STATE OF NEW HAMPSHIRE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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NH DIVISION OF Public Health Services
Improving health, preventing disease, reducing costs for all

Nicholas A. Toumpas
Commissioner

José Thier Montero
Director

November 14, 2012

Pamela J. Henderson, Deputy Director
Office of Federal and State Materials and Environment Programs
U.S. Nuclear Regulatory Commission
T8-E24
Washington, DC 20555-0001

Dear Ms. Henderson:

Enclosed is a copy of proposed revisions to the New Hampshire Rules for the Control of Radiation (NHRCR), as follows:

- Revisions of Part He-P 4035.

It is anticipated that these proposed revisions will be made available for public comment on March 21, 2013 with a request for comments with ten days of that date. The proposed regulatory revisions correspond to the following equivalent amendments to NRC's regulations:

- RATS ID 1995-1 Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use Part 35
- RATS ID 1995-7 Medical Administration of Radiation and Radioactive Materials Part 35
- RATS ID 1997-3 Criteria for the Release of Individuals Administered Radioactive Material Part 35
- RATS ID 1998-5 Minor Corrections, Clarifying changes, and a Minor Policy Change Part 35
- RATS ID 2002-2 Medical Use of Byproduct Material Part 35
- RATS ID 2005-2 Medical Use of Byproduct Material – Recognition of Specialty Boards Part 35
- RATS ID 2006-1 Minor Admendments Part 35
- RATS ID 2007-1 Medical Use of Byproduct Material – Minor Corrections and Clarifications Part 35
- RATS ID 2009-1 Medical Use of Byproduct Material – Authorized User Clarification Part 35

We do not believe that that there are significant differences between the proposed revisions to the NHRCRs and each of the comparable NRC rules.

We believe that adoption of these revisions, which we anticipate will occur in June 2013, will satisfy the compatibility and health and safety categories established in

the Office of Federal and State Materials and Environmental Programs (FSME) Procedure SA-200.

If you have any questions, please feel free to contact me at (603) 271-4585 or at e-mail address augustinus.ong@dhhs.state.nh.us.

Sincerely,

Augustinus Ong
Administrator
Radiological Health Section
Department of Health and Human Services

Enclosures: As stated
Cc: Kathleen Schneider

PART He-P 4035 USE OF ~~RADIONUCLIDES~~ BYPRODUCT MATERIALS IN THE HEALING ARTS

He-P 4035.01 Purpose and Scope. ~~This part shall~~He-P 4035 establishes requirements and provisions for the production, preparation, compounding and, use of ~~radionuclides~~ byproduct materials in the healing arts and for issuance of licenses authorizing the medical use of ~~this~~ these materials which provide for the protection of the public health and safety.

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~~He-P 4035.02 Scope.~~

~~(a)~~ The requirements and provisions of ~~this part~~ He-P 4035 shall be in addition to, and not in substitution for, other parts in ~~this chapter.~~these regulations unless specifically exempted.

He-P 4035.0~~3~~2 Definitions.

(a) "Accredited institution" means a teaching facility for nuclear medicine technology or radiation therapy technology whose standards are accepted by the Unites States Department of Education.

(~~a~~b) "Address of use" means the building or buildings that are identified on the license and where ~~radioactive~~ byproduct material may be produced, prepared, received, used, or stored.

(c) "Agreement State" means any State with which the Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.

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(~~b~~d) "Area of use" means a portion of a physical structure that has been set aside for the purpose of producing, preparing, receiving, using, or storing ~~radioactive~~ byproduct material.

(e) "Authorized medical physicist" means an individual who:

(1) Meets the requirements in He-P 4035.25 or He-P 4035.28; or

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~~(b)~~ (2) Is identified as an authorized medical physicist on a specific license or equivalent permit issued by the Agency, Nuclear Regulatory Commission, Agreement State or Licensing State, or

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(3) Is identified as an authorized medical physicist on a permit issued by an Agency, Nuclear Regulatory Commission, Agreement State or Licensing State specific medical use license of broad scope that is authorized to permit the use of byproduct material.

(~~c~~f) "Authorized nuclear pharmacist" means a ~~"licensed~~ pharmacist~~"~~ who:

(1) Meets the requriements in He-P 4035.26 or He-P4035.28; or ~~as defined in RSA 318:1, VII, who is a qualified nuclear pharmacist under Ph 405.03 and who is identified~~

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~~as an authorized nuclear pharmacist on a DHHS/BRH license that authorizes the use of radioactive material in the practice of nuclear pharmacy.~~

(2) Is identified as an authorized nuclear pharmacist on a specific license or equivalent permit that authorizes medical use, the practice of nuclear pharmacy, commercial nuclear pharmacy or the manutacture and distribution of radiopharmaceuticals issued by an Agency, Nuclear Regulatory Commission, Agreement State or Licensing State; or

(3) Is identified as an authorized pharmacist on a permit issued by an Agency, Nuclear Regulatory Commission, Agreement State or Licensing State; or

(~~d~~g) "Authorized user" means a physician, dentist, or podiatrist who:

(1) Meets the requirements in He-P 4035.29 and He-P 4035.48(a), He-P 4035.51(a), He-P 4035.55(a), He-P 4035.56(a), He-P 4035.57(a), He-P 4035.66(a), He-P 4035.67, He-P 4035.69(a), or He-P 4035.73(a); or

~~(1)~~ (2) Is identified as an authorized user on a license or equivalent permit issued by ~~, as licensed or permitted by the appropriate state authority, who is identified on a DHHS/BRH~~ the Agency, Nuclear Regulatory Commission, Agreement State or Licensing State;~~license that authorizes the medical use of radioactive material.~~; or

(3) Is identified as an authorized user on a permit issued by an Agency, Nuclear Regulatory Commission, Agreement State or Licensing State specific license of broad scope that is authorized to permit the medical use of byproduct material.

(~~e~~h) "Brachytherapy" means a method of radiation therapy in which ~~sealed~~ sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, intraluminal or interstitial application. Brachytherapy includes radiation therapy using electronic remote afterloading devices.

(i) "Brachytherapy source" means a byproduct source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of few centimeters.

(j) "Client's address" means the address of use or a temporary job site for the purpose of providing mobile medical service in accordance with He-P 4035.43.

(~~f~~k) "Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

(l) "Dentist" means an individual licensed to practice dentistry by the state in which the Agency is located.

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(~~e~~m) "Diagnostic clinical procedures manual" means a collection of written procedures that describes each method, and other instructions and precautions, by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration, or in the case of sealed sources for diagnosis, the procedure.

(n) "High dose-rate remote afterloader" (HDR) means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the treatment site.

(o) "Low dose-rate remote afterloader" (LDR) means a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the treatment site.

(~~h~~p) ~~–~~"Management" means the chief executive officer, or ~~equivalent position, or that individual's designee.~~ other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates.

(q) "Manual brachytherapy" means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

(r) "Medical event" means an event that meets the criteria in subsection He-P 4035.117(a) of this section.

(~~i~~s) ~~–~~"Medical institution" means an organization in which several medical disciplines are practiced.

(~~j~~t) ~~–~~"Medical use" means the intentional internal or external administration of ~~radioactive~~ byproduct material, or the radiation ~~there~~from byproduct material~~,~~ to patients or human research subjects under the supervision of an authorized user.

(u) "Medium dose-rate remote afterloader" (MDR) means a brachytherapy device that remotely delivers a dose rate greater than 2 gray (200 rads) per hour, but less than or equal to 12 gray (1200 rads) per hour at the treatment site.

(v) "Mobile medical service" means a licensed service authorized to transport byproduct material to or its medical use at the client's address.

(w) "Nuclear medicine technologist" means an individual who meets the requirements of He-P 4035.27(a) and is under the supervision of an authorized user, to prepare or administer radioactive drugs to patients or human research subjects, or perform *in vivo* or *in vitro* measurements for medical purpose.

(x) "Nuclear medicine technology" means the science and art of *in vivo* and *in vitro* detection and measurement of radioactivity and the administration of radioactive drugs to patients or human research subjects for diagnostic and therapeutic purposes.

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(~~mm~~y) "Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a ~~teletherapy unit for a specified set of exposure conditions.~~brachytherapy source, or a teletherapy, or remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

(z) "Patient intervention" means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

(aa) "Pharmacist" means an individual licensed by the appropriate authority to practice pharmacy in the state in which the Agency is located.

(bb) "Physician" means a doctor of medicine or doctor of osteopathy licensed by the appropriate authority to prescribe drugs in the practice of medicine in the state in which the Agency is located.

(cc) "Podiatrist" means an individual licensed by the appropriate authority to practice podiatry in the state in which the Agency is located.

(dd) "Preceptor" means 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, nuclear medicine technologists, radiation therapy technologist, or a Radiation Safety Officer.

(~~nn~~ee) ~~–~~"Prescribed dosage" means the ~~quantity of radiopharmaceutical~~ specified activity or range of activity of radioactive drug as documented:

(1) In a written directive as specified in He-P 4035.20; or

(2) ~~Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.~~In accordance with the directions of the authorized user for procedures performed pursuant to He-P 4035.46, He-P 4035.49 and He-P 4035.52.

(~~oo~~ff) "Prescribed dose" means:

(1) ~~–~~For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(2) ~~–~~For teletherapy, the total dose and dose per fraction as documented in the written directive; ~~or~~

(3) ~~–~~For manual brachytherapy, either the total source strength and exposure time, or the total dose, as documented in the written directive; or~~.~~

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(4) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

(gg) "Pulsed dose-rate remote afterloader" means a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but-

(1) Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

(2) Is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.~~(p) "Recordable event" means the administration of:~~

~~(1) A radiopharmaceutical or radiation without a written directive where a written directive is required;~~

~~(2) A radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;~~

~~(3) A radiopharmaceutical dosage greater than 1.11 megabecquerels (30 µCi) of sodium iodide I-125 or I-131 when both the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage, and the difference between the administered dosage and the prescribed dosage exceeds 555 kilobecquerels (15 µCi);~~

~~(4) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage;~~

~~(5) A teletherapy radiation dose when the calculated weekly administered dose exceeds the weekly prescribed dose by 15 percent or more of the weekly prescribed dose; or~~

~~(6) A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose.~~

(hh) "Radiation Safety Officer" means an individual who

(1) Meets the requirements in He-P 4035.23 and He-P 4035.24, or He-P 4035.28; or

(2) Is identified as a Radiation Safety Officer on a Nuclear Regulatory Commission or Agreement State license or other equivalent permit or license recognized by the Agency for similar types and uses of byproduct material.

