U.S. NUCLEAR REGULATORY COMMISSION

TELEPHONE CONVERSATION RECORD

Date: 9/12/12

Mail Control or Report No(s).	578066	**License No(s).**	06-30933-02	**Docket No(s).**	03036825

Name of Licensee:	Pfizer New Haven Clinical Research Unit
Name of Participant(s):	Patricia Chandler, M.D., Medical Director
Telephone No.	203-401-0391
Subject: (NOTE: This will be used as the Documents Title in ADAMS)	RAI concerning change in RSO/AU

In the letter dated 8/1/12, Dr. Chandler requested that Arne Hansson, M.D. be named as the RSO/AU. Based on the information provided, Dr. Hansson does not meet the requirements to be an AU of 35.100 materials. 10 CFR 35.190 requires, in part, that an authorized user of unsealed byproduct material for the uses authorized under 35.100 be a physician that has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies and that has had work experience, under the supervision of an authorized user who meets the requirements in §§ 35.190, or equivalent Agreement State requirements. I suggested she review the regulation with Dr. Hansson and decided whether or not he has the required training. If he does, have him complete the NRC Form 313(AUD) and get it signed by his preceptor. Dr. Hansson would need to complete Part I Training and Experience, Items 3.a. and 3.b. and Part II Preceptor Attestation, First Section for 35.190 training and experience and the Second Section would need to be signed by a physician that is listed as an authorized user on an NRC or Agreement State for 35.100 materials and who is willing to attest to the fact that Dr. Hansson has had the described training and experience.

This is an excerpt from a letter dated 3/5/07 from Howard Uderman, M.D. It appears that obtaining an authorized user with the appropriate training for 35.100 materials has been a problem in the past. Although, based on this excerpt, it looks like a solution was found. "We had to spend some time sorting out the requirements of NRC form 313A. We have arranged for additional hours of training for Dr. Banerjee in the Department of Nuclear Medicine at Yale University Medical School - which is located across the street from our Research Unit. The Department routinely trains residents and research fellows in the use of radioactive material. Once satisfied with Dr. Banerjee's additional training, they are prepared to sign off on NRC form 313a on his behalf." This approached worked in the past because Dr. Banerjee was added to your license as an authorized user on Amendment No. 2.

Once a qualified RSO is selected and Dr. Hansson has documentation of his training and experience, then I would

submit an amendment request to (1) change the RSO to ____, (2) add Dr. Hansson as the authorized user, and (3) reactivation of your program.

The way the current regulations are written, it permits an authorized user, on the licensee's license, to be named as the RSO. Therefore, if you want Dr. Hansson to be the RSO he would first have to be put on the license as an authorized user. Then the RSO could provide training to him and sign off on a preceptor form (NRC Form 313A(RSO)). At that point you would submit another amendment request asking that Dr. Hansson be named as the RSO. .

Action Required: Wait for additional information. Decide whether or not the action should be voided.

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SUNSI Review Completed By: TLWeidner ***/ RA /***