June 22, 2000

Board of Pharmaceutical Specialties
ATTN: Mr. Richard Bertin
Executive Director
2215 Constitution Avenue, NW
Washington, DC 20037-2985

SUBJECT: RECOGNITION OF BOARDS

Dear Mr. Bertin:

As you know, the Nuclear Regulatory Commission (NRC) is revising its medical use regulations in 10 CFR Part 35, "Medical Use of Byproduct Material." I anticipate the Commission will publish the final rule in the Federal Register in 2000, with an effective date 6 months after publication. As part of this revision, the regulatory text will no longer incorporate a listing of the specific boards whose diplomates automatically fulfill the training and experience requirements for an authorized medical physicist, authorized nuclear pharmacist, authorized user, or Radiation Safety Officer. Rather, the NRC will recognize certification boards that require individuals to complete the training and experience requirements specified in the regulatory text. Once recognized, the board's name will be placed on the list of recognized boards maintained on the NRC website. This change is being made to eliminate the need for a rulemaking each time a board is added or deleted.

I am writing to notify you of our intent to initiate the recognition process immediately. Other specialty boards whose diplomates are likely to seek authorization are being similarly notified. If you are interested in having your board recognized by the NRC, please submit a letter to me listing each training and experience section of the rule for which you believe your Board's diplomates should be deemed to have met the requirements. Enclosures 1 and 2 should assist you in preparing your letter. Enclosure 1 lists all areas where NRC plans to recognize boards. Enclosure 2 is a copy of the draft final regulatory text that lists the training and experience criteria for authorized medical physicists, authorized nuclear pharmacists, authorized users, and Radiation Safety Officers.

Your letter should clearly state that an individual must have completed the training and experience required by a particular section prior to receiving board certification. For example, if your board would like to be recognized under 10 CFR 35.390, "Training for use of unsealed byproduct material for which a written directive is required," the letter should state:
(the name of your organization) has reviewed 10 CFR 35.390 and has determined that our

certification process requires an individual to meet all the requirements in paragraph (b) of this section prior to being certified by our board."
The letter should be dated and signed by the chief executive of your board. If you have any questions or comments, please contact Ms. Catherine Haney of my staff (301-415-6825 or E-mail at cxh@nrc.gov) .

Sincerely,

/RA/

Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety

Enclosures:
1. Areas where NRC plans to recognize boards
2. Draft Final Regulatory Text - Training and Experience Criteria

The letter should be dated and signed by the chief executive of your board. If you have any questions or comments, please contact Ms. Catherine Haney of my staff (301-415-6825 or E-mail at cxh@nrc.gov) .

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DRAFT FINAL REGULATORY TEXT

TRAINING AND EXPERIENCE CRITERIA

§ 35.50 Training for Radiation Safety Officer.

Except as provided in § 35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 35.24 to be an individual who --

(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed a structured educational program consisting of both:

(i) 200 hours of didactic training in the following areas--

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Radiation biology; and

(E) Radiation dosimetry; and

(ii) One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes similar type(s) of use(s) of byproduct material involving the following--

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(C) Securing and controlling byproduct material;

(D) Using administrative controls to avoid mistakes in the administration of byproduct

material;

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(F) Using emergency procedures to control byproduct material; and

(G) Disposing of byproduct material; and

(2) Has obtained written certification, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; or

(c) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities.

§ 35.51 Training for an authorized medical physicist.

The licensee shall require the authorized medical physicist to be an individual who --

(a) Is certified by a specialty board whose certification process includes all of the training and experience requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, or health physics and has completed 1 year of full-time training in therapeutic radiological physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist at a medical institution that includes the tasks listed in §§ 35.67, 35.433, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, and 35.652, as applicable; and

(2) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written certification must be signed by a preceptor authorized medical physicist who meets the requirements in § 35.51 or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

§ 35.55 Training for an authorized nuclear pharmacist.

The licensee shall require the authorized nuclear pharmacist to be a pharmacist who --

(a) Is certified as a nuclear pharmacist by a specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed 700 hours in a structured educational program consisting of both:

(i) Didactic training in the following areas --

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Supervised practical experience in a nuclear pharmacy involving --

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(D) Using administrative controls to avoid medical events in the administration of byproduct material; and

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(2) Has obtained written certification, signed by a preceptor authorized nuclear

pharmacist, that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

§ 35.190 Training for uptake, dilution, and excretion studies.