(ii) “Radiation therapist” means an individual who meets the requirements of He-P 4038.27(b) and is under the supervision of an authorized user to perform procedures and apply radiation emitted from sealed byproduct sources to patients or human research subjects for therapeutic purposes.

(jj) “Radiation therapy technology” means the science and art of applying radiation emitted from sealed byproduct sources to patients or human research subjects for therapeutic purposes.

(kk) “Radioactive drug” means any chemical compound containing byproduct material that may be used on or administered to patients or human research subjects as an aid in diagnosis, treatment, or prevention of disease or other abnormal condition.

(~~q~~ll) ~~-~~“Sealed source” means any ~~radioactive~~ byproduct material that is enclosed in a capsule designed to prevent leakage or escape of the ~~radioactive~~ byproduct material.

(mm) “Sealed Source and Device Registry” means the national registry that contains all the registration certificates, generated by Nuclear Regulatory Committee, that summarizes the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

~~(r) “Teletherapy physicist” means an individual identified as the qualified teletherapy physicist on an DHHS/BRH license.~~

(~~s~~nn~~)~~ "Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to precisely deliver a therapeutic dose to a treatment site.

(oo) “Structured educational program” means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

(pp) “Teletherapy” means therapeutic irradiation in which the source of radiation is delivered at a distance from the ~~body~~patient or human research subject.

(qq) “Teletherapy physicist” means an individual identified as the qualified teletherapy physicist on an Agency license.

(rr) “Temporary jobsite” means a location where mobile medical services are conducted other than those location(s) of use authorized on the license.

(ss) “Therapeutic dosage” means a dosage of sealed byproduct material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

(tt) “Therapeutic dose” means a radiation dose delivered from a source containing byproduct material to a patient or human research subject for palliative or curative treatment.

(uu) “Treatment site” means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

(vv) "Type of use" means use of byproduct material as specified under He-P 4035.46, He-P 4035.49, He-P 4035.52, He-P 4035.58, He-P 4035.68, He-P 4035.70 or He-P 4035.71.

(ww) "Unit dosage" means a dosage that:

(1) Is obtained or prepared in accordance with the regulations for uses described in He-P 4035.46, He-P 4035.49, or He-P 4035.52; and

(2) Is to be administered as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

(~~t~~xx) "Written directive" means an authorized user's written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject, as specified in He-P 4035.20.~~an order in writing for a specific patient or human research subject, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in (t)(6) below, containing the following information:~~

~~(1) For any administration of quantities greater than 1.11 megabecquerels (30 µCi) of sodium iodide I-125 or I-131: the radionuclide and the dosage;~~

~~(2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;~~

~~(3) For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;~~

~~(4) For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;~~

~~(5) For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or~~

~~(6) For all other brachytherapy:~~

~~a. Prior to implantation: the radioisotope, number of sources, and source strengths; and~~

~~b. After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).~~

He-P 4035.03 Maintenance of Records. Each record required by this part must be legible throughout the retention period specified by each Agency regulation. The record may be the original or a reproduced copy or an electronic copy provided that the copy or electronic copy is authenticated by authorized personnel and that the electronic copy is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability

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for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

He-P 4035.04 Previsions for the Protection of Human Research Subjects. A licensee may conduct research involving human subjects using byproduct material provided:

(a) That the research is conducted, funded, supported, or regulated by a Federal agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its Agency license before conducting such research. Both types of licenses shall, at a minimum, obtain prior informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects;

(b) The research involving human subjects authorized in He-P 4035.04(a) shall be conducted using byproduct material authorized for medical use in the license; and

(c) Nothing in He-P 4035.04 relieves licensees from complying with the other requirements in Part He-P 4035.

He-P 4035.05 U.S. Food and Drug Administration, Federal,and State Requirements. Nothing in this Part relieves the licensee from complying with applicable U.S. Food and Drug Administration, othe Federal, and State requirements governing radioactive drugs or devices.

He-P 4035.06 Implementation.

(a) A licensee shall implement the provisions in Part He-P 4035 on January 1, 2014;

(b) When a requirement in Part He-P 4035 differs from the requrement in an existing license condition, the requirement in this Part shall govern;

(c) Any existing license condition that is not affected by a requirement in Part He-P 4035 remains in effect until there is a license amendment or license renewal;

(d) If a license condition exempted a licensee from a provision of Part He-P 4035 on January 1, 2014, it will continue to exempt a licensee from the corresponding provision in Part He-P 4035;

(e) If a license condition cites provisions in Part He-P 4035 that will be deleted on Jaunuary 1, 2014, then the license condition remains in effect until there is a license amendment or license renewal that modifies or removes this condition; and

(f) Licensees shall continue to comply with any license condition that requires it to implement procedures required by He-P 4035.75, He-P 4035.81, He-P 4035.82, and He-P 4035.83 until there is a license amendment or renewal that modifies the license condtion.

He-P 4035.~~04~~07 License Required.

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(a) ~~No~~ A person shall only manufacture, produce, prepare, ~~compound,~~ acquire, receive, possess, use, or transfer ~~radioactive material~~byproduct material for medical use ~~except~~ in accordance with a specific license issued by the Agency, the Nuclear Regulatory Commission or an Agreement State, or as allowed in ~~pursuant to~~ He-P 403~~0~~5.07(b) ~~and~~ or He-P ~~4032~~4035.07(c).

(b) ~~-~~An individual may receive, possess, use, or transfer ~~radioactive~~ byproduct material in accordance with the regulations in He-P 4035 under the supervision of an authorized user as provided in He-P 4035.~~11~~19 unless prohibited by license condition.

(c) ~~-~~An individual may prepare unsealed ~~radioactive~~ byproduct material for medical use in accordance with He-P 4035 under the supervision of an authorized nuclear pharmacist or authorized user as provided in He-P 4035.~~11~~19 unless prohibited by license condition.

~~He-P 4035.05 License Amendments. A licensee shall apply for and receive a license amendment:~~

~~(a) Before using radioactive material for a method or type of medical use not permitted by the license issued under He-P 4035;~~

~~(b) Before permitting anyone to work as an authorized user or an authorized nuclear pharmacist, respectively, under the license;~~

~~(c) Before changing a Radiation Safety Officer or Teletherapy Physicist;~~

~~(d) Before receiving radioactive material in excess of the amount authorized on the license;~~

~~(e) Before adding to or changing the areas of use or address or addresses of use identified in the application or on the license; and~~

~~(f) Before changing statements, representations, and procedures which are incorporated into the license.~~

~~Source. (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07~~

~~New: #8959, eff 8-7-07~~

He-P 4035.08 Application for License, Amendment, or Renewal.

(a) An application must be signed by the applicant's or licensee's management.

(b) An application for a license for medical use of byproduct material as described in He-P 4035.46, He-P 4035.49, He-P 4035.52, He-P 4035.58, He-P 4035.68, He-P 4035.70, or He-P 4035.71 must be made by:

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(1) Filing an original and one copy of "Application for Radioactive Material License—Medical," and

(2) Submitting procedures required by sections He-P 4035.21, He-P 4035.33, He-P 4035.75, He-P 4035.81, He-P 4035.82, and He-P 4035.83, as applicable.

(c) A request for a license amendment or renewal must be made by:

(1) Submitting an original and one copy in letter format.

(2) Submitting procedures required by sections He-P 4035.21, He-P 4035.33, He-P 4035.75, He-P 4035.81, He-P 4035.82, He-P 4035.83, as applicable.

(d) In addition to the requirements in He-P 4035.08(b) and He-P 4035.08(c), an application for a license or amendment for medical use of byproduct material as described in He-P 4035.70 of this Part must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in He-P 4035.01 through He-P 4035.45, as well as any specific information on:

(1) Radiation safety precautions and instructions;

(2) Training and experience of proposed users;

(2) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

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(3) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

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(e) The applicant or licensee shall also provide any other information requested by the Agency in its review of the application.

(f) An applicant that satisfies the requirements specific in He-P 4033.05(a) may apply for a Type A specific license of broad scope.

He-P 4035.09 Mobile Medical Service Administrative Requirements.

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(a) The Agency shall license mobile medical services or clients of such services. The mobile medical service shall be licensed if the service receives, uses or possesses byproduct material. The client of the mobile medical service shall be licensed if the client receives or possesses byproduct material to be used by a mobile medical service.

(b) Mobile medical service licensees shall obtain a letter signed by the management of each location where services are rendered that authorizes use of byproduct material at the client's address of use. This letter shall clearly delineate the authority and responsibility of both the client and the mobile medical service. If the client is licensed, the letter shall document procedures for

notification, receipt, storage, and documentation of transfer of byproduct material delivered to the client's address for use by the mobile medical service.

(c) A mobile medical service shall not have byproduct material delivered directly from the manufacturer or the distributor to the client, unless the client has a license allowing possession of the byproduct material. Byproduct material delivered to the client shall be received and handled in conformance with the client's license.

(d) A mobile medical service shall inform the client's management who is on site at each client's address of use at the time that byproduct material is being administered.

(e) A licensee providing mobile medical services shall retain the letter required in He-P 4035.09(b) in accordance with He-P 4035.99.

(f) A mobile medical service licensee shall, at a minimum, maintain the following documents on each mobile unit:

(1) The current operating and emergency procedures;

(2) A copy of the license;

(3) Copies of the letter required by He-P 4035.09(b);

(4) Current calibration records for each survey instrument and diagnostic equipment or dose delivery device in use; and

(5) Survey records covering uses associated with the mobile unit during, at a minimum, the preceding 30 calendar days.

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(g) A mobile medical service licensee shall maintain all records required by He-P 4035.09(e), He-P 4035.09(f), and He-P 4035 of these regulations at a location within the Agency's jurisdiction that is:

(1) A single address of use:

a. Identified as the records retention location; and

b. Staffed at all reasonable hours by individual(s) authorized to provide the Agency with access for purpose of inspection; or

(2) When no address of use is identified on the license for records retention, the mobile unit:

a. Identified in the license; and

b. Whose current client's address schedule and location schedule is reported to the Agency.

He-P 4035.10 License Amendments. A licensee shall apply for and must receive a license amendment:

(a) Before it receives, prepares or uses byproduct material for a type of use that is permitted under Part He-P 4035, but that is not authorized on the licensee's current license issued pursuant to Part He-P 4035:

(b) Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except an individual who is:

(1) For authorized user, an individual who meets the requirements in He-P 4035.29 and He-P 4035.48(a), He-P 4035.51(a), He-P 4035.55(a), He-P 4035.56(a), He-P 4035.57(a), He-P 4035.66(a), He-P 4035.69(a), or He-P 4035.73(a); or

(2) For an authorized nuclear pharmacist, an individual who meets the requirements in He-P 4035.26(a) and He-P 4035.29;

(3) For an authorized medical physicist, an individual who meets the requirements in He-P 4035.25(a) and He-P 4035.29;

(4) Identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist on a Nuclear Regulatory Commission or Agreement State license or Licensing State or other equivalent permit or license recognized by the Agency that authorizes the use of byproduct material in medical use or in the practice of nuclear pharmacy, respectively; or

(5) Identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist on a permit issued by a Nuclear Regulatory Commission or Agreement State or Licensing State specific license of broad scope that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy, respectively.

