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February 11, 2021

Maryann Ayoade

Division of Materials Safety, Security, State and Tribal Programs

Office of Nuclear Material Safety and Safeguards

US Nuclear Regulatory Commission

11545 Rockville Pike

Rockville, MD 20852

Re: American Board of Radiology Request for AU-E designation for Interventional Radiology/Diagnostic Radiology (IR/DR) Board Certification

Dear Ms. Ayoade:

As of July 1, 2020, I became the new executive director for the American Board of Radiology (ABR). As such, I have assumed responsibility as the ABR designee for all official correspondence with the NRC.

Please consider this letter the ABR's official request for approval to issue the designation of Authorized User-Eligible (AU-E) for candidates successfully completing the Interventional Radiology/Diagnostic Radiology (IR/DR) board certification process.

Details regarding the IR/DR AU-E requirements, process and documentation can be found in Addendum A.

Please let me know if you have any additional questions or need anything else.

Regards,

Brent Wagner, MD, MBA
Executive Director

Enclosure: Addendum A

cc: Donna-Beth Howe, Ph.D

M. Elizabeth Oates, MD, ABR Nuclear Radiology Trustee

David Laszakovits, ABR Director of Communications

Compliance with NRC Regulations

NRC Training and Experience Requirements for Interventional Radiology/Diagnostic Radiology (IR/DR)

The information below covers NRC §35.290, §35.392 and §35.394.

Training for Imaging and Localization Studies:

Candidates seeking specialty certification in IR/DR must meet all specific training and experience requirements described in:

§35.290 (c)(1)(i) through (c)(2)(ii)(G), “Training for imaging and localization studies”.

Each IR/DR candidate seeking Authorized User (AU) eligibility status through the ABR pathway must have completed, at a minimum:

700 hours of training and experience, including a minimum of **80** hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. This training and experience must include, at a minimum:

Classroom and laboratory training in:

- Radiation physics and instrumentation;
- Radiation protection;
- Mathematics pertaining to the use and measurement of radioactivity;
- Chemistry of byproduct material for medical use; and
- Radiation biology;

And

Work experience, under the supervision of a preceptor AU who meets the requirements in §35.57, §35.290, §§35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements. Work experience must involve:

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

- Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;
- Administering dosages of radioactive drugs to patients or human research subjects; and
- Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs.

Each IR/DR candidate must demonstrate hands-on work experience in performing the supervised experience requirements. **Observation alone is not sufficient.**

Training for Oral Administration of Sodium Iodide I-131 Requiring a Written Directive:

Candidates seeking specialty certification in IR/DR must meet all specific training and experience requirements described in:

§35.392 (c)(1)(i) through (c)(2)(vi), “Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)”

and

§35.394 (c)(1)(i) through (c)(2)(vi), “Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)”.

Each IR/DR candidate seeking Authorized User (AU) eligibility status through the ABR pathway must have successfully completed **80** hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. This training must include:

- Radiation physics and instrumentation;
- Radiation protection;
- Mathematics pertaining to the use and measurement of radioactivity;
- Chemistry of byproduct material for medical use; and
- Radiation biology;

And

Work experience, under the supervision of a preceptor AU who meets the requirements in §§35.57, 35.390, 35.394, or equivalent Agreement State requirements. A supervising AU who meets requirements in §35.390(b) must also have experience in administering dosages as specified in §35.390(b)(1)(ii)(G)(2). The work experience must involve:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- Performing quality-control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- Calculating, measuring, and safely preparing patient or human research subject dosages;

- Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
- Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;
- Administering dosages of radioactive drugs to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and
- Administering dosages of radioactive drugs to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131.

Under the supervision of a qualified AU, each IR/DR candidate must meet all of the training and experience requirements specified in both §35.392 and §35.394 for medical uses of oral sodium iodide I-131 (≤ 33 mCi and > 33 mCi, respectively) for procedures requiring a written directive. **Candidates for AU eligibility via the ABR Pathway must meet all training and experience requirements specified in §35.394.**

Each IR/DR candidate must demonstrate hands-on work experience in performing the supervised experience requirements. **Observation alone is not sufficient.**

Detailed information may be accessed via the NRC Medical Uses Licensee Toolkit (<https://www.nrc.gov/materials/miau/med-use-toolkit.html>), the NRC Medical Regulations in 10 CFR Part 35 (<https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/>), and the Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses, Final Report (NUREG-1556, Volume 9, Revision 3 (<https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/>)).

