August 1, 2002

RECOMMENDATIONS OF THE NRC ACMUI SUBCOMMITTEE ON TRAINING AND EXPERIENCE REQUIREMENTS

INTRODUCTION

A revision of 10 CFR Part 35, Medical Use of Byproduct Material, was published on April 24, 2002 (Federal Register Vol. 67(79) 20371-20397). The revision contains new training and experience requirements for individuals to become authorized as a radiation safety officer (RSO), authorized medical physicist (AMP), authorized nuclear pharmacist (ANP), and authorized user (AU). These new requirements provide several options for individuals to become authorized. One option is for individuals to be certified by a specialty board whose certification process includes all the requirements in an alternate pathway. The alternate pathway includes specified numbers of hours of training and written certification signed by a preceptor that the individual has satisfactorily completed the training requirements and has achieved a level of competency sufficient to function independently as an RSO, AMP, ANP, or AU. Currently, most specialty boards do not require candidates to meet these specific requirements.

The Advisory Committee on Medical Uses of Isotopes (ACMUI) appointed a subcommittee on training and experience requirements to develop recommendations that would restore board certification as the default pathway for individuals to become authorized as RSO, AMP, or AU. The subcommittee held a meeting on June 21 in Rockville, Maryland and a meeting on July 8 by conference call to discuss draft recommendations and to receive public input. The following recommendations include consideration of discussion from these meetings.

For completeness these recommendations are written to resemble rule language. However, it is not the intention of the subcommittee to specify rule language.

RATIONALE

These recommendations are based on the following assumptions:

(1) Currently accepted boards should be listed explicitly in the regulations;
(2) To facilitate addition of future certification mechanisms to the T&E qualification process without rulemaking initiatives, criteria should be included in the rule to provide a basis for recognizing new boards;
(3) It is expected that the currently accepted boards will meet the criteria in (2);
(4) The preceptor concept should be modified to become documentation for completion of a training program rather than a testament to clinical competence; and;
(5) Specific training should be required for certain new devices or modalities. This training is considered to be a separate requirement that is decoupled from the core training and supervised experience.

The intent of these recommendations is to provide minimum training and experience requirements for an individual to become an AMP, ANP, AU, or RSO. The objective of these requirements is to assure the safe use of byproduct material used in medical practice.

Several pathways are provided to demonstrate adequate knowledge of the safe use of byproduct material. For AMP, ANP, RSO, and most categories of use for AU, adequate knowledge may be demonstrated by obtaining certification by a specialty board. The subcommittee's examination of

various specialty board criteria for admission of candidates revealed that few specialty boards meet the specific requirements of revised Part 35 published April 24, 2002. However, the subcommittee concluded that individuals who had completed the certification process by appropriate specialty boards had demonstrated adequate knowledge in the safe use of byproduct material for their specialty. Thus the subcommittee recommends that these boards be specifically listed as approved boards.

Additional specialty boards may be identified in the future. Therefore, the subcommittee developed specific criteria for recognition of specialty boards. To the best of our knowledge, those specialty boards that are listed in these recommendations meet these specific criteria.

As an alternative to board certification, an individual may demonstrate completion of specified training and experience requirements as provided in revised Part 35.

In addition to meeting the minimum training and experience requirements, authorized individuals would be expected to demonstrate training or experience in the use of byproduct material or specific modalities, as appropriate, which are identified on the licensee's license. This would require a licensee to assure that newly hired authorized individuals have appropriate training and experience and that current authorized individuals receive appropriate training when a new modality is added to the licensee's program.

§ 35.50 Training for Radiation Safety Officer

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

(a) Is certified by:
  (1) American Board of Health Physics in Comprehensive Health Physics;
  (2) American Board of Medical Physics in Medical Health Physics; or
  (3) American Board of Science in Nuclear Medicine in Radiation Protection; or

(b) Is certified by a specialty board whose certification has been recognized by the Commission and requires all diplomates:

  (1) To hold a bachelors or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;
  (2) To have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics;
  (3) To provide a written statement from the supervising physicist or Radiation Safety Officer attesting that the individual has completed the training and experience described in paragraph (b)(2) of this section; and
  (4) To pass an examination administered by diplomates of the specialty board, which evaluate knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, and radiation biology; or

(c) (1) Has completed a structured educational program consisting of 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

(2) Has one year of full-time radiation safety experience under the supervision of an individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes similar types(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 materials;
(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

(3) Has provided a written statement from the supervising physicist(s) or Radiation Safety Officer(s) attesting that the individual has completed the training and experience described in paragraph (c)(1) and (c)(2) of this section; or

(d) 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.