(c) Before it changes Radiation Safety Officers, except as provided in He-P 4035.15(c);

(d) Before it receives byproduct material in excess of the amount, or in a different physical or chemical form than is authorized on the license;

(e) Before it adds to or changes the areas of use identified in the application or on the license, except as specified in He-P 4035.11(b)(4);

(f) Before it changes the address(es) of use identified in the application or on the license;

(g) Before it changes statements, representations, and procedures which are incorporated into the license; and

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(h) Before it releases licensed facilities for unrestricted use.

He-P 4035. ~~06~~11 Notifications.

(a) A licensee shall ~~notify the DHHS/BRH in writing within 30 days when an authorized user, an authorized nuclear pharmacist, Radiation Safety Officer, or Teletherapy Physicist, permanently discontinues performance of duties under the license.~~provide to the Agency a copy of the board certification, the Nuclear Regulatory Commission, Agreement State or Licensing State license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist or an athourized medical physicist, pursuant to He-P 4035.10(b).

(b) A licensee shall notify the Agency by letter no later than 30 days after:

(1) An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;

(2) The licensee's mailing address changes;

(3) The licensee's name changes, but the name change does not constitute a transfer of control of the license as describe in He-P 4030.16(a) of these regulations; or

(4) The licensee has added to or changed the areas where byproduct material is used in accordance with He-P 4035.46 and He-P 4035.49.

He-P 4035.12 Exemptions Regarding Type A Specific Licenses of Broad Scope. A licensee possessing a Type A specific license of broad scope for medical use is exempt from:

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(a) The provisions of He-P 4035.08(d) regarding the need to file an amendment to the license for medical use of byproduct material as described in He-P 4035.70;

(b) The provisions of He-P 4035.10(b) regarding the need to file an amendment before permitting anyone to work as an authorized user, an authorized nuclear pharmacist or an authorized medical physicist under the license;

(c) The provisions of He-P 4035.10(e) regarding additions to or change in the areas of use at the addresses specified in the license;

(d) The provisions of He-P 4035.11(a) regarding notification to the Agency for new authorized users, new authorized nuclear pharmacists and new authorized medical physicists;

(e) The provisions of He-P 4035.22(a) regarding suppliers for sealed sources.

He-P 4035.13 License Issuance.

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(a) The Agency shall issue a license for the medical use of byproduct material if:

(1) The applicant has filed an "Application for Radioactive Material License—Medical," in accordance with the instructions in He-P 4035.08;

(2) The applicant has paid any applicable fee;

(3) The applicant meets the requirements of He-P 4030.10 of these regulations; and

(4) The Agency finds the applicant equipped and committed to observe the safety standards established by the Agency in these regulations for the protection of the public health and safety.

(b) The Agency shall issue a license for mobile services if the applicant:

(1) Meets the requirements in He-P 4035.13(a); and

(2) Assures that individuals to whom radioactive drugs or radiation from implants containing byproduct material will be administered, may be released following treatment in accordance with He-P 4035.42.

He-P 4035.14 Specific Exemptions. The Agency may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations in Part He-P 4035 as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

He-P 4035.15 Authority and Responsibilities for the Radiation Protection Program.

(a) In addition to the radiation protection program requirements of He-P 4020.04 of these regulations, a licensee's management must approve in writing:

(1) Requests for license application, renewal, or amendments before submittal to the Agency;

(2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist or authorized medical physicists; and

(3) Radiation protection program changes that do not require a license amendment and are permitted under He-P 4035.17.

(b) A licensee's management shall appoint a Radiation Safety Officer (RSO), who agrees in writing to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

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(c) For up to sixty days each year, a licensee may permit an authorized user or an individual qualified to be a Radiation Safety Officer to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in He-P 4038.15(e), provided the licensee takes the actions required in He-P 4035.15(b), (d), (e) and (h). A licensee may simultaneously appoint more than one temporary RSO, if needed, to ensure that the licensee has a temporary RSO that satisfies the requirements to be an RSO for each of the different uses of radioactive material permitted by the license.

(d) A licensee shall establish in writing the authority, duties, and responsibilities of the Radiation Safety Officer.

(e) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective actions;

(3) Stop unsafe operations; and,

(4) Verify implementation of corrective actions.

(f) Licensees that are authorized for two or more different types of byproduct material use under He-P 4035.52, He-P 4035.58, He-P 4035.70, and He-P 4035.71, or two or more types of units under He-P 4035.71 shall establish a Radiation Safety Committee in accordance to He-P 4035.16 to oversee all uses of byproduct material permitted by the license.

(g) A licensee's Radiation Safety Committee shall meet as necessary, but at a minimum shall meet at intervals not to exceed 3 months. The licensee shall maintain minutes of each meeting in accordance with He-P 4035.89.

(h) A licensee shall retain a record of actions taken pursuant to He-P 4035.15(a), He-P 4035.15(b) and He-P 4035.15(d) in accordance with He-P 4035.89.

He-P 4035.16 Radiation Safety Committee.

(a) Each medical institution licensee shall establish a Radiation Safety Committee to oversee the use of byproduct material.

(b) The Committee required in He-P 4035.16(a) shall meet the following administrative requirements:

(1) Membership shall consist of at least three individuals, as follows:

a. An authorized user of each type of use permitted by the license;

b. The Radiation Safety Officer;

c. A representative of the nursing service; and

d. A representative of management who is neither an authorized user nor a Radiation Safety Officer.

e. Other members may be included on the Radiation Safety Committee as the licensee deems appropriate;

(2) The Committee shall meet at least once each calendar quarter;

(3) To establish a quorum and to conduct business, one-half of the Committee's membership shall be present, including the Radiation Safety Officer and the management's representative;

(4) The minutes of each Radiation Safety Committee meeting shall include:

a. The date of the meeting;

b. Members present;

c. Members absent;

d. Summary of deliberations and discussions;

e. Recommended actions and the numerical results of all ballots; and

f. Documentation of any reviews required in He-P 4035.16(c) and He-P 4035.17(c); and

(5) The Committee shall provide each member with a copy of the meeting minutes, and retain one copy until the Agency authorizes its disposition.

(c) To oversee the use of byproduct material, the Committee shall:

(1) Be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable;

(2) Review, on the basis of safety and with regard to the training and experience standards of He-P 4035, and approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the Radiation Safety Officer, or Teletherapy Physicist before submitting a license application or request for amendment or renewal and before allowing an authorized user or authorized nuclear pharmacist to work under the license;

(3) Review on the basis of safety and approve or disapprove each proposed method of use of byproduct material;

(4) Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove procedures and radiation safety program changes prior to submittal to the Agency for licensing action;

(5) Review quarterly, with the assistance of the Radiation Safety Officer, occupational radiation exposure records of all personnel working with byproduct material;

(6) Review quarterly, with the assistance of the Radiation Safety Officer, all incidents involving byproduct material with respect to cause and subsequent actions taken;

(7) Review annually, with the assistance of the Radiation Safety Officer, the byproduct material program; and

(8) Establish a table of investigational and action levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the Radiation Safety Officer.

He-P 4035.~~07~~17 ALARA Program.

(a) ~~-~~Each licensee shall develop and implement a written program to maintain radiation doses and releases of ~~radioactive~~ byproduct material in effluents to unrestricted areas as low as reasonably achievable (ALARA).

(b) To satisfy the requirement of He-P 4035.~~07~~17(a):

(1) ~~-~~The management, Radiation Safety Officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by this chapter, the Radiation Safety Committee; or

(2) ~~-~~For licensees that are not medical institutions, management and all authorized users shall participate in the program as required by the Radiation Safety Officer.

(c) ~~-~~The ALARA program shall include an annual review by the Radiation Safety Committee for licensees that are medical institutions, or an annual review by management and the Radiation Safety Officer for licensees that are not medical institutions.

(d) The program review required in He-P 4035.~~07~~17(c) shall include summaries of the types and amounts of ~~radioactive~~ byproduct material used, occupational dose reports, and continuing education and training for all personnel who work with or in the vicinity of ~~radioactive~~ byproduct material.

(e) The purpose of the review required in He-P 4035.~~07~~17(c) shall ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of ~~radioactive~~ byproduct material as low as reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.

(f) The licensee shall retain a current written description of the ALARA program for the duration of the license.

(g) The written description shall include:

(1) A commitment by management to keep occupational doses as low as reasonably achievable;

(2) A requirement that the Radiation Safety Officer brief management once each year on the radiation safety program;

(3) Personnel exposure investigational levels as established in accordance with He-P 4020(c)(8) that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure; and

(4) Personnel exposure action levels that, when exceeded, will initiate a prompt investigation by the Radiation Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.

(h) ALARA program changes.

(1) A licensee may revise its ALARA program withouth Agency approval if—

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a. The revision does not require a license amendment under He-P 4035.10 of this section;

b. The revision is in compliance with the regulations and the license;

c. The revision has been reviewed and approved by the Radiation Safety Officer, licensee management and licensee's Radiation Safety Committee (if applicable); and

d. The affected individuals are instructed on the revised program before the changes are implemented.

(2) A licensee shall retain a record of each change in accordance with He-P 4035.90 of this chapter.

He-P 4035.18 Duties of Authorized User and Authorized Medical Physicist.

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(a) A licensee shall assure that only authorized users for the type of byproduct material used:

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(1) Prescribe the radiopharmaceutical dosage and/or dose to be administered through the issuance of a written directive or reference to the diagnostic clinical procedures manual; and

(2) Direct, as specified in He-P 4035.19 and He-P 4035.20, or in license conditions, the administration of byproduct material for medical use to patients or human research subjects;

(3) Prepare and administer, or supervise the preparation and administration of byproduct material for medical use, in accordance with He-P 4035.07(b), He-P 4035.07(c) and He-P 4035.19;

(4) Perform the final interpretation of the results of tests, studies, or treatments.

(b) A licensee shall assure that only authorized medical physicists perform, as applicable:

(1) Full calibration measurements as described in He-P 4035.78, He-P 4035.79, and He-P 4035.80;

(2) Periodic spot checks as described in He-P 4035.81, He-P 4035.82, He-P 4035.83; and

(3) Radiation surveys as described in He-P 4035.85.