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.100 to be a physician who --

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Is an authorized user under §§ 35.290 or 35.390 or equivalent Agreement State requirements; or

(c)(1) Has completed 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies; the training and experience must include --

(i) Classroom and laboratory training in the following areas --

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in § 35.190, § 35.290, or § 35.390 or equivalent Agreement State requirements, involving --

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.190, 35.290, or 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.100.

§ 35.290 Training for imaging and localization studies.

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.200 to be a physician who --

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Is an authorized user under § 35.390 or equivalent Agreement State requirements; or

(c)(1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies; the training and experience must include, at a minimum, --

(i) Classroom and laboratory training in the following areas --

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use;

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in §§ 35.290 or 35.390 or equivalent Agreement State requirements, involving --

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject

dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(G) 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; and

(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.290 or 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200.

§ 35.390 Training for use of unsealed byproduct material for which a written directive is required.

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.300 to be a physician who --

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive; the training and experience must include --

(i) Classroom and laboratory training in the following areas --

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in § 35.390(a), § 35.390(b), or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)(1), (2), (3), or (4)) as the individual requesting authorized user status. The work experience must involve --

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;

(F) Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(G) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status--

(1) Oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131;

(2) Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131[1];

(3) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; and/or

(4) Parenteral administration of any other radionuclide; and

(2) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets

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[1]Experience with at least 3 cases in Category (G)(2) also satisfies the requirement in Category (G)(1).

the requirements in § 35.390(a), § 35.390(b), or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)(1), (2), (3), or (4)) as the individual requesting authorized user status.

§ 35.392 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).

Except as provided in § 35.57, the licensee shall require an authorized user 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), to be a physician who--

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Is an authorized user under § 35.390(a), § 35.390(b), for uses listed in § 35.390(b)(1)(ii)(G)(1) or (2), § 35.394, or equivalent Agreement State requirements; or

(c)(1) Has 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; the training must include --

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in § 35.390(a), § 35.390(b), § 35.392, § 35.394, or equivalent Agreement State requirements. A supervising authorized user who meets the requirements in § 35.390(b), must have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or (2). The work experience must involve --

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the

related radiation surveys;

(ii) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for 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 byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Administering dosages 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

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.390(a), § 35.390(b), or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirement in § 35.390(b), must have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or (2).

§ 35.394 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries).

Except as provided in § 35.57, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who--

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Is an authorized user under § 35.390(a), § 35.390(b), for uses listed in § 35.390(b)(1)(ii)(G)(2), or equivalent Agreement State requirements; or

(c)(1) Has 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; the training must include --

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in § 35.390(a), § 35.390(b), § 35.394, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2). The work experience must involve --

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the

related radiation surveys;

(ii) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for 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 byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Administering dosages 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; and

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.390(a), § 35.390(b), or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2).

§ 35.490 Training for use of manual brachytherapy sources.

Except as provided in § 35.57, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under § 35.400 to be a physician who --

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes --

(i) 200 hours of classroom and laboratory training in the following areas --

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements at a medical institution, involving --

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Checking survey meters for proper operation;

(C) Preparing, implanting, and removing brachytherapy sources;

(D) Maintaining running inventories of material on hand;

(E) Using administrative controls to prevent a medical event involving the use of byproduct material;

(F) Using emergency procedures to control byproduct material; and

(2) Has obtained 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under § 35.400.

§ 35.491 Training for ophthalmic use of strontium-90.

Except as provided in § 35.57, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who --

(a) Is an authorized user under § 35.490 or equivalent Agreement State requirements; or

(b)(1) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy; the training must include --

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology; and

(2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve --

(i) Examination of each individual to be treated;

(ii) Calculation of the dose to be administered;

(iii) Administration of the dose; and

(iv) Follow up and review of each individual's case history; and

(3) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in § 35.490, § 35.491, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a) and (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

§ 35.590 Training for use of sealed sources for diagnosis.

Except as provided in § 35.57, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under § 35.500 to be a physician, dentist, or podiatrist who --

(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Has had 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device; the training must include --

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity;

(4) Radiation biology; and

(5) Training in the use of the device for the uses requested.

§ 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Except as provided in § 35.57, the licensee shall require an authorized user of a sealed source for a use authorized under § 35.600 to be a physician who --

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes --

(i) 200 hours of classroom and laboratory training in the following areas --

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements at a medical institution, involving --

(A) Reviewing full calibration measurements and periodic spot-checks;

(B) Preparing treatment plans and calculating treatment doses and times;

(C) Using administrative controls to prevent a medical event involving the use of byproduct material;

(D) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(E) Checking and using survey meters; and

(F) Selecting the proper dose and how it is to be administered; and

(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status.