

**RADIATION SAFETY DEPARTMENT**

**West Virginia University • Health Sciences Center • WVU Hospitals
Jefferson Medical Center • Fairmont Regional Cancer Center**

G-139 Health Sciences Center • PO Box 9006 • Morgantown, WV 26506-9006 • Phone: 304-293-3413 • Fax: 304-293-4529

**APPLICATION TO REQUEST AUTHORIZATION FOR THE DIAGNOSTIC
OR THERAPEUTIC USE OF RADIATION IN OR ON HUMANS**

**For Uses Under 10 CFR 35.100, 35.200, and 35.500
Unsealed Byproduct Material - Written Directive Not Required
Use of Sealed Sources for Diagnosis**

APPLICATION PROCESS

1. Prospective AUs must submit this completed application and all required attachments to the Radiation Safety Department no later than the end of the month prior to a radiation safety committee meeting month in order for the application to be considered during that meeting. Committee meeting months are January, April, July, and October. The completed application with attachments may be submitted via email to: **radiationsafety@hsc.wvu.edu**.
2. The WVU Radiological Safety Committee has chosen to go above and beyond NRC work experience requirements and, therefore, requires prospective AUs complete additional clinical case experience in each modality in which they are applying. Cases must be completed at WVU Hospitals, under the direct supervision of an AU for that modality under the WVUH NRC radioactive materials license. If you were an active AU at another institution and have completed at least 10 cases within the last year in each modality in which you are applying, you will only need to complete 3 cases at WVUH. All other applicants must complete 10 cases in each modality in which they are applying under the supervision of a AU under the WVUH NRC radioactive materials license.
3. The Radiation Safety Officer (RSO) will review the application. If the RSO approves the application, it will be forwarded to the Human Use Committee (HUC) and the Radiation Safety Committee (RSC) for final review and approval. If the RSO denies the application, the prospective AU will be given an opportunity to amend their application.
4. If approved by the HUC and RSC, a notification of approval letter will be sent to you, your supervisor, department, and others as necessary.
5. AUs wishing to amend their current authorization will follow the same application process as described above, however they will submit a modified application. The AU is required to fulfill all training requirements in 10 CFR Part 35 for the modality in which they are amending their application and will be required to complete 10 supervised cases before the amendment is approved. The application must be approved by the RSO, HUC, and RSC.

DESCRIPTION OF PATHWAYS TO OBTAIN AUTHORIZATION

A prospective Authorized User (AU) may obtain authorization by meeting the requirements in one of the following three training and experience pathways.

- Pathway 1: The prospective AU is currently or had previously been an AU on another institution's NRC or Agreement State radioactive materials license or permit.
- Pathway 2: The prospective AU has a certification in a specialty board recognized by the NRC under 10 CFR Part 35. The applicant must have passed the certifying exam to meet the requirements of this pathway. Being eligible to sit for the certifying exam does not meet the requirements for this pathway.
- Pathway 3 "Alternate route": If the prospective AU does not meet the requirements in pathways 1 or 2, they will need to provide documentation of classroom and laboratory training, supervised work experience, and supervised clinical experience for the use requested. This pathway also requires written attestation, signed by a preceptor physician AU, or the residency program director that the training and experience requirements were satisfactorily completed and that the individual is able to independently fulfill the radiation safety-related duties as an AU for the requested uses.

INSTRUCTIONS TO APPLICANT

1. The following sections will guide the applicant through the different pathways to authorization under 35.100, 200, and 500. The applicant should follow the directions in the sections closely, as they will indicate what information and attachments that the applicant must provide. Throughout the following application sections will be links (in blue) to various NRC and other reference documents. Applicants should reference these documents as necessary.
2. If training and experience (including Board Certification) has not been obtained within the last 7 years preceding the date of this application, attach recent continuing education and experience required by [10 CFR 35.59](#).
3. All new applicants, regardless of pathway to authorization must submit the following documents with their application: (select all that will be submitted with this application)

Your CV

A copy of your WV medical license

Letters of recommendation from at least two individuals who can corroborate your previous training history and experience with radioactive materials

4. Letters of recommendation provided with application should be addressed to:

Stephen Root
Co-Director and Radiation Safety Officer
PO Box 9006
Morgantown, WV 26506