He-P 4035.19 Supervision.

(a) A licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user as allowed by He-P 4035.07(b) shall:

(1) In addition to the requirements in He-P 4019.12 of these regulations, instruct the supervised individual in licensee's written radiation protection procedures, written directive procedures, regulations of Part He-P 4035, and license conditions with respect to the use of byproduct material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of byproduct material, written radiation protection procedures, written directive procedures, regulations of Part He-P 4035, and license conditions with respect to the medical use of byproduct material.

(b) A licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by He-P 4035.07(c), shall:

(1) Instruct the supervised individual in the preparation of byproduct material for medical use, as appropriate to the individual's involvement with byproduct material; and

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(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of byproduct material for medical use, the written radiation protection procedures, the regulations of Part He-P 4035, and license conditions.

(c) A licensee shall require the supervising authorized nuclear pharmacist or physician who is an authorized user to periodically review the work of the supervised individual as it pertains to preparing byproduct material for medical use and the records kept to reflect that work.

(d) A licensee that permits supervised activities under He-P 4035.19(a) and He-P 4035.19(b) is responsible for the acts and omissions of the supervised individual.

He-P 4035.20 Written Directives.

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(a) A written directive must be dated and signed by an authorized user pior to administration of I-131 sodium iodine greater than 1.11 megabecquerel (30 µCi), any therapeutic dosage of byproduct material or any therapeutic dose of radiation from byproduct material.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented as soon as possible in writing in the patient's record and a written directive prepared within 48 hours of the oral directive.

(b) The written directive must contain the patient's or human research subject's name and the following:

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(1) For an administration of a dosage of radioactive drug containing byproduct material, dosage, and route of administration;

(5) For gamma stereotactic radiosurgery, the total dose, treatment site, and number of target coordinate settings per treatment for each anatomically distinct treatment site;

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(3) For teletherapy, the total dose, dose per fraction, number of fractions, and treatment site;

(4) For high dose rate remote afterloading brachytherapy, the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

(5) For all other brachytherapy including LDR, MDR, and PDR:

a. Prior to implantation: treatment site, the radionuclide, and dose; and

b. After implantation but prior to completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or, the total dose).

(c) A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the dosage of radioactive drug containing byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fraction dose.

If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision.

(d) The licensee shall retain the wirtten directive in accordance with He-P 4035.91.

He-P 4035.21 Procedures for Administrations Requiring a Written Directive.

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(a) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

(1) The patient's or human research subject's identity is verified before each administration; and

(2) Each administration is in accordance with the written directive.

(b) The procedures required by He-P 4035.21(a) must, at a minimum, address the following items that are applicable for the licensee's use of byproduct material:

(1) Verifying the identity of the patient or human research subject;

(2) Verifying that the specific details of the administration are in accordance with the treatment plan, if applicable, and the written directive;

(3) Checking both manual and computer-generated dose calculations; and

(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units anthorized by He-P 4035.71.

He-P 4035.22 Suppliers for Sealed Sources or Devices for Medical Use. For medical use, a licensee may only use:

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(a) Sealed sources or devices initially manufactured, labeled, packaged, and distributed in accordance with license issued pursuant to He-P 4032.07 of these regulations, an Agreement State or a Licensing State; or

(b) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to He-P 4032.07 of these regulation, an Agreement State or Licensing State.

He-P 4035.~~08~~ 23 Radiation Safety Officer.

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(a) ~~–~~A licensee shall appoint a Radiation Safety Officer who, with the approval of the ~~DHHS/BRH~~Agency, will be responsible for implementing the radiation safety program.

(b) ~~–~~The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's ~~radioactive~~ byprodct material program.

(c) The Radiation Safety Officer shall:

(1) ~~-~~Investigate overexposure, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposal, ~~misadministration~~medical event, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(2) Implement written policy and procedures for:

a. Authorizing the purchase of ~~radioactive~~ byproduct material;

b. Receiving and opening packages of ~~radioactive~~ byproduct material;

c. Storing ~~radioactive~~ byproduct material;

d. Keeping an inventory record of ~~radioactive~~ byproduct material;

e. Using ~~radioactive~~ byproduct material safely;

f. Taking emergency action if control of ~~radioactive~~ byproduct material is lost;

g. Performing periodic radiation surveys;

h. Performing checks of survey instruments and other safety equipment;

i. Disposing of ~~radioactive~~ byproduct material;

j. ~~–~~Training personnel who work in or frequent areas where ~~radioactive~~ byproduct material is used or stored; and

k. ~~-~~Keeping a copy of all records and reports required by the ~~DHHS/BRH~~Agency, a copy of He-P 4019 through He-P 4023, a copy of each licensing request and license and amendments, and the written policy and procedures required by the regulations;

(3) ~~-~~For medical use not cited at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management prior to submittal to

the ~~DHHS/BRH~~ Agency for licensing action; and

(4) ~~-~~For medical use cited at a medical institution, assist the Radiation Safety Committee in the performance of its duties.

He-P 4035.24 Training for Radiation Safety Officer. Except as provided in He-P 4035.28, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in He-P 4035.15 to be an individual who:

(a) Is certified by a specialty board whose certification include all of the requirements in He-P 4035.24(b) and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State, Licensing Date certification for NARM, or:

(b)

(1) Has completed 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. Radiation biology; and

5. Radiation dosimetry; and

b. One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Nuclear Regulatory Commission or Agreement State license that authorizes similar type(s) of use(s) of byproduct material 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 instruments used to measure radionuclides;

3. Securing and controlling byproduct material;

4. Using administrative controls to avoid mistakes in the administration of byproduct material;

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

6. Using emergency procedures to control byproduct material;

7. Disposing of byproduct material; and

(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.

~~He-P 4035.09 Radiation Safety Committee.~~

~~(a) Each medical institution licensee shall establish a Radiation Safety Committee to oversee the use of radioactive material.~~

~~(b) The Committee required in He-P 4035.09(a) shall meet the following administrative requirements:~~

~~(1) Membership shall consist of at least three individuals, as follows:~~

~~a. An authorized user of each type of use permitted by the license;~~

~~b. The Radiation Safety Officer;~~

~~c. A representative of the nursing service; and~~

~~d. A representative of management who is neither an authorized user nor a Radiation Safety Officer.~~

~~e. Other members may be included on the Radiation Safety Committee as the licensee deems appropriate;~~

~~(2) The Committee shall meet at least once each calendar quarter;~~

~~(3) To establish a quorum and to conduct business, one-half of the Committee's membership shall be present, including the Radiation Safety Officer and the management's representative;~~

~~(4) The minutes of each Radiation Safety Committee meeting shall include:~~

~~a. The date of the meeting;~~

~~b. Members present;~~

~~c. Members absent;~~

~~d. Summary of deliberations and discussions;~~

~~e. Recommended actions and the numerical results of all ballots; and~~

f. Documentation of any reviews required in He-P 4035.07(c) and He-P 4035.09(e); and

(5) The Committee shall provide each member with a copy of the meeting minutes, and retain one copy until the DHHS/BRH authorizes its disposition.

(c) To oversee the use of licensed material, the Committee shall:

(1) Be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable;

(2) Review, on the basis of safety and with regard to the training and experience standards of He-P 4035, and approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the Radiation Safety Officer, or Teletherapy Physicist before submitting a license application or request for amendment or renewal and before allowing an authorized user or authorized nuclear pharmacist to work under the license;

(3) Review on the basis of safety and approve or disapprove each proposed method of use of radioactive material;

(4) Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove procedures and radiation safety program changes prior to submittal to the DHHS/BRH for licensing action;

(5) Review quarterly, with the assistance of the Radiation Safety Officer, occupational radiation exposure records of all personnel working with radioactive material;

(6) Review quarterly, with the assistance of the Radiation Safety Officer, all incidents involving radioactive material with respect to cause and subsequent actions taken;

(7) Review annually, with the assistance of the Radiation Safety Officer, the radioactive material program; and

(8) Establish a table of investigational and action levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the Radiation Safety Officer.

Source. (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New: #8959, eff 8-7-07

He-P 4035.25 Training for an Authorized Medical Physicist. The licensee shall require the authorized medical physicist to be an individual who:

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(a) Is certified by a specialty board whose certification process includes all of the training and experience requirements in He-P 4035.25 and whose certification has been recognized by the Nuclear Regulatory Commission, an Agreement State, or Licensing State certification for NARM; or:

(b)

(1) Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, or health physics, or an equivalent training program approved by the Nuclear Regulatoy Commission, another Agreement State or the Agency and has completed one year of full-time training in therapeutic radiological physics and an additional year of full-time practical experience under the supervision of a medical physicist at a medical institution that includes the tasks listed in He-P 4035.38, He-P 4035.63(e), He-P 4035.78, He-P 4035.79, 80, He-P 4035.81, He-P 4035.82, He-P 4035.83 and He-P 4035.85 as applicable; and

(2) Has obtained written certification, signed by a preceptor authorized medical physicist, that the individual has satisfactorily completed the requirements in He-P 4035.25(b)(1) and has achieved a level of competency sufficient to independently function as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

He-P 4035.26 Training for an Authorized Nuclear Pharmacist. The licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

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(a) Is certified as a nuclear pharmacist by a specialty board whose certification process includes all of the requirements in He-P 4035.26(b) and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State, or Licensing State certification for NARM; or

(b)

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

a. Didactic 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:

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; and

5. 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 He-P 4035.26(b)(1) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

He-P 4035.27 Training and Technical Requirements for Nuclear Medicine Technologists and Radiation Therapists.

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(a) The licensee shall require a nuclear medicine technologist using byproduct materials under the supervision of an authorized user to be an individual who:

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(1) Is certified in:

a. Nuclear Medicine by the Nuclear Medicine Technology Certification Board;

b. Nuclear Medicine by the American Registry of Radiologic Technologists with competency in Nuclear Medicine; or,

(2) Be board eligible to take the CNMT or ARRT(N) examination; or,

(3) Has successfully completed a training program in nuclear medicine which has resulted in a cerificate, associate degree, or baccalaureate degree in a nuclear medicine technology program from an accredited institution; or,

(4) Has performed as a full-time nuclear medicine technologist for a minimum of two years during the past five-year period under the supervision of an authorized user who certifies the experience in writing; or,

(5) Has completed 80 hours of training and experience in basic radionuclear handling techniques applicable to the medical use of unsealed byproduct material that include:

a. Classroom and labortory training in the following areas:

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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. Work experience, under the supervision of an authorized user involving:

1. Ordering, receiving, and unpacking byproduct materials safely and performing the radiation surveys;

2. Quality Control checking of instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

3. Calculating, measuring, and safely preparing patient or human research subject dosages;

4. Using administrative controls to prevent a medical event involving the use or unsealed byproduct material;

5. Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;

6. Administering dosages to patients or human research subjects; and

c. Has obtained written certification, signed by a preceptor authorized user that the individual has satisfactorily completed the requirements of this section and has achieved a level of radiation safety competency sufficient to independently function as a nuclear medicine technologist.

