He-P 4035.61 Training for Radiation Safety Officer and Associate Radiation Safety Officer. Except as provided in He-P 4035.71, the licensee shall require an individual fulfilling the responsibilities of the radiation safety officer or an individual assigned duties and tasks as an associate radiation safety officer as provided in He-P 4035.10 to be an individual who:

(a) Is certified by a specialty board whose certification process has been recognized by DHHS/RHS, or an agreement state, or the Nuclear Regulatory Commission, and which meets the requirements in He-P 4035.61(e). The names of board certifications that have been recognized by DHHS/RHS, an agreement state, or the Nuclear Regulatory Commission are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Hold a bachelor's 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) Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and

(3) Pass an examination administered by diplomats of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(4) Hold a master's or doctorate level degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and

(5) Have 2 years full-time practical training; and supervised experience in medical physics; under either:

a. The supervision of a medical physicist who is certified in medical physics by a specialty board recognized by DHHS/RHS, or an agreement state or the Nuclear Regulatory Commission; or

b. In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in He-P 4035.64, He-P 4035.65 or He-P 4035.71; and

(6) Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

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

(1) 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 measurements of radioactivity;

d. Radiation biology;

e. Radiation dosimetry; and

(2) One year of full-time radiation safety experience under the supervision of the individual identified as the radiation safety officer on a DHHS/RHS, or agreement state, or Nuclear Regulatory Commission license, or permit issued by a Nuclear Regulatory Commission master material license that authorized similar type(s) of use(s) of byproduct material. An associate radiation safety officer shall provide supervision for those areas for which the associate radiation safety officer is authorized on a DHHS/RHS or an agreement state license or permit issued by a Nuclear Regulatory Committee master material license. The full radiation safety experience shall involve 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

(3) Obtaining a written attestation, signed by a preceptor radiation safety officer or associate radiation Safety officer who has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is seeking approval as a radiation safety officer or an associate radiation safety officer. The written attestation shall state that the individual has satisfactorily completed the requirements in He-P 4035.61 (b)(1), (b)(2), and He-P 4035.61(e) and is able to independently fulfill the radiation safety-related duties as a radiation safety officer or as an associate radiation safety officer for a medical use license; or

(c) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by DHHS/RHS under 4035.70(a), or an agreement state, or the Nuclear Regulatory Commission, and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as radiation safety officer or as associate radiation safety officer, and who meets the requirements in He-P 4035.61(e); or

(d) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on a DHHS/RHS or agreement state or Nuclear Regulatory Commission license, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by DHHS/RHS or agreement state or Nuclear Regulatory Commission licensee of broad scope, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee, and has experience with:

(1) The radiation safety aspects of similar types of use of byproduct material for which the licensee seeks the approval of the individual as the radiation safety officer or associate radiation safety officer, and meets the requirements in He-P 4035.61(e); or

(2) has experience with the radiation safety aspects of the types of use of byproduct material for which the individual is seeking simultaneous approval both as the radiation safety officer and the authorized user on the same new medical use license or new medical use permit issued by a Nuclear Regulatory Commission master material licensee. The individual shall also meet the requirements in He-P 4035.61(e).

(e) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a radiation safety officer, associate radiation safety officer, authorized medical physicist, authorize nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

He-P 4035.71 Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist.

(a) An individual identified as:

(1) A radiation safety officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist, or an authorized nuclear pharmacist on a license issued by the DHHS/RHS, an agreement state, or the Nuclear Regulatory Commission, or a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by the DHHS/RHS, or an agreement state, or the Nuclear Regulatory Commission broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee before January 14, 2019, need not comply with the training requirements of He-P 4035.61, He-P 4035.70, or He-P 4035.74, respectively except the radiation safety officers and authorized medical physicists identified in He-P 4035.71(a)(1) shall meet the training requirements in He-P 4035.61(e) or He-P 4035.70(c), as appropriate, for any material or uses for which they were not authorized prior to this date;

(2) An individual certified by the American Board of Health Physics in comprehensive health physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of He-P 4035.61 to be identified as a radiation safety officer or as an associate radiation safety officer on a DHHS/RHS, an agreement state, or Nuclear Regulatory Commission license or Nuclear Regulatory Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005; or

(3) An individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in He-P 4035.70, for those materials and uses that these individuals performed on or before October 24, 2005.

(b) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the DHHS/RHS, an agreement state, or the Nuclear Regulatory Commission, or a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by the DHHS/RHS, or an agreement state, or the Nuclear Regulatory Commission broad scope licensee, or a

permit issued by a Nuclear Regulatory Commission master material license broad scope permittee on or before January 14, 2019, who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements of He-P 4035 subparts equivalent to 10 CFR 35 Subparts D through H.

(c) Physicians, dentists, or podiatrists not identified as authorized users for the medical use of byproduct material on a license issued by DHHS/RHS, an agreement state, or the Nuclear Regulatory Commission, or a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by DHHS/RHS, an agreement state, or Nuclear Regulatory Commission broad scope licensee, or a permit issued in accordance with a Nuclear Regulatory Commission master material license of broad scope on or before October 24, 2005, need not comply with the training requirements of He-P 4035 subparts equivalent to 10 CFR 35 Subparts D through H for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

(1) For uses authorized under He-P 4035.27 or He-P 4035.31, or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

(2) For uses authorized under He-P 4035.35, a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

(3) For uses authorized under He-P 4035.41 or He-P 4035.47, a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British “Fellow of the Faculty of Radiology” or “Fellow of the Royal College of Radiology”; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

(4) For uses authorized under He-P 4035.39, a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

(e) Individuals who need not comply with training requirements as described in He-P 4035.71(a) through (c) above may serve as preceptors for, and supervisors of, applicants seeking authorization on DHHS/RHS licenses for the same uses for which these individuals are authorized.

He-P 4035.74 Training for an Authorized Nuclear Pharmacist. Except as provided in He-P 4035.71, the licensee shall require the authorized nuclear pharmacist to be a licensed pharmacist, as defined in RSA 318:1, VII, who:

(a) Is certified by a specialty board whose certification process has been recognized by DHHS/RHS, or an agreement state, or the Nuclear Regulatory Commission. The names of board certifications that have been recognized by DHHS/RHS, an agreement state, or the Nuclear Regulatory Commission are posted on the NRC's medical use licensee toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Have graduated from a pharmacy program accredited by the Accreditation Council on Pharmaceutical Education (ACPE) (previously named the American Council on Pharmaceutical Education) 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 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

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

(b) Has met the following requirements:

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

a. 200 hours of classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Chemistry of byproduct material for medical use; and

5. Radiation biology; and

b. Supervised practical experience in a nuclear pharmacy involving the following:

1. Shipping, receiving, and performing related radiation surveys;

2. 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;

3 Calculating, assaying, and safely preparing dosages for patients or human research subjects;

4 Using administrative controls to avoid medical events in the administration of byproduct material;

5. Using procedures to prevent or minimize radioactive contamination and using proper .decontamination procedures; and

(2) Has obtained a written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in He-P 4035.74(b)(1) and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.