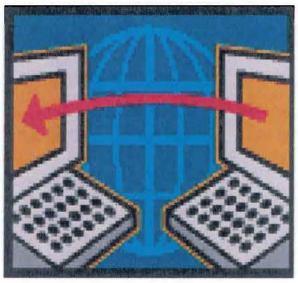
UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BLVD
ARLINGTON, TEXAS 76011-4511

EMAIL



Name:	Joseph Harmon, Ph.D., DABR	License: 50-35123-01
Organization:	Alaska Cancer Treatment Center	Docket: 030-38705
Phone:	907-276-2803	Control: 602569
E-mail Address:	fharmon@akmed.com	
From:	Jacqueline D. Cook	
Date:	May 10, 2018	
Subject:	Letter dated February 22, 2018 for License Amendment	
Pages:	2	

Dr. Harmon:

Per your letter dated February 22, 2018, the item on the next page is a deficiency which requires your response. **Please respond to this e-mail by Wednesday, May 23, 2018.** Our fax number is (817) 200-1263. **Please provide a response in a signed and dated letter in pdf format when responding via email.** My email address is Jackie.Cook@nrc.gov. When responding to this e-mail, please include the license, docket, and control numbers located at the top of this page.

Thanking you in advance for your cooperation, assistance, and prompt response in this matter.

/RA/
Jacqueline D. Cook
Senior Health Physicist

PUBLIC
☐ Immediate Release
☑ Normal Release

NON-PUBLIC
☐ A.3 Sensitive-Security Related
☐ A.7 Sensitive Internal
☐ Other:

Reviewer: JDC Date: 5/10/18

1. Although you are asking to include authorization for 10 CFR 35.100, "Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required" (https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0100.html), page 2 of Regulatory Issue Summary (RIS) 2008-31 states that in the case of sentinel lymph node (SLN) procedures, the administered Tc-99m is regulated under 10 CFR 35.200, "Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required." (https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0200.html).

   Please clarify this discrepancy.

2. In order to add a new modality (10 CFR 35.100 and/or 10 CFR 35.200 authorization), please use the licensing guidance in NUREG-1556, Volume 9, Revision 2, *Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses*, (https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/) specifically Table C.1, *Applicability Table* and Tables C.2 and C.3, *Items 5 and 6 on NRC Form 313: Radioactive Material and Use; Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal.*

3. Please note that the training and experience (T&E) regulations for 10 CFR 35.200 material authorization can be found in 10 CFR 35.290 (https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0290.html).

   It appears that your requested proposed authorized user, Dr. Mary Jo Wright, is authorized for 10 CFR 35.100 material (uptake, dilution, and excretion studies).

   Please demonstrate Dr. Wright's T&E for 10 CFR 35.200 material by either submitting a copy of her board certification, an NRC or Agreement State license she is listed on as an authorized user for imaging and localization studies, or follow the alternate pathway outlined in 10 CFR 35.290. In addition, please feel free to utilize NRC Form 313A(AUD) (https://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a(aud).pdf) to demonstrate Dr. Wright's T&E.