(b) The licensee shall require a radiation therapist using byproduct materials under the supervision of an authorized user to be an individual who:

(1) Is certified in Radiation Therapy by the American Registry of Radiologic Technologists (ARRT(T)); or

(2) Be board eligible to the ARRT(T) examination; or,

(3) Has successfully completed a training program in radiation therapy which has resulted in a certificate, associate degree, or baccalaureate degree in a radiologic technology program that complies with the requirements of the Joint Review Committee on Education in Radiologic Technology; or,

(4) Has performed as a full-time radiation therapist for a minimum of two years during the past five–year period under the supervision of an authorized user who certifies the experience in writing; or

(5) Has completed 200 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of byproduct material that includes:

a. Classroom and laboratory training in the following areas:

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1. Radiation physics and instrumentation;

2. Radiation protection;

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

4. Radiation biology; and

b. Work experience, under the supervision of an authorized user involving:

1. Ordering, receiving, and unpacking byproduct materials safely and performing the related radiation surveys;

2. Assisting the authorized user in simulating the patient for treatment;

3. Preparing the patient for treatment;

4. Implementing treatment plans as prescribed by the authorized user;

5. Providing written documentation of treatment setup and patient treatments;

6. Quality control checks to determine that devices used to deliver the radiation doses are in compliance with institutional standards and performing checks for proper operation of survey meters;

7. Preparing or assisting in the preparation of sources, and implantation and removal of sealed sources;

8. Delivering doses to patients or human research subjects under the supervision of the authorized user;

9. Maintaining running inventories of byproduct material on hand;

10. Using administrative controls to prevent a medical event involving the use of byproduct material; and

11. Properly implementing emergency procedures; and

c. Has obtained written certification, signed by a preceptor authorized user that the individual has satisfactorily completed the requirements of this section and has achieved a level of radiation safety competency sufficient to independently function as a radiation therapist.

(c) Individuals working as nuclear medicine technologists or radiation therapists for a facility holding an Agency license prior to January 1, 2014 need not comply with the training requirements of this section.

(d) The licensee shall maintain records of the above training as specified in He-P 4035.102.

He-P 4035.28 Provisions for Experienced Radiation Safety Officer, Medical Physicist, Authorized User, and Nuclear Pharmacist. Formatted

(a) An individual identified as a Radiation Safety Officer, a medical physicist, or a nuclear pharmacist on a Nuclear Regulatory Commission, an Agreement State License or on a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope license that authorizes medical use or the practice of nuclear pharmacy, before January 1, 2014 need not comply with the training requirements of He-P 4035.24, He-P 4035.25, and He-P 4035.26, respectively.

(b) Physicians, dentists, or podiatrists identified as authorized users for the medical, dental, or podiatric use of byproduct material on a Nuclear Regulatory Commission of Agreement State license or on a permit isssued by a Nuclear Regulatory Commission or Agreement State broad scope license that authorizes medical use or the practice of nuclear pharmacy, issued before January 1, 2014 who perform only those medical uses for which they were authorized on that date need not comply with the training requirments of He-P 4035.48, He-P 4035.51, He-P 4035.55, He-P 4035.56, He-P 4035.57, He-P 4035.66, He-P 4035.67, He-P 4035.68 and He-P 4035.73.

He-P 4035.29 Recentness of Training. The training and experience specified in Part He-P 4035 must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience were completed. Formatted

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He-P 4035.~~10~~30 Statement of Authorities and Responsibilities.

(a) A licensee shall provide sufficient authority and organizational freedom to the Radiation Safety Officer and the Radiation Safety Committee to:

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide solutions; and

(3) Verify implementation of corrective actions.

(b) A licensee shall establish in writing the authorities, duties, responsibilities, and radiation safety activities of the Radiation Safety Officer and the Radiation Safety Committee.

~~He-P 4035.11 Supervision.~~

~~(a) A licensee who permits the receipt, possession, production, preparation, compounding, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by He-P 4035.04 shall:~~

~~(1) Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material and in the licensee's written quality management program;~~

~~(2) Periodically review the supervised individual's use of radioactive material, the records kept to reflect this use, and provide re-instruction as needed;~~

~~(3) Require an authorized user to be immediately available to communicate with the supervised individual; and~~

~~(4) Require that only those individuals permitted under state and local regulations and specifically trained, and designated by the authorized user, be permitted to administer radionuclides or radiation to patients or human research subjects.~~

~~(b) A licensee shall require the supervised individual receiving, possessing, producing, preparing, compounding, using or transferring radioactive material under He-P 4035.04 to:~~

~~(1) Follow the instructions of the supervising authorized nuclear pharmacist or user;~~

~~(2) Follow the written radiation safety and quality management procedures established by the licensee; and~~

~~(3) Comply with He-P 4019 through He-P 4023 and the license conditions with respect to the use of radioactive material.~~

~~(c) A licensee shall require the supervising authorized nuclear pharmacist or physician who is an authorized user to periodically review the work of the supervised individual as it pertains to preparing radioactive material for medical use and the records kept to reflect that work.~~

~~(d) A licensee that supervises an individual shall be responsible for the acts and omissions of the supervised individual.~~

~~Source: (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07~~

~~New: #8959, eff 8-7-07~~

He-P 4035.~~12~~31 -Mobile Nuclear Medicine Service Administrative Requirements.

(a) -The ~~DHHS/BRH~~Agency shall license mobile nuclear medicine services and or clients of such services, limited to the following services:

(1) Uptake, dilution and excretion;

(2) Imaging and localization;

(3) Sealed sources in diagnosis; and

(4) Certain in-vitro clinical or laboratory testing.

(b) ~~-~~The client of the mobile nuclear medicine service shall be licensed by the ~~DHHS/BRH~~ Agency if the client receives or possesses ~~radioactive~~ byproduct material to be used by a mobile nuclear medicine service.

(c) ~~-~~Mobile nuclear medicine service licensee~~s~~ shall retain for the duration of service a letter signed by the management of each location where services are rendered that authorizes use of ~~radioactive~~ byproduct material.

(d) ~~-~~If the client is licensed, the letter shall document procedures for notification, receipt, storage and documentation of transfer of ~~radioactive~~ byproduct material delivered to the client's location for use by the mobile nuclear medicine service.

(e) ~~-~~A mobile nuclear medicine service shall not have ~~radioactive~~ byproduct material delivered directly from the manufacturer or the distributor to the client's address of use, unless the client has a license to receive and possess that ~~radioactive~~ byproduct material.

(f) ~~Radioactive~~ Byproduct material delivered to the client's address of use shall be received and handled in conformance with the client's license.

(g) ~~-~~A mobile nuclear medicine service shall inform a responsible individual, such as a representative of management or a registered nurse in charge of the patient or the registered nurse in charge of the nursing unit, who is on site at each client's address of use at the time that ~~radiopharmaceuticals~~ byproduct materials are being administered.

(h) A licensee providing mobile medical service shall:

(1) Transport to each client's address only syringes or vials containing prepared drugs or byproduct materials that are intended for reconstitution of radioactive drug kits;

(2) Bring into each client's address all byproduct material to be used and, before leaving, remove all unused byproduct material and associated radioactive waste;

(3) Secure or keep under constant surveillance and immediate control all byproduct material when in transit or at a client's address;

(4) Check instruments used to measure the activity of unsealed byproduct material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function shall include a constancy check;

(5) Check survey instruments for consistent response with a dedicated check source before use at each client's address;

(6) Prior to leaving a client's address, perform area surveys and survey for removable contamination in all areas of use, to ensure compliance with He-P 4020 of these regulations;

(7) Use radioactive gases only in areas of use and under conditions which have been evaluated and approved by the Agency for compliance with airborne release standards; and

(8) Retain a record of each survey required by He-P 4035.31(h)(6) in accordance with He-P 4035.99.

He-P 4035.~~13~~32 Quality Management Program.

(a) ~~–~~Each licensee shall establish and maintain a written quality management program to provide assurance that ~~radioactive~~ byproduct material or radiation therefrom will be administered as directed by ~~the~~ an authorized user.

(b) ~~–~~The quality management program shall include written policies and procedures to meet the following specific objectives:

(1) That, prior to administration, a written directive is prepared for:

a. Any teletherapy radiation dose;

b. Any gamma stereotactic radiosurgery radiation dose;

c. Any brachytherapy radiation dose;

d. ~~–~~Any administration of quantities greater than 1.11 megabecquerels (30 μCi) of either sodium iodide I-125 or I-131; or

e. ~~–~~Any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131;

(2) ~~-~~That, prior to each administration, the patient or human research subject's identity is verified by more than one method as the individual named in the written directive;

(3) ~~-~~That final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;

(4) That each administration is in accordance with the written directive; and

(5) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

(c) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive shall be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

(d) A written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose.

(e) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive as required by He-P 4035. ~~13~~32(d) would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

(f) Each licensee shall:

(1) Develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation of a representative sample of patient or human research subject administrations, all recordable events, and all misadministrations to verify compliance with all aspects of the quality management program; these reviews shall be conducted at intervals no greater than 12 months;

(2) Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, take modifications to meet the objectives of He-P 4035. ~~13~~32(a); and

(3) Retain records of each review, including the evaluations and findings of the review, in an auditable form for 3 years.

(g) The licensee shall evaluate and respond to each recordable event, within 30 days after discovery of the recordable event, by:

(1) Assembling the relevant facts including the cause;

(2) Identifying what, if any, corrective action is required to prevent recurrence; and

(3) Retaining a record, in an auditable form, for 3 years, of the relevant facts and what corrective action, if any, was taken.

(h) Each licensee shall retain:

(1) Each written directive; and

(2) A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in He-P 4035. ~~13~~32(b)(1) in an auditable form, for 3 years after the date of administration.

(i) ~~-~~The licensee may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased.

(j) ~~-~~Each applicant for a new license shall submit to the ~~DHHS/BRH~~ Agency a quality management program as part of the application for a license and implement the program upon issuance of the license by the ~~DHHS/BRH~~Agency.

(k) ~~-~~Each existing licensee, under He-P 4035, shall submit a written certification that a quality management program has been implemented.