(e) In addition to meeting the requirements of (a), (b), (c), or (d) of this section, the licensee shall require a Radiation Safety Officer to have training in the radiation safety, regulatory issues, emergency procedures, and proposed clinical procedures of any modality for which the licensee seeks authorization. This training requirement may be satisfied by completing training that is supervised by an Authorized Medical Physicist, Authorized User, or Radiation Safety Officer as appropriate, who is authorized for the modality for which the licensee is seeking authorization.

§ 35.51 Training for an Authorized Medical Physicist.

Except as provided in § 35.57, the licensee shall require the authorized medical physicist to be an individual who –

(a) Is certified by the one of the following specialty boards in radiation oncology physics ("radiation oncology physics" understood to be that branch of medical or radiological physics that is applied to clinical practice of radiation oncology)
(1) American Board of Radiology in therapeutic radiological physics;
(2) American Board of Radiology in roentgen ray and gamma ray physics;
(3) American Board of Radiology in x-ray and radium physics;

(4) American Board of Radiology in radiological physics; or
(5) American Board of Medical Physics in radiation oncology physics; or

(b) Is certified by a specialty board in radiation oncology physics whose certification has been recognized by the Commission and requires all diplomates;
(1) To hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an institution accredited by a regional accrediting body;
(2) To have two years of full-time practical training and/or supervised experience in radiation oncology physics
(i) Under the supervision of a medical physicist who is certified in radiation oncology physics by the board in question, a board specified in paragraph (a) of this section; or a specialty board recognized by the Commission according to this paragraph (b) of this section
(ii) In a clinical radiation oncology facility providing megavoltage external beam therapy and brachytherapy services under the direction of physicians who meet the requirements for authorized users in 35.400 or 35.600;
(3) To obtain a written statement from a medical physicist, certified by a specialty board listed in paragraph (a) of this section or recognized by the Commission according to paragraph (b) of this section and who has personal knowledge of the candidate's training and experience, attesting that the individual has satisfactorily completed the training and experience described in paragraph (b)(2) of this section;and
(4) To pass an examination administered by diplomates of the specialty board, which assesses knowledge and competence in clinical radiation oncology, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy and stereotactic radiosurgery; or

(c)
(1) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an institution accredited by a regional accrediting body;
(2) Has completed 1 year of full-time training in radiation oncology 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 for the modality in which the individual is seeking authorization in a clinical radiation oncology facility that provides megavoltage external beam therapy and brachytherapy services that include
(A) performing sealed source leak tests and inventories;
(B) performing decay corrections;
(C) performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and
(D) conducting radiation surveys around external beam, remote afterloading and stereotactic radiosurgery units as applicable; and
(3) Has obtained a written statement from the supervising medical physicist attesting that the individual has satisfactorily completed the training and experience described in paragraph (c)(2) of this section and identifies the byproduct material modalities included.

(d) In addition to meeting the requirements of (a), (b), or (c) of this section, an authorized medical physicist must have training in the modality for which authorization is sought that includes "hands on" device operation, safety procedures, clinical use, and operation of treatment planning system. This training requirement may be satisfied by satisfactorily completing a training program provided by the vendor or by training supervised by an AMP authorized for the modality in which the individual is seeking authorization.

§ 35.55 Training for an authorized nuclear pharmacist.

Except as provided in § 35.57, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who --

(a) Is certified as a nuclear pharmacist by Board of Pharmaceutical Specialties in Nuclear Pharmacy; or

(b) Is certified as a Nuclear Pharmacist by a Nuclear Pharmacy specialty board whose certification process has been recognized by the Commission and requires that all diplomates:

(1) Have graduated from a pharmacy program accredited by the American Council On Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

(2) Hold a current, active license to practice pharmacy;

(3) Provide evidence of having acquired at least 4,000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2,000 hours of the required training and experience.

