From: Powell, Rhonda
To: Roberto Torres
Subject: [External_Sender] RE: NRC request for information - Cole Ziegler (proposed authorized user)
Date: Monday, August 26, 2024 10:53:12 AM
Attachments: CZ AU Attest.pdf

Good morning Mr. Torres,

I received the attached this morning.

Thank you,
Rhonda

From: Roberto Torres <RobertoJ.Torres@nrc.gov>
Sent: Monday, August 26, 2024 6:03 AM
To: Powell, Rhonda <RSPowell@kh.org>
Subject: RE: NRC request for information - Cole Ziegler (proposed authorized user)

Rhonda Powell, MBA, CNMT, RSO:

Can you please provide an estimate of when will I receive a response to this request for information for Cole Ziegler, proposed authorized user?

Thank you.

Roberto J. Torres
U.S. NRC Region IV

From: Roberto Torres
Sent: Friday, August 9, 2024 1:06 PM
To: Powell, Rhonda <RSPowell@kh.org>
Subject: NRC request for information - Cole Ziegler (proposed authorized user)

Rhonda Powell, MBA, CNMT, RSO:

The following information was missing in your license amendment request dated August 7, 2024 for NRC license 11-27307-01. Please submit by reply email a revised NRC Form 313A(AUT) to complete the review of the training and experience credentials for Cole Ziegler.

1. See yellow highlights in the attached NRC Form 313A(AUT) that was submitted to the NRC. The preceptor from Duke University Medical Center, Terence Z. Wong,

M.D., Ph.D., (license NC 032-0247-4) did not verify that he is an authorized user for parenteral administration, did not attest to the completion of parenteral clinical cases for Cole Ziegler, M.D., and did not provide an attestation that Cole Ziegler, M.D., is able to independently fulfill radiation-related duties involving parenteral administration. Please provide revised NRC Form 313A(AUT) signed and dated by Dr. Wong.

Thank you for your attention on this matter.

Roberto J. Torres, M.S.
Senior Health Physicist
U.S. Nuclear Regulatory Commission
Region IV
Division of Radiological Safety and Security
1600 East Lamar Boulevard
Arlington, TX 76011-4511
817-200-1189

NRC FORM 313A (AUT) (07-31-2023) U. S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 07/31/2026

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Library, and Information Collections Branch (T-6 A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by email to Infocollects.Resource@nrc.gov, and the OMB Reviewer at: OMB Office of Information and Regulatory Affairs, (3150-0120), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street NW, Washington, DC 20503; email: oira_submission@omb.eop.gov. The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

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]

Name of Proposed Authorized User	State or Territory Where Licensed
Cole Ziegler, MD	Idaho

Requested Authorization(s) *(check all that apply)*:

☐ 35.300 Use of unsealed byproduct material for which a written directive is required

OR

☑ 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☑ 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)

☑ 35.300 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.

PART I -- TRAINING AND EXPERIENCE
(Select one of the three methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

☐ **1. Board Certification**

a. Provide a copy of the board certification.

b. For 35.**390**, provide documentation on supervised case experience. The table in section 3.c. may be used to document this experience.

c. 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. Skip to and complete Part II Preceptor Attestation.

d. For a board certification issued on or before October 24, 2005 that is listed in 10 CFR 35.57(b)(2)(ii), provide the following:

(i) Documentation that the individual performed each use checked above on or before October 24, 2005.

(ii) Dates, duration, and description of continuing education and experience within the past seven years for each use checked above.

e. Stop here.

☐ **2. Current 35.300, 35.400, or 35.600 Authorized User Seeking Additional Authorization**

a. Authorized User on Materials License _____ under the requirements below or equivalent Agreement State requirements *(check all that apply)*:

☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.490 ☐ 35.690

b. If currently authorized for a subset of clinical uses under 35.300, provide documentation on additional required supervised case experience. The table in section 3.c. may be used to document this experience. If board certified, provide a copy of the certificate and stop here. If not board certified then provide completed Part II Preceptor Attestation.

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	Duke U. Medical Center Integrated Diagnostic/ Interventional (DR/IR) Radiology Residency Program	70	7/1/2019-6/30/2024
Radiation protection	Duke U. Medical Center Integrated DR/IR Residency Program	70	7/1/2019-6/30/2024
Mathematics pertaining to the use and measurement of radioactivity	Duke U. Medical Center Integrated DR/IR Residency Program	20	7/1/2019-6/30/2024
Chemistry of byproduct material for medical use	Duke U. Medical Center Integrated DR/IR Residency Program	20	7/1/2019-6/30/2024
Radiation biology	Duke U. Medical Center Integrated DR/IR Residency Program	20	7/1/2019-6/30/2024
	Total Hours of Training: 200		

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:** 500		
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	Duke U. Medical Center / NC 032-0247-4	☑ Yes ☐ No	7/1/2019-6/30/2024
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Duke U. Medical Center / NC 032-0247-4	☑ Yes ☐ No	7/1/2019-6/30/2024
Calculating, measuring, and safely preparing patient or human research subject dosages	Duke U. Medical Center / NC 032-0247-4	☑ Yes ☐ No	7/1/2019-6/30/2024
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Duke U. Medical Center / NC 032-0247-4	☑ Yes ☐ No	7/1/2019-6/30/2024
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Duke U. Medical Center / NC 032-0247-4	☑ Yes ☐ No	7/1/2019-6/30/2024

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)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Terence Z. Wong, MD, PhD	032-0247-4

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:*

- ☑ 35.390
- ☑ 35.392
- ☑ 35.394
- ☑ 35.396
- ☐ 35.57

With experience administering dosages of:

- ☑ 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.

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

c. Supervised Clinical Case Experience

If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.

Description of Experience	Number of Cases Involving Personal Participation	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	3	Duke U. Medical Center / NC 032-0247-4	6/10/2020, 1/28/2022, 3/10/2022
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	3	Duke U. Medical Center / NC 032-0247-4	6/3/2020, 6/24/2020, 1/26/2022
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.	3 Lu-177 PSMA-617 (Pluvicto)	Duke U. Medical Center / NC 032-0247-4	4/17/2024 5/6/2024 5/16/2024

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)

3. Training and Experience for Proposed Authorized User (continued)

c. Supervised Clinical Case Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Terence Z. Wong, MD, PhD	032-0247-4

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:*

☑ 35.390	With experience administering dosages of:
☑ 35.392	☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
☑ 35.394	☑ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
☑ 35.396	☑ 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.
☐ 35.57	

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

d. Provide completed Part II Preceptor Attestation.

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

By checking the boxes below, the preceptor is not attesting to the individual's "general clinical competency."

First Section
Check one of the following for the requested authorization:

For 35.390:

☑ I attest that Cole Ziegler, MD (Name of Proposed Authorized User) has satisfactorily completed the 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).

For 35.392:

☑ I attest that Cole Ziegler, MD (Name of Proposed Authorized User) has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.392(c)(1), and the supervised work and clinical case experience required in 35.392(c)(2).

For 35.394:

☑ I attest that Cole Ziegler, MD (Name of Proposed Authorized User) has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.394 (c)(1), and the supervised work and clinical case experience required in 35.394(c)(2).

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 Cole Ziegler, MD 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 Cole Ziegler, MD 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:	
Duke University Medical Center	032-0247-4	
Name of Preceptor or Residency Program Director (Typed or Printed)	Telephone Number	Date
Terence Z. Wong, MD, PhD	(919) 684-7748	8/26/2024
Signature: Terence Z Wong		