(l) ~~-~~Each existing licensee shall retain a copy of the quality management program for review by the ~~DHHS/BRH~~Agency.

~~He-P 4035.14 Records, Notifications, and Reports of Misadministrations.~~

~~(a) For a misadministration, the licensee shall:~~

~~(1) Notify the DHHS/BRH by telephone no later than 24 hours after discovery of the misadministration;~~

~~(2) Submit a written report to the DHHS/BRH within 15 days after discovery of the misadministration which:~~

~~a. Shall include:~~

~~1. The licensee's name;~~

~~2. The prescribing physician's name;~~

~~3. A brief description of the event;~~

~~4. Why the event occurred;~~

~~5. The effect on the patient or human research subject;~~

~~6. What improvements are needed to prevent recurrence; actions taken to prevent recurrence;~~

~~7. Whether the licensee notified the patient or human research subject, or the patient's responsible relative or guardian, and if not, why not; and~~

8. If the patient or human research subject was notified, what information was provided to the patient or human research subject; and

b. Shall not include the patient's or human research subject's name or other information that could lead to identification of the patient or human research subject;

(3) Notify the referring physician and also notify the patient or human research subject of the misadministration not later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the patient or human research subject or that, based on medical judgment, telling the patient or human research subject would be harmful;

(4) Not be required to notify the patient or human research subject without first consulting the referring physician unless the referring physician or patient or human research subject cannot be reached within 24 hours, the licensee shall notify the patient or human research subject as soon as possible thereafter;

(5) Not delay any appropriate medical care for the patient or human research subject, including any necessary remedial care as a result of the misadministration, because of any delay in notification; and

(6) Furnish, within 15 days after discovery of the misadministration, if the patient or human research subject was notified a written report to the patient or human research subject by sending:

a. A copy of the report that was submitted to the DHHS/BRH; or

b. A brief description of both the event and the consequences, as they may affect the patient or human research subject, provided a statement is included that the report submitted to the DHHS/BRH can be obtained from the licensee.

(b) Each licensee shall retain a record of each misadministration for 5 years.

(c) The record required in He-P 4035.14(b) shall contain the names of all individuals involved, the patient's or human research subject's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the patient or human research subject, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

(d) Aside from the notification requirement, nothing in He-P 4035.14(a) - (c) shall affect any rights or duties of licensees and physicians in relation to each other, patients, or human research subjects, or the patient's or the human research subject's responsible relatives or guardians.

~~Source. (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07~~

~~New. #8959, eff 8-7-07~~

~~He-P 4035.15 Suppliers. A licensee shall use for medical use only:~~

~~(a) Radioactive material manufactured, produced, labeled, prepared, compounded, packaged, and distributed in accordance with a license issued pursuant to He-P 4030, and He-P 4032.05, He-P4032.06, or He-P 4032.07 or the equivalent regulations of another Agreement State, a Licensing State or the U.S. Nuclear Regulatory Commission; and~~

~~(b) Reagent kits, radiopharmaceuticals, and/or radiobiologics that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the U.S. Department of Health and Human Services, Food and Drug Administration (FDA); or~~

~~(c) Radiopharmaceuticals compounded from a prescription in accordance with the rules of the New Hampshire Board of Pharmacy; and~~

~~(d) Teletherapy and brachytherapy sources manufactured and distributed in accordance with a license issued pursuant to He-P 4030, or the equivalent regulations of another Agreement State, a Licensing State, or the NRC.~~

~~Source. (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07~~

~~New. #8959, eff 8-7-07~~

He-P 4035.~~16~~33 Quality Control of Diagnostic Gamma Camera Equipment.

(a) ~~-~~Each licensee shall establish written quality control procedures for all diagnostic gamma camera equipment used for ~~radionuclide~~ byproduct material studies.

(b) ~~-~~As a minimum, quality control procedures and frequencies shall be those recommended by equipment manufacturers or procedures which have been approved by the ~~DHHS/BRH~~Agency.

(c) ~~–~~The licensee shall conduct quality control procedures in accordance with written procedures.

~~He-P 4035.17 Possession, Use, Calibration, and Check of Dose Calibrators.~~

~~(a) A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity administered to each patient or human research subject.~~

(b) In the case where the ionization type dose calibrator required in He-P 4035.17(a) cannot be used effectively to verify the administered activity, the licensee shall use an alternative method.

(c) Any alternative method to the use of a dose calibrator shall be approved by the DHHS/BRH.

(d) Any alternative method shall provide for acceptable verification of constancy, accuracy, linearity, and geometry dependence as applicable.

(e) Each licensee shall establish written quality control procedures for all dose calibrators used for measuring the amount of activity administered to a patient of human research subject.

(f) Each licensee shall have written procedures for the use of the instrumentation required in this section.

(g) As a minimum, quality control procedures and frequencies shall be those recommended by the American National Standards Institute in ANSI N42.13-2004, or the licensee shall:

(1) At the beginning of each day of use, check each dose calibrator for constancy on a frequently used setting with a dedicated check source of not less than 1.85 megabecquerels (50 μCi) of any photon-emitting radionuclide with a half-life greater than 90 days;

(2) Test each dose calibrator for accuracy upon installation and at least annually thereafter by assaying at least 2 sealed calibration sources, traceable to National Institute of Standards and Technology (NIST) or other standards recognized as being equivalent to NIST:

a. Which contain different radionuclides whose activity:

1. The manufacturer has determined within 5 percent of its stated activity; and

2. Is at least 10 microcuries for radium-226 and 50 microcuries for any other photon-emitting radionuclide; and

b. At least one of which has principal photon energy between 100 keV and 500 keV;

(3) Test each dose calibrator for linearity upon installation and at intervals not to exceed 3 months thereafter over the range of use between 10 microcuries (370 kilobecquerels) and the highest dosage that will be assayed;

(4) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used; and

(5) Keep a record of the geometry dependence tests required in (g)(4) above for the

~~duration of the use of the dose calibrator.~~

~~(h) A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.~~

~~(i) A licensee shall also perform checks and tests required by He-P 4035.17(g) following adjustment or repair of the dose calibrator.~~

~~(j) A licensee shall retain a record of each check and test required by He-P 4035.17 for 3 years.~~

~~(k) The records required by He-P 4035.17(g) shall include:~~

~~(1) For He-P 4035.17(g)(1) the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings, and the initials of the individual who performed the check;~~

~~(2) For He-P 4035.17(g)(2) the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings, and the signature of the individual who performed the test;~~

~~(3) For He-P 4035.17(g)(3) the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the signature of the individual who performed the test; and~~

~~(4) For He-P 4035.17(g)(4) the model and serial number of the dose calibrator, the configuration and calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test, and the signature of the individual who performed the test.~~

~~Source: (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07~~

~~New: #8959, eff 8-7-07~~

He-P 4035.34 Possession, Use, and Testing of Instruments to Measure the Activity of Unsealed Byproduct Materials.

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(a) For direct measurements performed in accordance with He-P 4035.36, a licensee shall possess and use instrumentation to measure the activity of unsealed byproduct materials prior to administration to each patient or human research subject.

(b) A licensee shall test the instrumentation required in He-P 4035.34(a) in accordance with nationally recognized standards or the manufacturer's instructions.

(c) Thes tests required in He-P 4035.34(b) shall at a minimum include tests for constancy, linearity, accuracy and geometry dependence, as appropriate to demostrate proper operation of the instrument;

(d) A licensee shall retain a record of each instrument test required by He-P 4035.34 in accordance with He-P 4035.93.

He-P 4035.~~18~~ 35 Calibration and Check of Survey Instruments.

(a) A licensee shall ensure that the survey instruments used to show compliance with He-P ~~4035~~ 4020 and He-P 4035 have been calibrated before first use, annually, and following any repair that will affect the calibration.

(b) To satisfy the requirements of He-P 4035.~~18~~35(a), the licensee shall:

(1) Calibrate all required scale readings up to 10 millisieverts (1000 mrem) per hour with a radiation source;

(2) Have each radiation survey instrument calibrated:

a. At energies appropriate for use and at intervals not to exceed 12 months or after instrument servicing, except for battery changes;

b. For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at 3 points between 0.02 and 10 millisieverts (2 and 1000 mrem) per hour; and

c. For dose rate instruments, so that an accuracy within plus or minus 20 percent of the true radiation dose rate can be demonstrated at each point checked.

(3) Conspicuously note on the instrument the date of calibration.

(c) The licensee shall not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is greater than 20 percent.

(d) A licensee shall check, but shall not be required to record, each survey instrument for proper operation with the dedicated check source before each use.

(e) The licensee shall retain a record of each calibration required in He-P 4035.~~18~~35(a) for 3 years.

(f) Each calibration record shall include:

(1) A description of the calibration procedure;

(2) A description of the source used;

(3) The certified dose rates from the source;

(4) The rates indicated by the instrument being calibrated;

(5) The correction factors deduced from the calibration data;

(6) The signature of the individual who performed the calibration; and

(7) The date of calibration.

(g) ~~–~~To meet the requirements of He-P 4035.~~18~~35(a) – (~~e~~f), the licensee may obtain the services of individuals licensed by the ~~DHHS/BRH~~Agency, the ~~U.S.~~ Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform calibrations of survey instruments.

(h) ~~Records of calibrations which contain information required by He-P 4035.18(e) and (f) shall be maintained by the licensee~~The licensee shall retain a record of each survey instrument calibration in accordance with He-P 4035.94.

He-P 4035.~~19~~36 ~~Assay of Radiopharmaceutical~~ Determination of Dosages of Unsealed Byproduct Material for Medical Use ~~Dosages~~. A licensee shall meet the following requirements for ~~assay~~ determination of ~~radiopharmaceutical~~ dosages of unsealed byproduct material~~dosages~~:

(a) ~~Assay, before medical use, the activity of each radiopharmaceutical dosage that contains more than 370 kilobecquerels (10 µCi) of a photon-emitting radionuclide~~A licensee shall determine and record the activity of each dosage prior to medical use. For photon-emitting byproduct material, this determination shall be within 30 minutes prior to medical use. For all other byproduct materials, this determination shall be within the period before medical use that is no greater than 10 percent of the physical half-life of the byproduct material.~~;~~

~~(b) Assay, before medical use, the activity of each radiopharmaceutical dosage emitting alpha and/or beta radiation as the radiation of principal interest, unless such radiopharmaceutical has been obtained:~~

~~(1) In unit dosage form, for individual patients or human research subjects from a manufacturer or preparer licensed pursuant to He-P 4032.05 or the equivalent requirements of the U.S. Nuclear Regulatory Commission, an Agreement State or Licensing State; and~~

~~(2) From a supplier which participates in a measurement quality assurance program with the National Institute of Standards and Technology, and which is designed to ensure that unit dosages have a calibration traceable to a national standard;~~

(b) For a unit dosage, this determination must be made either by direct measurement or by a decay correction, based on the measurement made by a manufacturer or preparer licensed pursuant to He-P 4032.05 of these regulations or equivalent provisions of the Nuclear Regulatory Commission, Agreement State or Licensing State.