Authorized User (AU)-eligible Designation for IR/DR: Oral Sodium Iodide I-131 Case Experience Documentation

Work experience for the oral administration of sodium iodide I-131 requiring a written directive must be performed under the supervision of an AU who meets the requirements in §35.390, §35.394, or equivalent Agreement State requirements. A supervising AU who meets requirements in §35.390(b)(1)(ii)(G)(2) must have experience in the oral administration of dosages of sodium iodide I-131 for which a written directive is required in that dosage category or categories.

Work experience must involve administering therapeutic dosages to patients or human research subjects that include, at a minimum:

- **Three** cases involving the oral administration of ≤ 33 mCi of sodium iodide I-131; and
- **Three** cases involving the oral administration of > 33 mCi of sodium iodide I-131.

A logbook of these therapies must be kept by the IR/DR candidate and submitted to the ABR in the format given below.

Candidates for AU eligibility via the ABR Pathway must, at a minimum, meet all training and experience requirements specified in §35.394.

Forms to Be Submitted to the ABR

Two forms, contained within one document, are available to document compliance with and completion of the required NRC/Agreement State training and experience. Both completed forms must be submitted by the program on behalf of each IR/DR candidate for the candidate to be eligible for an ABR IR/DR Certificate with the *Authorized User (AU)-eligible* designation.

- ABR Form A (IR/DR Program Director Attestation);
- ABR Form B (IR/DR Candidate sodium iodide I-131 Case Log).

ABR Form A – IR/DR Program Director Attestation

This form assures the ABR (and the NRC/Agreement State) that each IR/DR candidate has completed the required training and experience in keeping with the NRC curriculum for AU status. The program director must submit an attestation form for each candidate, not a “blanket approval” for a residency class, because the training and experience in NRC-related aspects may vary within the group.

Under no circumstances should program directors designate as NRC-compliant a candidate who has not completed the full course of study mandated in the NRC curriculum for an AU. A false attestation of completion of NRC training would jeopardize the reputation and integrity of the residency program and the ABR and would threaten the relationship among these organizations and the NRC.

The ABR reserves the right to audit the manner in which candidates have completed the submitted curricular requirements. Regardless of whether or not a candidate completed the full NRC-mandated curriculum, the candidate must have completed 16 or more clinical weeks (approximately four months, or a minimum of 700 hours) of training and experience during the five years. Time away (e.g., vacations, AIRP, etc.) cannot be counted toward this requirement.

The candidate will be expected to answer NRC-related questions on all ABR exams. The exams will assess knowledge and competence in radiation safety, radionuclide handling, quality control, and related topics including but not limited to radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, chemistry of byproduct material for medical use, radiation biology, applicable to imaging and localization studies as well as applicable to oral sodium iodide I-131 procedures for which a written directive is required in both dosages ≤ 33 mCi and > 33 mCi.

ABR Form B – IR/DR Candidate Sodium Iodide I-131 Case Log

Because of HIPAA concerns, no patient identifying data should be included on Form B. For IR/DR candidates, participation in at least **three** oral sodium iodide I-131 administrations in each categories is required. Because patients requiring sodium iodide I-131 therapy in dosages ≤ 33 mCi and > 33 mCi present in different clinical settings, and to assure appropriate clinical experience with both levels of sodium iodide I-131 administrations, each set of **three** cases must be discrete and listed in the proper category. Thus, the exact administered dosages of oral sodium iodide I-131 in each category, ≤ 33 mCi and > 33 mCi, must be recorded accurately within the appropriate category in the case log. That is, administered activity > 33 mCi of sodium iodide I-131 cannot be used in the category designated for ≤ 33 mCi of sodium iodide I-131, or vice versa.

Candidates for AU eligibility must, at a minimum, meet the training and experience requirements for §35.394.

ABR Exams and the NRC Curriculum for Specialty Certification in IR/DR

The NRC/Agreement States accept ABR certification as evidence that a practitioner is properly trained to use radioactive materials safely and effectively in the practice of interventional radiology/diagnostic radiology. Content addressing safety and the handling of radionuclides (radiopharmaceuticals), as specified by the NRC-required curriculum, is embedded in the ABR Core and Certifying exams leading to initial certification in IR/DR.

A candidate's performances on the NRC-related portions of the Core and Certifying exams jointly comprise the Radioisotope Safety Exam (RISE). The results of the RISE will be determined only after a candidate successfully completes and passes the Certifying Exam.

The ABR recommends that all IR/DR residency programs ensure that their training is compliant with all elements specified by the NRC as listed on the ABR website. In this way, all candidates will be well prepared to take the NRC-related portions of the ABR Core and Certifying exams and will be qualified to provide services safely and effectively.

The ABR AU-eligible Designation for Specialty Certification in IR/DR

Timely submission of the ABR forms documents completion of the required NRC training and allows candidates who fulfill all requirements listed on Forms A and B and who pass all their ABR exams, including the RISE content, to receive an ABR certificate that contains the additional designation of *AU-eligible*. This designation will appear near the left lower corner of the certificate.

If Forms A and B are not completed or submitted to the ABR for a candidate, *AU-eligible* certificate designation will not be possible, even though the NRC-required training and experience may have been met, and the exams may have been passed by the candidate.

An *AU-eligible* IR/DR certificate indicates that the diplomate has fulfilled all the training and experience requirements of the NRC/Agreement State and has passed all the ABR exams, including the RISE. It means that the diplomate is eligible through the ABR board certification pathway to be approved by the NRC/Agreement State as an Authorized User (AU) for the medical use of radionuclides (radiopharmaceuticals) for imaging and localization studies and for the oral administration of sodium iodide I-131 in dosages ≤ 33 mCi and > 33 mCi for procedures requiring a written directive.

AU-eligible diplomates should work with their employer institution to apply to the NRC/Agreement State for AU status. Such AU status allows the diplomate to be listed on the institutional or practice site license in order to oversee the safe and effective medical use of byproduct material (radionuclides/radiopharmaceuticals), including sodium iodide I-131.

ABR diplomates who do not have the designation *AU-eligible* on their certificates may have their institution or practice site apply for status as an AU via the NRC's alternate pathway, for which they will be required to provide detailed information about their relevant training and experience.

Frequently Asked Questions

Non-Authorized User Duties

If a radiologist is not named as an Authorized User (AU) on an NRC license at an institution, what duties may he or she perform at that facility?

The NRC recognizes that it is frequently necessary for an Authorized User (AU) to delegate to other individuals the specific tasks associated with preparing and administering byproduct material (radionuclides or radiopharmaceuticals) for medical use in patients (§35.27). These individuals include technologists and other physicians who may not be AUs.

If the policies and procedures of the institution holding an NRC radioactive materials license allow, the NRC regulations permit delegation of these duties if the individuals performing the duties are properly instructed and supervised. Specifically:

Subpart D – Unsealed Byproduct Material – Written Directive Not Required:

- §35.100 “Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required”;

- §35.200 “Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required”;

And

Subpart E—Unsealed Byproduct Material – Written Directive Required:

- §35.300 “Use of unsealed byproduct material for which a written directive is required”.

The supervising AU need not be physically present for delegated use of byproduct material under subparts D and E. Furthermore, there is no NRC requirement that diagnostic examinations performed using byproduct material must be interpreted by an AU. Thus, the NRC regulations do not restrict who can interpret and report diagnostic imaging or the results of therapeutic procedures (i.e., radiologists who are not AUs may interpret and report such examinations and procedures). However, it is strongly recommended that those non-AU and AU radiologists practicing in NRC Agreement States consult the appropriate state regulatory agency to ensure that the state regulations allow for this delegation.

According to NRC regulations, only an AU can sign a written directive, including those necessary for therapeutic procedures involving unsealed byproduct material (e.g., treatment of hyperthyroidism, ablation of residual functional thyroid tissue, or treatment of functioning thyroid metastases using oral sodium iodide I-131). However, administration of the therapeutic unsealed byproduct dosage specified in the written directive may be delegated if the individuals performing the administration are properly instructed in the written directive procedures and supervised accordingly.

Radioisotope Safety Exam (RISE) FAQs

What is the nature of the exam?

This is a computer-based examination. Candidates may review the [Core Practice Exam](#) to help them understand the types of items that will be included on the exam.

How long is the exam?

Exam details, including the number of questions and exam length, are located [here](#).

What material does the exam cover?

Questions on radiopharmaceuticals, including radioiodines, clinically relevant beta emitters, and PET radionuclides should be anticipated. Considerable content regarding radionuclides/radiopharmaceuticals will be included, and the exam will include all NRC-related issues. The exams will assess knowledge and competence in radiation safety, radionuclide handling, quality control, and related topics including but not limited to radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, chemistry of byproduct material for medical use, radiation biology, applicable to imaging and localization studies as well as applicable to oral sodium iodide I-131 procedures for which a written directive is required in both dosages ≤ 33 mCi and > 33 mCi. The candidate will be expected to answer NRC-related questions on [all](#) ABR exams.

Does the ABR provide guidelines to facilitate preparation?

The NRC website provides the general areas of training content under §35.290, §35.392, and §35.394, which are pertinent to the exam. The NRC website also provides rules and regulations applicable to the safe use of radiopharmaceuticals and compliance issues that are included on the exam. In addition, a study guide for the exam is available [here](#) on the ABR website. Candidates may also review the [Core Exam Study Guide](#).

If I need to take a separate RISE, what options/dates will be available to me later?

The separate RISE is given annually in the spring. Registration information is available on this website each year beginning December 1. Candidates are eligible to take the RISE up to seven years from the date of completion of their residency.

What is the fee to take the exam?

The exam fee is located [here](#) on this website.

Where can I take the exam?

The separate RISE is administered at the Tucson Exam Center.

What benefit/rights does AU eligibility give me?

Being AU-eligible through the ABR gives the potential to more efficiently comply with some of the requirements set forth by the NRC to become an Authorized User. However, the ABR suggests candidates contact their institution/workplace for information regarding its particular AU requirements.

FORM A

12/18



American Board of Radiology – Program Director Attestation

FOR INTERVENTIONAL RADIOLOGY/DIAGNOSTIC RADIOLOGY

COMPLIANCE WITH NRC TRAINING AND EXPERIENCE REQUIREMENTS

Note: the training and experience in the ACGME Interventional Radiology program requirements may not meet all of the minimum NRC requirements for §35.290, §35.392 and §35.394. Please carefully read each requirement below to ensure the listed candidate has completed the required NRC training and experience for Authorized User eligibility.

Forms A and B must be submitted after completion of the candidate’s NRC training and experience

More information can be found at the following links:

NRC Medical Uses Licensee Toolkit (<https://www.nrc.gov/materials/miau/med-use-toolkit.html>), the NRC Medical Regulations in 10 CFR Part 35 (<https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/>), and the Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses, Final Report (NUREG-1556, Volume 9, Revision 3 (<https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/>)).

Candidate Name	Program Name	Program Number
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Training for Imaging and Localization Studies (§35.290)	YES	NO
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We attest that this candidate completed **700** hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies

	<input type="checkbox"/>	<input type="checkbox"/>
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- We attest that this candidate completed a minimum of **80** hours of classroom and laboratory training in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies (§35.290).
- We attest that this classroom and laboratory training included radiation physics and instrumentation (§35.290).
- We attest that this classroom and laboratory training included radiation protection (§35.290).
- We attest that this classroom and laboratory training included mathematics pertaining to the use and measurement of radioactivity (§35.290).
- We attest that this classroom and laboratory training included chemistry of byproduct material for medical use (§35.290).
- We attest that this classroom and laboratory training included radiation biology (§35.290).
- We attest that this work experience, under the supervision of an Authorized User (AU), included ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys (§35.290).
- We attest that this work experience, under the supervision of an Authorized User (AU), included performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters (§35.290).
- We attest that this work experience, under the supervision of an Authorized User (AU), included calculating, measuring, and safely preparing patient or human research subject dosages (§35.290).
- We attest that this work experience, under the supervision of an Authorized User (AU), included using administrative controls to prevent a medical event involving the use of unsealed byproduct material (§35.290).
- We attest that this work experience, under the supervision of an Authorized User (AU), included using procedures to safely contain spilled radioactive material and using proper decontamination procedures (§35.290).
- We attest that this work experience, under the supervision of an Authorized User (AU), included administering dosages of radioactive drugs to patients or human research subjects (§35.290).
- We attest that this work experience, under the supervision of an Authorized User (AU), included eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare radioactive drugs (§35.290).
- We attest that the work experience cited above for §35.290 was completed under the supervision of an Authorized User (AU) who meets the requirements under relevant sections of §35.290 or

equivalent Agreement State requirements, and that this candidate has achieved a level of competency sufficient to function independently as an Authorized User (AU) for the medical use authorized under §35.290.

We attest that an hour is not counted more than once in the total number of hours of training and experience, and if electronic training (including web-based and on-line training) is provided during the residency program, the candidate is credited with only the actual hours spent on the electronic training.

Training for Oral Administration of Sodium Iodide I-131 Requiring a Written Directive (§35.392 and §35.394).

YES NO

We attest that this candidate successfully completed **80** hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive (§35.392 and §35.394).

We attest that this classroom and laboratory training included radiation physics and instrumentation (§35.392 and §35.394).

We attest that this classroom and laboratory training included radiation protection (§35.392 and §35.394).

We attest that this classroom and laboratory training included mathematics pertaining to the use and measurement of radioactivity (§35.392 and §35.394).

We attest that this classroom and laboratory training included chemistry of byproduct material for medical use (§35.392 and §35.394).

We attest that this classroom and laboratory training included radiation biology (§35.392 and §35.394).

We attest that this work experience, under the supervision of an Authorized User (AU), included ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys (§35.392 and §35.394).

We attest that this work experience, under the supervision of an Authorized User (AU), included performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters (§35.392 and §35.394).

We attest that this work experience, under the supervision of an Authorized User (AU), included calculating, measuring, and safely preparing patient or human research subject dosages (§35.392 and §35.394).

We attest that this work experience, under the supervision of an Authorized User (AU), included using administrative controls to prevent a medical event involving the use of unsealed byproduct material (§35.392 and §35.394).

We attest that this work experience, under the supervision of an Authorized User (AU), included using procedures to safely contain spilled radioactive material and using proper decontamination procedures (§35.392 and §35.394).

We attest that this work experience, under the supervision of an Authorized User (AU), included administering dosages of radioactive drugs to patients or human research subjects, that includes at least **3** cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 (§35.392). (Refer to Case Log, Form B.)

This candidate’s log of these sodium iodide I-131 therapy experiences (date, exact dosage, and preceptor attestation, including attestation to experience in administering dosages in the same dosage category) is attached (Form B).

We attest that the work experience cited above for §35.392 was completed under the supervision of an Authorized User (AU) who meets the requirements under §35.390, §35.392, §35.394, or equivalent Agreement State requirements, and that this candidate has achieved a level of competency sufficient to function independently as an Authorized User (AU) for the medical uses authorized under §35.392.

We attest that this work experience, under the supervision of an Authorized User (AU), included administering dosages of radioactive drugs to patients or human research subjects, that includes at least **3** cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 (§35.394). (Refer to Case Log, Form B.)

This candidate’s log of these sodium iodide I-131 therapy experiences (date, exact dosage, and preceptor attestation, including attestation to experience in administering dosages in the same dosage category) is attached (Form B).

We attest that the work experience cited above for §35.394 was completed under the supervision of an Authorized User (AU) who meets the requirements under §35.390, §35.394, or equivalent Agreement State requirements, and that this candidate has achieved a level of competency sufficient to function independently as an Authorized User (AU) for the medical uses authorized under §35.394.

Residency Program Director (print name)

Residency Program Director (signature)

Date

Preceptor Authorized User (print name)

Preceptor Authorized User (signature)

Date

FORM B

Sodium Iodide I-131 Therapy Experience Log

Candidate Name

Program Name

Program Number

≤ 33 mCi

Date

Exact Dosage Administered

Supervising Preceptor (AU) – Print and Sign Name

1. _____

Print Name

Sign Name

I attest that I have experience in administering dosages of ≤33 mCi.

2. _____

Print Name

Sign Name

I attest that I have experience in administering dosages of ≤33 mCi.

3. _____

Print Name

Sign Name

I attest that I have experience in administering dosages of ≤33 mCi.

> 33 mCi

<u>Date</u>	<u>Exact Dosage Administered</u>	<u>Supervising Preceptor (AU) – Print and Sign Name</u>
1. _____	_____	_____ Print Name
		_____ Sign Name
		<input type="checkbox"/> I attest that I have experience in administering dosages of >33 mCi.
2. _____	_____	_____ Print Name
		_____ Sign Name
		<input type="checkbox"/> I attest that I have experience in administering dosages of >33 mCi.
3. _____	_____	_____ Print Name
		_____ Sign Name
		<input type="checkbox"/> I attest that I have experience in administering dosages of >33 mCi.