(4) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, which assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, provision of information and consultation, monitoring patient outcomes, research and development; or

(c) (1) Has completed 700 hours in a structured educational program applicable to consisting of

(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 a written statement signed by a preceptor authorized nuclear pharmacist (ANP) attesting that the individual has completed the required training listed in (c) (1)(ii) of this section.

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

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

(a) Is certified in--

(1) Nuclear medicine by the American Board of Nuclear Medicine;

(2) Diagnostic radiology by the American Board of Radiology;

(3) Diagnostic radiology by the American Osteopathic Board of Radiology;

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada;

(5) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or

(b) Is certified by a medical specialty board whose certification has been recognized by the Commission and:

(1) Includes all of the requirements in paragraph (d) of this section; and

(2) Requires diplomates to pass an examination administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(c) Is an authorized user under Secs. 35.290 or 35.390 or equivalent Agreement State requirements; or

(d)(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 Sec. 35.190, Sec. 35.290, or Sec. 35.390 or equivalent Agreement State requirements, involving--

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

(B) Performing quality control procedures on 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 a written statement, signed by a preceptor authorized user who meets the requirements in Secs. 35.190, 35.290, or 35.390 or equivalent Agreement State requirements, or, if the training was received in conjunction with a residency or

fellowship program, a written statement signed by the training program director, attesting that the individual has satisfactorily completed the requirements in paragraph (d)(1) of this section.

Sec. 35.290 Training for imaging and localization studies.

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

(a) Is certified in--
(1) Nuclear medicine by the American Board of Nuclear Medicine;
(2) Diagnostic radiology by the American Board of Radiology;
(3) Diagnostic radiology by the American Osteopathic Board of Radiology;
(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada;
(5) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine;
(6) Nuclear cardiology by the Certification Board of Nuclear Cardiology; or

(b) Is certified by a medical specialty board whose certification process has been recognized by the Commission and:
(1) Includes all of the requirements in paragraph (d) of this section; and
(2) Requires diplomates to pass an examination administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; and

(c) Is an authorized user under Sec. 35.390 or equivalent Agreement State requirements; or

(d)(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 Secs. 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) Performing quality control procedures on 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 a written statement, signed by a preceptor authorized user who meets the requirements in Secs. 35.290 or 35.390 or equivalent Agreement State requirements, or, if the training was received in conjunction with a residency or fellowship program, a written statement signed by the training program director, attesting that the individual has satisfactorily completed the requirements in paragraph (d)(1) of this section.

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

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

(a) Is certified by
(1) The American Board of Nuclear Medicine;
(2) The American Board of Radiology in radiation oncology;
(3) The Royal College of Physicians and Surgeons of Canada in nuclear medicine or radiation oncology;
(4) The British Royal College of Radiology in radiation oncology; or
(5) The American Osteopathic Board of Radiology in radiation oncology; or

(b) Is certified by a medical specialty board whose certification has been recognized by the Commission and requires all diplomates
(1) To successfully complete a minimum of three years of residency training in a radiation oncology or nuclear medicine training program or a program in a related medical specialty that includes 700 hours of training and experience as described in paragraphs (c)(1) of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association;
(2) To provide a written statement from the residency program director attesting to successful completion of the training requirement in paragraph (b)(1) of this section and;
(3) To pass an examination administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material; 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 requiring a written directive. This 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 Sec. 35.390(a), Sec. 35.390(b), or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in Sec. 35.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., Sec. 35.390(b)(1)(G)(1), (2), (3), or (4)) as the individual requesting authorized user status. This work experience must involve--

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(B) Performing quality control procedures on instruments used to determined 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

(2) Has obtained written statement attesting that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section. The written statement must be signed by a preceptor authorized user who meets the requirements in Sec. 35.390(a), Sec. 35.390(b), or equivalent Agreement State requirements, or, if the training was received in conjunction with a residency or fellowship program, the written statement must be signed by the training program director. The preceptor authorized user, who meets the requirements in Sec. 35.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., Sec. 35.390(d)(1), (2), (3), or (4)) as the individual requesting authorized user status.