(c) For other than unit dosages, this determination must be made by direct measurement of radioactivity or by a combination of measurements of radioactivity and mathematical calculations or combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed pursuant to He-P 4032.05 of these regulations or equivalent provisions of the Nuclear Regulatory Commission, Agreement State or Licensing State.

(d) Unless otherwise directed by the authorized user, a licensee shall not use a dosage if the dosage differs from the prescribed dosage by more than 20 percent.

(~~e~~c) ~~Retain a record of the assays or calibrations required by He-P 4035.19(a) and (b) for 3 years; and~~A Licensee shall retain a record of the dosage determination required by Part He-P 4035 in accordance with He-P 4035.95.

He-P 4035.~~20~~37 Authorization for Calibration, Transmission, and Reference Sources. Any person authorized by He-P 4035.~~04~~07 for medical use of ~~radioactive~~byproduct ~~-~~material may receive, possess, and use the following radioactive material for check, calibration, and reference use:

(a) Sealed sources manufactured and distributed by persons specifically licensed pursuant to He-P 4032 or equivalent provisions of the U.S. Nuclear Regulatory Commission, Agreement State, or Licensing State and that do not exceed ~~555 megabecquerels (15 mCi)~~ 1.11 gigabecquerels (30 mCi) each;

(b) Any radioactive material with a half-life of ~~100~~ 120 days or less in individual amounts not to exceed ~~555 megabecquerels~~ 0.56 gigabecquerels (15 mCi);

(c) Any radioactive material with a half-life greater than ~~100~~ 120 days in individual amounts not to exceed 7.4 megabecquerels (200 μCi) each; and

(d) ~~-~~Technetium-99m in ~~individual amounts not to exceed 1.85 gigabecquerels (50 mCi).~~amounts as needed.

He-P 4035.~~21~~38 Requirements for Possession of Sealed Sources and Brachytherapy Sources.

(a) A licensee in possession of any sealed source or brachytherapy source shall:

(1) ~~-~~Follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the ~~DHHS/BRH~~Agency; and

(2) ~~-~~Maintain the instructions for the duration of source use in a legible form convenient to users.

(b) A licensee in possession of a sealed source shall assure that:

(1) ~~-~~The source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and

(2) ~~-~~The source is tested for leakage at intervals not to exceed 6 months or at intervals approved by the ~~DHHS/BRH~~Agency, another Agreement State, a Licensing State, or the ~~U.S.~~ Nuclear Regulatory Commission in the Sealed Source and Device Registry.

(c) To satisfy the leak test requirements of He-P 4035. ~~21~~38(b), the licensee shall assure that:

(1) ~~-~~Leak tests are capable of detecting the presence of 185 becquerels (0.005 µCi) of radioactive material on the test sample~~, or in the case of radium, the escape of radon at the rate of 37 becquerels (0.001 µCi) per 24 hours~~;

(2) ~~-~~Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and

(3) Test samples are taken when the device containing the source is in the "off" position.
~~(7) The date of the test; and~~

~~(8) The signature of the Radiation Safety Officer.~~

(~~f~~d) If the leak test reveals the presence of 185 becquerels (0.005 µCi) or more of removable contamination, the licensee shall:

(1) ~~-~~Immediately withdraw the sealed source from use and store, repair or dispose of it in accordance with the requirements of He-P 4020, He-P 4023, and He-P 4031; and

(2) ~~-~~File a report with the ~~DHHS/BRH~~Agency within 5 days of receiving the leak test results ~~describing the equipment involved, the test results, and the action taken.~~in accordance with He-P 4035.118.

(~~h~~e) ~~-~~A licensee in possession of a sealed source or brachytherapy source, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources ~~at intervals not to exceed 3 months~~. The licensee shall retain each inventory record in accordance with He-P 4035.96.

He-P 4035.~~22~~39 Syringe Shields and Labels.

(a) ~~–~~A licensee shall keep syringes that contain ~~radioactive~~ byproduct material to be administered in an appropriate radiation shield or shielded area.

(b) ~~-~~A licensee shall require each individual who prepares or administers radiopharmaceuticals to use an appropriate syringe radiation shield unless the use of the shield is contraindicated for that patient or human research subject.

(c) ~~–~~A licensee shall conspicuously identify each syringe, or syringe radiation shield as to contents or intended patient or human research subject.

He-P 4035.~~23~~40 Vial Shields and Labels.

(a) ~~–~~A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

(b) ~~–~~A licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical with the radiopharmaceutical name~~ or its abbreviation~~.

He-P 4035.~~24~~41 Surveys for Ambient Radiation Dose Rate and Contamination.

(a) ~~A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are prepared for use or administered.~~Except as provided in He-P 4035.41(b), a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radioactive drugs containing byproduct material requiring a written directive were prepared for use or administered.

(b) ~~–~~A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored.

(c) A licensee shall conduct the surveys required by He-P 4035. ~~25~~41(a) and (b) so as to be able to measure dose rates as low as 1.0 microsievert (0.1 mrem) per hour.

(d) A licensee shall:

(1) Establish dose rate action levels for the surveys required by He-P 4035. ~~24~~41(a) and (b); and

(2) Require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.

(e) ~~–~~A licensee shall survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

(f) ~~-~~A licensee shall conduct the surveys required by He-P 4035. ~~24~~41(e) so as to be able to detect contamination on each wipe sample of 33.3 becquerels (2000 dmp). ~~as required by He-P 4021.21.~~

(g) A licensee shall:

(1) ~~–~~Establish removable contamination action levels for the surveys required by He-P

4035. 2441(e); and

(2) Require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.

(h) A licensee does not need to perform the surveys required by He-P 4035.41(a) in area(s) where patients or human research subjects are confined when they can not be released pursuant to He-P 4035.42.

(hj) A licensee shall retain a record of each survey required by He-P 4035.24(a)(b) and (e) for 3 years97.

(i) The survey record shall include:

(1) The date of the survey;

(2) A sketch of each area surveyed;

(3) Action levels established for each area;

(4) The measured dose rate at several points in each area expressed in microsieverts (mrem) per hour or the removable contamination in each area expressed in becquerels (dpm) per second per 100 square centimeters;

(5) The serial number and the model number of the instrument used to make the survey or analyze the samples; and

(6) The initials of the individual who performed the survey.

He-P 4035.2542 Release of Patients or Human Research Subjects Containing Radiopharmaceuticals Unsealed Byproduct Material or Permanent Implants Containing Byproduct Material.

(a) A licensee shall notmay authorize the release from confinement for medical care any patient or human research subject administered a radiopharmaceutical until eitherunsealed byproduct material or implants containing byproduct material when:

(1) The dose rate from the patient or human research subject is less than 50 microsieverts (5 mrem) per hour at a distance of one meter; orThe total effective dose equivalent (TEDE) to any other individual from exposure to the released individual is not likely to exceed 5 millisievert (0.5 rem);

(2)(b) The activity in the patient or human research subject is less than 1.11 gigabecquerel (30 mCi).A licensee shall provide the released individual, or the individual's parent or guardian, with written instructions on actions recommended to maintain doses to other individuals ALARA if the total effective dose equivalent (TEDE) to any other individuals is likely to exceed 1 millisievert (0.1

rem). If the TEDE to a nursing infant or child could exceed 1 millisievert (0.1 rem), assuming there was no interruption of breast-feeding, the instructions shall also include the following:

(1) Guidance on the interruption or discontinuation of breast-feeding;

(2) The instructions provided to a breast-feeding woman, if the radiation dose to the infant or child from continued breast-feeding could result in a TEDE exceeding 5 millisievert (0.5 rem); and

(3) Information on the potential consequences, if any, of failure to follow the guidance.

(~~b~~c) Release of the patient must be approved by an individual listed as an authorized user on the Agency license, and who is approved for the type of byproduct material use for which the patient being released has received.

(d) ~~A licensee shall not authorize release from confinement for medical care any patient or human research subject administered a permanent implant until the dose rate from the patient or human research subject is less than 50 microsieverts (5 mrem) per hour at a distance of 1 meter.~~The licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with He-P 4035.98

(e) The licensee shall maintain a record of instructions provided to breast-feeding women in accordance with He-P 4035.98.

(f) Nothwithstanding He-P 4035.42(a), the licensee may be held responsible for the proper disposal of any individual's radioactive waste discovered in a solid waste stream that can be traced to the licensee.

(g) The licensee shall immediately notify the Agency in accordance with He-P 4035.119 if a patient departs prior to an authorized release.

(h) The licensee shall notify the Agency in accordance with He-P 4035.120:

(1) When they are aware that a patient containing byproduct material and who has been released in accordance with He-P 4035.42 dies; and,

(2) If it is possible that any individual could receive exposure in excess of 5 millisievert (0.5 rem) as a result of the deceased body.

He-P 4035.~~26~~ ~~43~~ Mobile Nuclear Medicine Service Technical Requirements. A license providing mobile nuclear medicine service shall:

(a) ~~—~~Transport to each address of use only syringes or vials containing diagnostic radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

(b) ~~–~~Bring into each ~~area of use~~client's address ~~all radioactive~~byproduct material to be used and, before leaving, remove all unused ~~radioactive~~ byproduct material and associated ~~radioactive~~ byproduct waste;

(c) ~~–~~Secure or keep under constant surveillance and immediate control all ~~radioactive~~ byproduct material when in transit or at ~~an area of use~~a client's address;

(d) ~~In addition to complying with He-P 4035.17 and He-P 4035.18, check~~ Check survey instruments ~~and dose calibrators for constancy and response, and check all other transported equipment for proper function before medical use at each area of use~~used to measure the activity of unsealed byproduct material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function shall include a constancy check;

(e) ~~Carry a survey meter calibrated in accordance with He-P 4035.18 in each vehicle that is being used to transport radioactive material~~Check survey instruments for consistent response with a dedicated check source before use at each client's address;

(f) Before leaving a ~~client area of use~~client's address, ~~survey all areas of radiopharmaceutical use with a radiation detection survey instrument to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed~~perform area surveys and survey for removable contamination in all areas of use, to ensure compliance with He-P 4020 of these regulations;

(g) Retain a record of each survey required by He-P 4035.~~26~~43(f) ~~for 3 years, including:~~in accordance with He-P 4035.99.