PART A: APPLICANT INFORMATION

Name:

MD PhD

Department:

Title:

Section:

Lab #:

Office Rm #:

PO Box:

Off Phone:

Dept. Chair:

Fax:

Email:

I understand the authorization to use such materials is a privilege granted by the WVUH Human Use of Radiation and Radionuclides Committee and the WVUH Radiation Safety Committee, and is regulated by the US Nuclear Regulatory Commission. I agree to abide by all applicable laws, to follow recognized safe practices in the use of radioactive materials and radiation producing devices. I have received the required training in radiation safety practices and obtained a copy of the applicable regulations and Radiation Safety Manual from Radiation Safety. I am hereby submitting this application for approval.

Select One:

☐**New Application.**☐**Modification** to previously approved application and/or authorization.**(Only complete sections that require modification and review.)**

Briefly describe modification to previously approved application:

Signed:

Date:

PART B: REQUESTED USE(S)

B.1 What use(s) regulated under NRC 10 CFR 35 Subparts D - Unsealed Byproduct Material - Written Directive Not Required and G - Sealed Sources for Diagnosis, are you applying for? (check all that apply)

35.100 Uptake, dilution and excretion studies

35.200 Imaging and localization studies

35.500 Sealed sources for diagnosis (specify device):

PART C: SELECTED PATHWAY TO AUTHORIZATION

C.1 Select the pathway by which the applicant is seeking approval as an Authorized User (AU) (after making your selection you will be redirected to the Part of this application that you need to complete):

Pathway 1: Previously listed on, or authorized under, an NRC or Agreement State license (**if you selected this pathway complete Part D only**)

Pathway 2: Applicable Board Certification (**if you selected this pathway complete Part E only**)

Pathway 3 "Alternate route": Preceptors' written attestation of applicant's completion of specified Training and Experience (**if you selected this pathway complete Part F only**)

PART D: PATHWAY 1 PREVIOUS OR CURRENT AUTHORIZED USER (AU)

D.1 Are you currently or were you previously an Authorized User under 35.200 on another NRC or Agreement State license or permit?

Yes No

* If you answered Yes to D.1, you may skip to D.6. If you answered No to D.1, continue with question D.2.

D.2 Are you currently an AU under 35.300 seeking additional 35.100 and 35.200 authorization?

Yes No

* If you answered Yes to D.2 you may skip to D.5, but you will have to provide documentation of additional training in elute generator systems appropriate for radioactive drug preparation for imaging & localization studies, measure & test eluate for radionuclidic purity, and process eluate with reagent kits to prepare labeled radioactive drugs under as per 10 CFR 35.290(c)(1)(ii)(G). Documentation can be provided on NRC 313A (AUD) form linked here:

[For AU training, experience and preceptor attestation for uses under 35.100, 25.200, and 35.500](#)

* If you answered No to D.2, continue with questions D.3.

D.3 Are you currently or were you previously an Authorized User under 35.100?

Yes No

*If you selected Yes to D.3, continue with question D.4. If you selected No to D.3, this will **not** be your pathway to Authorization. You should select the Board Certification, or Training and Experience pathway.

D.4 Are you currently or were previously an Authorized user under 35.100 and seeking additional authorization under 35.200?

Yes No

*If you selected Yes to D.4, your pathway to authorization for uses under 35.200 will **not** be through this pathway. You will need to provide a Board Certification or document Training and Experience through Part E or Part F of this application. If you selected No to D.4, continue with question D.5.

D.5 Are you seeking authorization for uses under 35.500?

Yes No

*If you answered Yes to D.5, you will need to submit documentation of completion of training in the use of the device requested.

D.6 Have you completed at least 10 cases within the last year as an AU in each modality in which you were previously an AU for at another NRC or Agreement State license or permit?

Yes

No

*If you checked Yes, you will be required to complete at least 3 cases in each modality in which you are applying at WVUH under the supervision of an AU in that modality under the WVUH NRC radioactive materials license. If you checked no, you will be required to complete at least 10 cases in each modality in which you are applying at WVUH under the supervision of an AU in that modality under the WVUH NRC radioactive material license. If you are applying for an additional authorization under 35.100, 200, or 500, you will need to complete 10 cases in that modality.