(d) In addition to meeting the requirements of (a), (b), or (c) of this section, an authorized user of byproduct material authorized under 35.300 must have experience, under the supervision of an authorized user, 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) or sodium iodide I-131;
(2) Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) or sodium iodide I-131. Experience with at least three cases in Category (d)(2) also satisfies the requirement in Category (d)(1);
(3) Parenteral administration of therapeutic quantities of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV;
(4) Parenteral administration of any other radionuclide in therapeutic quantities.

Sec. 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).

(c)(3) Has obtained written statement attesting that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section. [**competency statement removed].** The written certification must be signed by **[….remainder of paragraph unchanged]**

Sec. 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).

(c)(3) Has obtained written statement attesting that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section. [**competency statement removed].** The written certification must be signed by **[….remainder of paragraph unchanged]**

Sec. 35.490 Training for use of manual brachytherapy sources.

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

(a) Is certified by

(1) The American Board of Radiology in radiation oncology;
(2) The Royal College of Physicians and Surgeons of Canada in radiation oncology;
(3) The British Royal College of Radiology in radiation oncology; or
(4) The American Osteopathic Board of Radiology in radiation oncology; or

(b) Is certified by a medical specialty board whose certification has been recognized by the Commission and requires all diplomates

(1) To successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association;
(2) To obtain a written statement from the residency program director attesting to successful completion of the training requirement in paragraph (b)(1) of this section and;
(3) To pass an examination administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of high and low dose-rate brachytherapy; or

(c)(1) Has completed a structured educational program in basic radionuclide 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 Sec. 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 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 completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in Sec. 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 Royal College of Physicians and Surgeons of Canada 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 (c)(1) of this section; and

(3) Has obtained a written statement attesting that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section. The written certification must be signed by the supervising authorized user or if the training was obtained in a residency training program, by the program director.

Sec. 35.491 Training for ophthalmic use of strontium-90.

(b)(3) Has obtained a written statement signed by a preceptor authorized user who meets the requirements in Sec. 35.490, Sec. 35.491, or equivalent Agreement State requirements, attesting that the individual has satisfactorily completed the requirements in paragraphs (a) and (b) of this section. **[competency statement removed].**

Sec. 35.590 Training for use of sealed sources for diagnosis.

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

(a) Is certified in–

1)Diagnostic radiology, or radiation oncology by the American Board of Radiology;

(2) Nuclear medicine by the American Board of Nuclear Medicine;

(3) Diagnostic radiology by the American Osteopathic Board of Radiology; or

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

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

(c) Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include--

(A) Radiation physics and instrumentation;
(B) Radiation protection;
(C) Mathematics pertaining to the use and measurement of radioactivity; and
(D) Radiation biology.

(d) In addition to meeting the requirements of paragraph (a), (b), or (c) of this section, an authorized user under this section must have training in the use of the device for the uses requested.

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

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

(a) Is certified by

(1) The American Board of Radiology in radiation oncology;
(2) The Royal College of Physicians and Surgeons of Canada in radiation oncology;
(3) The British Royal College of Radiology in radiation oncology; or
(3) The American Osteopathic Board of Radiology in radiation oncology; or

(b) Is certified by a specialty board whose certification has been recognized by the Commission and requires all diplomates

(1) To successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association;
(2) To obtain a written statement from the residency program director attesting to successful completion of the training requirement in paragraph (b)(1) of this section and;
(3) To pass an examination administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, high and low dose-rate brachytherapy, and external beam therapy; or

(c)(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 Sec. 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 Sec. 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 Royal College of Physicians and Surgeons of Canada 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 (c)(1) of this section; and

(3) Has obtained a written statement attesting that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this. The written statement must be signed by the supervising authorized user or if the training was obtained in a residency training program, by the program director.

(d) In addition to meeting the requirements of paragraphs (a), (b), or (c) of this section, an authorized user of a sealed source authorized under 35.600 must have training in the modality for which authorization is sought. This includes training in device operation, safety procedures, and clinical use. This training requirement may be satisfied by satisfactorily completing the training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the modality in which the individual is seeking authorization.