UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

July 19, 2022

Mr. Edward E. Wroblewski, M.A.
Radiation Safety Officer
Ascension St. Vincent Hospital
2001 W 86th St.
Indianapolis, IN 46260

SUBJECT: ADDITIONAL INFORMATION NEEDED REGARDING AMENDMENT TO ASCENSION ST. VINCENT HOSPITAL, NRC LICENSE NO. 13-00133-02

Dear Mr. Wroblewski:

Our office has reviewed the June 22, 2022 request (including May 20, 2022 NRC Form 313A (AUT) preceptor attestations signed by Title 10 of the *Code of Federal Regulations* (10 CFR) Section 35.300 Authorized User (AU) Robert Liebross, M.D.) for NRC to amend Ascension St. Vincent Hospital's (your) U.S. Nuclear Regulatory Commission (NRC) Materials License No. 13-00133-02. Upon review, our office has determined that additional information is needed to amend the license, regarding the (1) name to be listed on the license for existing AU Jessica Zhou, M.D., and (2) training & experience for both Dr. Zhou and for Vasu Maruthi Tumati, M.D. Your amendment request is available electronically from NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML22178A187. The NRC's ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

For additional guidance, please refer to NUREG 1556 Volume 9, revision 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses," Section 8.7.2, "Authorized Users (AUs)," pp. 8-26 to 8-31, Appendix C, Table C-2, "Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal," pp. C-12 to C-17, and Appendix D, "Documentation of Training and Experience to Identify Individuals on a License," pp. D-1 to D-6. Please also refer to the NRC Form 313A (AUT) form, expiration date January 31, 2021, found at NRC's online medical use toolkit.

AU NAMES TO BE LISTED ON THE LICENSE:

1. The current name for one of the indicated AUs, as listed on your license in Subitem No. 12.B., is Jessica Zhou, M.D. However, the request listed her name as Jessica Durk (Zhou), M.D. The name to be listed on the license, and the reason for the change, is unclear.

   Please indicate the correct name to be listed on the license. If the name to be listed has changed since the previous amendment, please explain the reason for the change. If documentation is needed to support the explanation, please attach that in your response.

DOCUMENTATION NEED FOR INDIVIDUALS TO BE LISTED ON THE LICENSE AS AUTHORIZED FOR RADIUM-223 DICHLORIDE AS PERMITTED UNDER 10 CFR 35.300, USING THE 10 CFR 35.396 PATHWAY

2. In the referenced request, some training outlined in 10 CFR 35.396, "Training for the parenteral administration of unsealed byproduct material requiring a written directive," was omitted for both Dr. Zhou and Dr. Tumati.

   Please provide documentation of training & experience as needed:

   (a) Classroom & Laboratory training, in accordance with 10 CFR 35.396(b)(1), was not included for either AU.

   Please confirm that both Dr. Zhou and Dr. Tumati have received classroom & laboratory training, applicable to parenteral administrations as permitted under 10 CFR 35.300. In the alternative, please complete the Table 3.a. for each AU as found in the NRC 313A (AUT) form, p.2., attached.

   (b) Work experience was omitted from the request regarding either Dr. Zhou's or Dr. Tumati's work experience, with respect to the 10 CFR 35.396(b)(2) topics of:

   (i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;
   (ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
   (iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
   (iv) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material; and
   (v) Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures.

   Please complete please complete the Table 3.b. for each AU as found in the NRC 313A (AUT) form, p.2., attached.

   (c) The preceptor attestations for Dr. Zhou & Dr. Tumati – from Dr. Liebross – were inconsistent with the preceptor attestation specified in 10 CFR 35.396(c).

   Please obtain updated preceptor attestations for Dr. Zhou & Dr. Tumati as outlined in the Fourth and Fifth sections of PART II – PRECEPTOR ATTESTATION portion of the NRC 313A (AUT) form, pp. 5-6, attached.

Please provide a response via a signed and dated letter within 14 days (on or prior to August 2, 2022). For quickest processing, please submit your response as a pdf file attached to an email message. You may also submit a response via fax or via regular mail. If you have any questions regarding this message, please do not hesitate to reach out to me at 630-829-9892.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS, accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

Sincerely,

Sara A. Forster

Digitally signed by Sara A. Forster
Date: 2022.07.19 09:56:28 -05'00'

Sara A. Forster, M.S.
Health Physicist
Materials Licensing Branch
Division of Nuclear Materials Safety

Docket No.: 030-01579
License No.: 13-00133-02

Control No.: 631654

Enclosure: NRC Form 313A (AUT), pp. 2, 5 & 6
(non-fillable version)

AUTHORIZED USER TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION (for uses defined under 35.300) [10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396] (continued)

c. If currently authorized under 35.490 or 35.690 and requesting authorization for 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

☐ **3. Training and Experience for Proposed Authorized User**

a. Classroom and Laboratory Training ☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use			
Radiation biology			
	Total Hours of Training:		

b. Supervised Work Experience ☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396

(If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)

Supervised Work Experience	**Total Hours of Experience:**		
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		☐ Yes ☐ No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		☐ Yes ☐ No	
Calculating, measuring, and safely preparing patient or human research subject dosages		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		☐ Yes ☐ No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		☐ Yes ☐ No	

AUTHORIZED USER TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION (for uses defined under 35.300) [10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396] (continued)

Second Section

☐ I attest that _____ has satisfactorily completed the required clinical case
Name of Proposed Authorized User

experience required in 35.390(b)(1)(ii)G listed below:

☐ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☐ Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.

Third Section

☐ I attest that _____ is able to independently fulfill the radiation safety-related
Name of Proposed Authorized User

duties as an authorized user for the medical uses authorized under 10 CFR 35.300 for:

☐ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☐ Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.

Fourth Section

For 35.396:

Current 35.490 or 35.690 authorized user:

☐ I attest that _____ is an authorized user under 10 CFR 35.490 or 35.690
Name of Proposed Authorized User

or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.396 (b)(1), and the supervised work and clinical case experience required by 35.396(b)(2), and is able to independently fulfill the radiation safety-related duties as an authorized user under 10 CFR 35.300 for:

☐ Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.

OR

Board Certification:

☐ I attest that _____ has satisfactorily completed the board certification
Name of Proposed Authorized User

requirements of 35.396(a)(3), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396 (b)(1) and the supervised work and clinical case experience required by 35.396(b)(2), and is able to independently fulfill the radiation safety-related duties as an authorized user under 10 CFR 35.300 for:

AUTHORIZED USER TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION (for uses defined under 35.300) [10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396] (continued)

Fifth Section

Complete one of the following for the attestation and signature:

☐ **Authorized User**

☐ I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396 ☐ 35.57 for 35.300 uses

☐ I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization:

☐ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☐ Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.

OR

☐ **Residency Program Director:**

☐ I affirm that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements below or equivalent Agreement State requirements:

☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396 ☐ 35.57 for 35.300 uses

☐ I affirm that this facility member has experience in administering dosages in the same dosage category or categories for which the individual is requesting authorized user status and concurs with the attestation I am providing as program director.

☐ I affirm that the residency training program is approved by the:

☐ Residency Review Committee of the Accreditation Council for Graduate Medical Education

☐ Royal College of Physicians and Surgeons of Canada

☐ Council on Post-Graduate Training of the American Osteopathic Association

☐ I affirm that the residency training program includes training and experience specified in:

☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396

Name of Facility:	License/Permit Number:	
Name of Preceptor or Residency Program Director (Typed or Printed)	Telephone Number	Date
Signature		