D.7 Provide the name of the institution that you are currently or were previously an AU. Provide the name and contact information of the Radiation Safety Officer or another individual who would be able to provide documentation of your AU status (e.g. NRC or Agreement State radioactive materials license, or Radiation Safety Committee approval letter).

Institution:

Contact person:

Phone number:

Email address:

D.8 In addition to the required documentation listed in Instruction to Applicants in line number 3, you will need to provide the following additional information as attachments to this application. Check all attachments that you will be submitting with this application. Please submit any other documentation not included in this list (certifications, including board certification, additional coursework or training, publications) that may be relevant.

NRC or Agreement State license from institution in which you were previously an AU

Radiation Safety Committee approval letter (if NRC or Agreement State license does not specifically list AUs on the license.)

Documentation of cases completed within the last year at the institution in which you were previously an AU.

Documentation of additional training required under 10 CFR 35.290(c)(1)(ii)(G), if applicable.

Documentation of cases required at WVUH under supervision of an AU under the WVUH NRC radioactive materials license.

Documentation of training on use of device requested under 35.500, if applicable.

PART E: BOARD CERTIFICATION**E.1** Provide the name of the Board Certification and the date received?

Reference NRC specialty board(s) certification recognized by NRC under 10 CFR Part 35 for each modality at this link: <https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>

Name of specialty board:

Date received:

E.2 You must complete at least 10 cases at WVUH in each modality in which you are applying under the supervision of an AU in that modality under the WVUH NRC radioactive materials license. Have you completed this requirement?

Yes

No

E.3 In addition to the required documentation listed in Instruction to Applicants in line number 3, you will need to provide the following additional information as attachments to this application. Check all attachments that you will be submitting with this application. Please submit any other documentation not included on this list (certifications, additional coursework or training, publications) that may be relevant.

A copy of the Board Certification

Documentation of 10 cases in each modality required at WVUH under supervision of an AU under the WVUH NRC radioactive materials license.

If applying for use under 35.500, provide documentation of training in device operation, safety procedures and clinical use as required by [10 CFR 35.590\(d\)](#) for each device in which you are applying.

A copy of the NRC or Agreement State radioactive materials license where you completed supervised work and clinical experience.

PART F: TRAINING AND EXPERIENCE

F.1 Applicants must provide documentation of classroom and laboratory training, supervised work experience, and supervised clinical experience. Below are links to training and experience requirements for each use as specified in 10 CFR Part 35. Applicants should reference these training and experience requirements to ensure all training and experience documentation is submitted with this application.

[For uses under 35.100 Uptake, dilution, and excretion studies - 10 CFR 35.190](#)

[For uses under 35.200 Imaging and localization studies - 10 CFR 35.290](#)

[For uses under 35.500 Sealed sources for diagnosis - 10 CFR 35.590](#)

F.2 Applicants should submit training and experience documentation on the NRC Form 313 A series form, below.

[For AU training, experience and preceptor attestation for uses under 35.100, 25.200, and 35.500](#)

F.3 You must complete at least 10 cases at WVUH in each modality in which you are applying under the supervision of an AU in that modality under the WVUH NRC radioactive materials license. Have you completed this requirement?

Yes

No

F.4 In addition to the required documentation listed in Instruction to Applicants in line number 3, you will need to provide the following additional information as attachments to this application. Check all attachments that you will be submitting with this application. Please submit any other documentation not included on this list (certifications, additional coursework or training, publications) that may be relevant.

Documentation of the classroom and laboratory training, supervised work experience, and supervised clinical experience (NRC 313A series form)

A written attestation, signed by a preceptor physician AU, or if applicable, the residency program Director (this may be completed on NRC 313A series form).

Documentation that the preceptor physician AU is authorized in that modality.

Documentation of 10 cases in each modality required at WVUH under supervision of an AU under the WVUH NRC radioactive materials license.

A copy of the NRC or Agreement State radioactive materials license where you completed supervised work and clinical experience.

Human Use Application Processing Data (For Radiation Safety Department Only)

Application Received _____/_____/_____

Returned for Additional Info _____/_____/_____

Application Received _____/_____/_____

Temp approval: _____/_____/_____ Signed: _____

Committee approval: _____/_____/_____ Denied: _____/_____/_____

Comments:
