APPENDIX D

DOCUMENTATION OF TRAINING AND EXPERIENCE TO IDENTIFY INDIVIDUALS ON A LICENSE

Documentation of Training and Experience to Identify Individuals on a License

Licensees should use the most current version of the applicable NRC Form 313A. Refer to the NRC Medical Uses Licensee Toolkit Web page for the most current version of the forms and their associated instructions. Also refer to the NRC Forms Web site at: https://www.nrc.gov/reading-rm/doc-collections/forms/ for the NRC Form 313A series. Verify that the most current version of the NRC Form 313A is being used by checking the "Expires" date in the right, top-hand corner of the form.

I. Experienced Authorized Users, Authorized Medical Physicists, Ophthalmic Physicists, Authorized Nuclear Pharmacists, Radiation Safety Officer, or Associate Radiation Safety Officers

An applicant or licensee who is adding an experienced authorized user (AU) for medical uses, authorized medical physicist (AMP), ophthalmic physicist (OP), authorized nuclear pharmacist (ANP), radiation safety officer (RSO) or associate radiation safety officer (ARSO) to its medical use license or application only needs to provide evidence that the individual is listed on a medical use license issued by the NRC or Agreement State, a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad scope licensee, or a permit issued by an NRC master material broad scope permittee, provided that the individual is authorized for the same types of use(s) requested in the application under review, and the individual meets the recentness of training criteria described in 10 CFR 35.59. When adding an experienced ANP to the license, the applicant also may provide evidence that the individual is listed on an NRC or Agreement State commercial nuclear pharmacy license or identified as an ANP by a commercial nuclear pharmacy authorized to identify ANPs. For individuals who have been previously authorized by, but not listed on, the commercial nuclear pharmacy license, medical broad scope license, or Master Materials License medical broad scope permit, the applicant should submit either verification of previous authorizations granted or evidence of acceptable training and experience. Applicants are reminded that in accordance with 10 CFR 35.310, 10 CFR 35.410, and 10 CFR 35.610 instruction on the licensee's operating and emergency procedures are required for the above personnel.

II. Experienced Physicians, Podiatrists, Dentists, Nuclear Pharmacists, Medical Physicists, and Radiation Safety Officers Who Only Used Accelerator-Produced Nuclear Materials, or Discrete Sources of Ra-226, or Both, for Medical or Nuclear Pharmacy Uses

Pursuant to 10 CFR 35.57(a)(4) and 10 CFR 35.57(b)(3), the NRC "grandfathered" RSOs, physicians, podiatrists, dentists, medical physicists, and nuclear pharmacists that used only accelerator-produced radioactive materials, discrete sources of radium (Ra)-226, or both for medical or nuclear pharmacy uses at a Government agency or federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, when using these materials for the same uses. The applicant or licensee that is adding one of these experienced individuals to its medical use license should document that the individual used only accelerator-produced radionuclides, or discrete sources of Ra-226, or both, for medical or nuclear pharmacy uses before or during the dates specified and that the materials were used for the same uses requested. This documentation may be, but is not restricted to, evidence that the individual was listed on an Agreement State or non-Agreement State license or permit authorizing these materials for the requested uses.

III. Applications that Include New Authorized User, Authorized Medical Physicist, Ophthalmic Physicist, Authorized Nuclear Pharmacist, Radiation Safety Officer or Associate Radiation Safety Officer Recognition by NRC

Applicants should submit the appropriate completed form in the NRC Form 313A series to show that the individuals meet the correct training and experience criteria in 10 CFR Part 35, Subparts B, D, E, F, G, and H. For the applicant's convenience, a separate NRC Form 313A is available for each type of user (e.g., RSO, AMP, Diagnostic AU). When an applicant wants to identify one or more ARSOs, the applicant must identify the types of use (e.g., 10 CFR 35.200, 10 CFR 35.300) of byproduct material for which the individual may be assigned duties and tasks under the licensee's program in the oversight of the radiation safety operations.

The regulations provide multiple pathways which applicants can use to demonstrate that individuals are qualified as an AU, AMP, RSO, and ARSO. Applicants should provide documentation that each individual is qualified under one pathway. There are two primary training and experience routes to qualify an individual as a new AU, AMP, ANP, RSO or ARSO. The first is by means of certification by a board recognized by NRC and listed on the NRC Web site as provided in 10 CFR 35.50(a), 10 CFR 35.51(a), 10 CFR 35.55(a), 10 CFR 35.190(a), 10 CFR 35.290(a), 10 CFR 35.390(a), 10 CFR 35.392(a), 10 CFR 35.394(a), 10 CFR 35.396(a), 10 CFR 35.490(a), 10 CFR 35.590(a), or 10 CFR 35.690(a), or included in the regulations in 10 CFR 35.57(a)(2), 10 CFR 35.57(a)(3), 10 CFR 35.57(b)(2). Additional training may also need to be documented for RSOs, ARSOs, AMPs, and AUs under 10 CFR 35.50, 10 CFR 35.51, 10 CFR 35.390, 10 CFR 35.396, and 10 CFR 35.690.

The second route is by meeting the structured educational program, supervised work experience, and preceptor attestation requirements in 10 CFR Part 35, Subparts B, D, E, F, G, and H. Ophthalmic physicists can only qualify under this route as the NRC does not have a regulation under which it recognizes ophthalmic physicist boards. For RSOs, ARSOs, ANPs, and AU's, the NRC requires supervised work experience conducted under the supervision of an authorized individual in a licensed material use program. In this case, a supervisor is an individual who provides frequent direction, instruction, and direct oversight of the student as the student completes the required work experience in the use of byproduct material. Supervision may occur at various licensed facilities, from a large teaching university hospital to a small private practice.

In some cases, there may be additional training and experience routes and requirements for recognized AUs, ANPs, AMPs, RSOs or ARSOs to seek additional authorizations.

IV. Recentness of Training

The required training and experience, including board certification and prior approval on a license, described in 10 CFR Part 35 must be obtained within the 7 years preceding the date of the application, or the individual must document having completed related continuing education, and experience since obtaining the required training and experience as described in 10 CFR 35.59. Acceptable continuing education and experience for physicians include the following, to be reviewed on a case-by-case basis:

- successful completion of classroom and laboratory review courses that include radiation safety practices relative to the proposed type of authorized medical use (this review may include various types of instruction, including online training, as long as the subject

matter relates to radiation safety and safe handling of byproduct material for the uses requested)

- practical and laboratory experience with patient procedures using radioactive material for the same use(s) for which the applicant is requesting authorization

- practical and laboratory experience under the supervision of an AU at the same or another licensed facility that is authorized for the same use(s) for which the applicant is requesting authorization

- for therapy devices, experience with the therapy unit and/or comparable linear accelerator experience and completion of an in-service review of operating and emergency procedures relative to the therapy unit to be used by the applicant

V. General Instructions and Guidance for Filling Out NRC Form 313A Series

If the applicant is proposing an individual for more than one type of authorization, the applicant may need to either submit multiple forms in the NRC Form 313A series or fill out some sections more than once. For example, an applicant that requests a physician be authorized for 10 CFR 35.200 and 10 CFR 35.300 medical uses and as the RSO, should provide three completed NRC Form 313A series forms [i.e., NRC Form 313A (RSO), NRC Form 313A (AUD) and NRC Form 313A (AUT)]. If the applicant has multiple supervising individuals, more than one form may be used to document supervised work experience. To identify any individual (i.e., proposed individual or supervising individual or preceptor) currently or previously listed on a license, provide the license number (if issued by the NRC) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master materials licensee on which the individual was identified. If the Agreement State license authorizes possession of Category 1 or Category 2 sources, submission of the Agreement State license is not required as this license should be in WBL. If the applicant knows that the referenced Agreement State license is contained within WBL for other licenses, submission of the license is not required. To identify an individual who is authorized under a broad scope license or broad scope permit of a Master Materials License, provide a complete copy of the permit issued by the broad scope licensee/permittee. Alternatively, provide a statement signed by the RSO or chairperson of the RSC similar to the following: "_____ (name of individual) was authorized under _____ (name of licensee/permittee) broad scope license number_____ to use_____ (materials) during _____ (time frame)."

INTRODUCTORY INFORMATION

Name of Individual

Provide the individual's complete name so that the NRC can distinguish the individual from others with a similar name. Include terminal degree designation(s) documentation as applicable to the review of the individual that the applicant is requesting to be listed on the license.

***Note**:* Do not include personal or private information (e.g., date of birth, social security number, home address, personal telephone number) as part of the qualification documentation.

State or Territory Where Licensed

The NRC requires physicians, dentists, podiatrists, and pharmacists to be licensed by a State or territory of the U.S., the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine, as well as licensed in the practice of dentistry, podiatry, or pharmacy, respectively (see definitions of "physician," "dentist," "podiatrist," and "pharmacist" in 10 CFR 35.2, "Definitions").

Requested Authorization(s)

Indicate authorizations requested and fill in the blanks as provided.

Training and Experience Documentation

Indicate the applicable training and experience pathway, as documented on the form.

Board Certification Pathway

The applicant or licensee may use this pathway if the proposed new authorized individual is certified by a board recognized by the NRC. Specialty board certifications recognized by the NRC are either posted on the Medical Uses Licensee Toolkit Web page or if certified prior to October 24, 2005, by a board listed in 10 CFR 35.57.

***Note**:* An individual that is board-eligible will not be considered for this pathway until the individual is actually board certified. Further, individuals holding other board certifications, but not certified by a board recognized by the NRC, will not be considered for this pathway.

The applicant or licensee will need to provide a copy of the board certification and other documentation of training, experience, or clinical casework, as indicated on the specific form of the NRC Form 313A series. To ensure that the board certification is current, applicants are reminded to review the sample certificate on NRC's Medical Uses Licensee Toolkit to assure that the language in the proposed individual's certificate is up to date.

With the exception of an applicant requesting a proposed individual under the provisions of 10 CFR 35.396, board certified applicants do not need to provide a preceptor attestation.

Alternate Pathway for Training and Experience for Proposed New Authorized Individuals or Individuals Seeking Additional Authorizations

The regulatory requirements refer to two categories of training: (i) classroom and laboratory training, and (ii) supervised work experience. All hours credited to classroom and laboratory training must relate directly to radiation safety and safe handling of byproduct material and be allocated to one of the topics in the regulations. Each hour of training involving performance of radiation safety tasks or hands-on use of byproduct material may be credited to either (i) classroom and laboratory training, or (ii) supervised work experience. Note that a single hour of training may only be counted once and may not be credited to both of these categories.

The proposed authorized individual may receive the required classroom and laboratory training, supervised work experience, and clinical casework at a single training facility or at multiple training facilities; therefore, space is provided to identify each location and date of training or experience. The date should be provided in the month/day/year (mm/dd/yyyy) format.

The specific number of hours needed for each training and experience element will depend upon the type of approval sought. On the form, provide the number of clock hours spent on the topics listed in the regulatory requirements, ensuring to document hours for each topic.

The proposed authorized individual may obtain the required "classroom and laboratory training" in any number of settings, locations, and educational situations. For example, at some medical teaching/university institutions, a course may be provided for that particular need and taught in consecutive days. In other training programs, the period may be a semester or quarter as part of the formal curriculum. Also, the classroom and laboratory training may be obtained using a variety of other instructional methods. Therefore, the NRC will broadly interpret "classroom and laboratory training" to include various types of instruction, including online training, as long as it meets the specific clock hour requirements and the subject matter relates to radiation safety and safe handling of byproduct material for the uses requested. For online or other training programs new to the NRC, the training entity may be contacted by the NRC to discuss the training program components (course outline, test, mechanism to ensure proposed individual completed the training and test) and to ensure that the program is robust.

The "supervised work experience" for physicians must include, but is not limited to, the subject areas listed in the applicable training and experience requirements. The NRC recognizes that physicians in training will not dedicate all of their supervised work experience time specifically to the subject areas listed in the regulatory requirements and will be attending to other clinical activities involving the medical use of byproduct material (e.g., reviewing case histories or interpreting scans). Hours spent on these other duties not directly related to radiation safety or hands-on use of byproduct material, even though not specifically required by the NRC, may be credited to the supervised work experience category but not to the classroom and laboratory training category.

For other authorized individuals (i.e. RSO, ARSO, ANP, AMP, OP), all the hours of supervised experience should be allocated to the topics specified in the regulations. Other than for individuals qualifying under 10 CFR Part 35, Subpart G, the applicant must submit a Preceptor Attestation for all non-board certified individuals.

***Note**:* If the proposed new authorized individual had more than one supervisor, provide the information requested for each supervising individual.

Preceptor Attestation

The NRC defines the term "preceptor" in 10 CFR 35.2, "Definitions," as "an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, a Radiation Safety Officer, or an Associate Radiation Safety Officer." While the supervising individual for the work experience may also be the preceptor, the preceptor does not have to be the supervising individual as long as the preceptor directs or verifies the training and experience required. The preceptor must attest in writing regarding the training and experience of any individual to serve as an authorized individual and attest that the individual has satisfactorily completed the appropriate training and experience requirements and is able to independently fulfill the radiation safety-related duties of an authorized individual. For authorized users, this does not require an attestation of general clinical competency but requires sufficient attestation to demonstrate that the individual is able to independently fulfill the duties of the position for which the attestation is sought. The preceptor also has to meet specific requirements and must have authorization for the same categories that the proposed candidate is seeking. In addition,

a residency program director may make the attestation by affirming in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user for the uses requested, and concurs with the attestation provided by the residency program director.

VI. Specific Instructions and Guidance for Filling out NRC Form 313A Series Forms

Because there are a number of different pathways to obtain the required training and experience for different authorized individuals, specific instructions are available for each form in the NRC 313A series. Please refer to the NRC's Medical Uses Licensee Toolkit for links to the current NRC 313A Series forms and associated instructions. Also refer to the NRC Forms Web site at: https://www.nrc.gov/reading-rm/doc-collections/forms/ for the NRC Form 313A series. Verify that the most current version of the NRC Form 313A is being used by checking the "Expires" date in the right, top-hand corner of the form.