~~(1) The date of the survey;~~

~~(2) A plan of each area that was surveyed;~~

~~(3) The measured dose rate at several points in each area of use expressed in microsieverts (mrem) per hour;~~

~~(4) Any removable contamination expressed in becquerels (dpm) per 100 square centimeters;~~

~~(5) The model and serial number of the instrument used to make the survey; and~~

~~(6) The initials of the individual who performed the survey; and~~

(h) Use radioactive gases and aerosols only in areas of use and under conditions which have been evaluated and approved by the ~~DHHS/BRH~~ Agency for compliance with airborne release standards.

He-P 4035.~~27~~ 44 Storage and Control of Volatiles and Gases.

(a) ~~-~~A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container.

(b) A licensee shall store and use a multi-dose container in a properly functioning fume hood.

(c) A licnesee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentration within the limits prescribed in He-P 4090.01 of these regulations.

(d) The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

(e) A licensee shall check the operation of collection systems monthly. Records of these checks shall be maintained for 3 years.

He-P 4035.~~28~~ ~~-~~45 Decay-In-Storage.

(a) A licensee may hold ~~radioactive~~ byproduct material for decay-in-storage if the material has a physical half-life of less than or equal to ~~65~~ 120 days ~~or, if the DHHS/BRH has approved it, material of longer half-life,~~ before disposal without regard to its radioactivity if the licensee:

(~~2~~1) Monitors radioactive material at the container surface before disposal ~~as ordinary trash~~ and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;

(~~3~~2) Removes or obliterates all radiation labels, except for material that will be handled as biomedical waste after release; and

(~~4~~3) ~~-~~Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

(~~c~~b) For radioactive material disposed in accordance with He-P 4035.~~28~~45(~~b~~a) of this section, the licensee shall retain a record of each disposal ~~for 3 years.~~ in accordance with He-P 4035.100.

He-P 4035.~~29~~46 Use of ~~Radiopharmaceuticals~~ Unsealed Byproduct Material for Uptake, Dilution, or Excretion Studies that Do Not Require a Written Directive. A licensee may use any ~~radioactive~~ unsealed byproduct material, ~~in a radiopharmaceutical~~ in quantities that do not require a written directive, for a diagnostic use involving measurements of uptake, dilution, or excretion that is:

(a) ~~Which has been granted acceptance or approval by the U.S. Food and Drug Administration; or~~Obtained from a manufacturer or prepared licensed pursuant to He-P 4032.07 of these regulations or equivalent regulations of another Agreement Sate, a Licensing State, or the Nuclear Regulatory Commission; or

(b) ~~Which is prepared and compounded in accordance with the regulations of the state Board of Pharmacy by an authorized nuclear pharmacist, an authorized user physician who meets the requirements of He-P 4035.64, or an individual supervised by either pursuant to He-P 4035.11.~~Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in He-P 4035.48, He-P 4035.51, or an individual under the supervision of either as specified in He-P 4035.19; or

(c) Obtained from and prepared by an Agency, Nuclear Regulatory Commission, Agreement State or Licensing State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug protocol accepted by FDA for use in research.

He-P 4035.~~30~~ 47 Possession of Survey Instrument. ~~for Use of Radiopharmaceuticals for Uptake, Dilution, or Excretion Studies.~~

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(a) A licensee authorized to use ~~radioactive~~ byproduct material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 1 microsievert (0.1 mrem) per hour to ~~1,000~~500 microsieverts (~~100~~ 50 mrems) per hour.

(b) The instrument in (a) above shall be operable and calibrated in accordance with He-P 4035.~~18~~35.

He-P 4035.48 Training for Uptake, Dilution, and Excretion Studies. Except as provided in He-P 4035.28, the licensee shall require an authorized user of an unsealed byproduct material for the uses authorized under He-P 4035.46 to be a physician who:

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(a) Is certified by a medical specialty board whose certification process includes all of the requirements in He-P 4035.48(c) and whose certification has been recognized by the Nuclear Regulatory Commission, or an Agreement State; or

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(b) Is an authorized user under He-P 4035.51 or He-P 4035.55, or equivalent Agreement State or Nuclear Regulatory Commission requirements; or

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(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 that includes:

a. 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. Work experience, under the supervision of an authorized user who meets the requirements in He-P 4035.48, He-P 4035.51 or He-P 4035.55 or equivalent Agreement State, or Nuclear Regulatory Commission requirements, involving:

1. Ordering, receiving, and unpacking byproduct materials safely and performing the related radiation surveys;

2. Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

3. Calculating, measuring, and safely preparing patient or human research subject dosages;

4. Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

5. Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

6. Administering dosages to patients or human research subjects; and

(2) Has obtained written certification, signed by a preceptor authorized user, who meets the requirements in He-P 4035.48, He-P 4035.51 or He-P 4035.55 or equivalent Agreement State, or Licensing State certification for NARM, or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in He-P 4035.48(c)(1) and has achieved a level of competency sufficient to independently function as an authorized user for the medical uses authorized under He-P 4035.46.

~~He-P 4035.31 Use of Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and Localization Studies.~~

~~(a) A licensee may use any radioactive material in a diagnostic radiopharmaceutical (except aerosol or gaseous forms) or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material:~~

~~(1) Which has been granted acceptance or approval by the Food and Drug Administration; or~~

~~(2) Which has been prepared and compounded in accordance with the regulations of the state Board of Pharmacy by an authorized nuclear pharmacist, an authorized user physician who meets the requirements of He-P 4035.64 or an individual supervised by either pursuant to He-P 4035.11.~~

~~(b) A licensee shall elute generators in compliance with He-P 4035.32.~~

~~(c) Provided the conditions of He-P 4035.33 are met, a licensee may use radioactive aerosols or gases if specific application is made to and approved by the DHHS/BRH.~~

~~Source. (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07~~

~~New: #8959, eff 8-7-07~~

He-P 4035.49 Use of Unsealed Byproduct Material for Imaging and Location Studies that Do Not Require a Written Directive. A licensee may use, for imaging and localization studies, any byproduct material prepared for medical use, in quantities that do not require a written directive as described in He-P 4035.20 that is:

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(a) Obtained from a manufacturer or preparer licensed pursuant to He-P 4032.07 of these regulations or equivalent regulations of another Agreement State, a Licensing State, or the Nuclear Regulatory Commission; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in He-P 4035.51, or an individual under the supervision of either as specified in He-P 4035.19; or

(c) Obtained from and prepared by an Agency, Nuclear Regulatory Commission, Agreement State, or Licensing State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

(e) Provided the conditions of He-P 4035.44 are met, a licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the Agency.

He-P 4035.~~32~~50 Radionuclide Contaminants.

(a) A licensee shall not administer to humans a radiopharmaceutical containing:

(1) More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 μCi of Mo-99 per mCi of Tc-99m);

(2) ~~–~~More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 µCi of Sr-82 per mCi of Rb-82 chloride); or

(3) ~~–~~More than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 µCi of Sr-85 per mCi of Rb-82).

(b) ~~—~~A licensee preparing radiopharmaceuticals from ~~radionuclide —~~molybdenum-99/technetium-99m generators shall measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for the generator system, to determine compliance with the limits specified in He-P 4035.~~32~~50(a).

(c) A licensee who must measure radionuclide contaminant concentration shall retain a record of each measurement ~~for 3 years.~~in accordance with He-P 4035.101.

~~(d) The record required in He-P 4035.32(c) shall include for each elution or extraction tested:~~

~~(1) The measured activity of the radiopharmaceutical expressed in megabecquerels or millicuries (mCi);~~

~~(2) The measured activity of contaminant expressed in kilobecquerels or microcuries (µCi);~~

~~(3) The ratio of the measures expressed as kilobecquerels (µCi) contaminant per megabecquerel (mCi) radiopharmaceutical;~~

~~(4) The date of the test; and~~

~~(5) The initials of the individual who performed the test.~~

(~~e~~d) A licensee shall report immediately to the ~~DHHS/BRH~~ Agency each occurrence of radionuclide contaminant concentration exceeding the limits specified in He-P 4035.~~32~~50(a).

He-P 4035.51 Training for Imaging and Localization Studies. Except as provided in He-P 4035.28, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under He-P 4035.46 to be a physician who:

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in He-P 4035.51(c) and whose certification has been recognized by an Agreement State, or the Licensing State certification for NARM or the Nuclear Regulatory Commission, or

(b) Is an authorized user under He-P 4035.55, or equivalent Agreement State, or Nuclear Regulatory Commission requirements; or

(c)

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(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 that includes, at a minimum:

a. 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;

5. Radiation biology; and

b. Work experience, under the supervision of an authorized user, who meets the requirements in He-P 4035.51 or He-P 4035.55, or equivalent Agreement State, or Nuclear Regulatory Commission requirements, involving:

1. Ordering, receiving, and unpacking byproduct materials safely and performing the related radiation surveys;

2. Calibrating instruments used to determine the acitivity of dosages and performing checks for proper operation of survey meters;

3. Calculating, measuring, and safely preparing patient or human research subject dosages;

4. Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

5. Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;

6. Administering byproduct dosages to patients and human research subjects; and

7. Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radiochemical 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 He-4035.51 or He-P 4035.55, or equivalent Agreement State, or Nuclear Regulatory Commission requirements, that the individual has satisfactorily

completed the requirements in He-P 4035.51(c)(1) and has achieved a level of competency sufficient to independently function as an authorized user for the medical uses authorized under He-P 4035.49.

~~He-P 4035.34 Possession of Survey Instruments for Use of Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and Localization Studies.~~

~~(a) A licensee authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 1,000 microsieverts (100 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (1 mrem) per hour to 10 millisieverts (1,000 mrems) per hour.~~

~~(b) The instruments required in He-P 4035.34(a) shall be operable and calibrated in accordance with He-P 4035.18.~~

~~Source. (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07~~

~~New: #8959, eff 8-7-07~~

He-P 4035.52 Use of Unsealed Byproduct Material for Which a Written Directive is Required. A licensee may use any unsealed byproduct material for diagnostic or therapeutic medical use for which a written directive is required that has been:

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(a) Obtained from a manufacturer or preparer licensed in accordance with He-P 4032.07 of these regulations; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in He-P 4035.51 or He-P 4035.55, or an individual under the supervision of either as specified in He-P 4035.28; or

(c) Obtained from and prepared by an Agency, Nuclear Regulatory Commission, Agreement State, or Licensing State licensee in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA for use in research; or

(d) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA for use in research.

He-P 4035.53 Safety Instruction. In addition to the requirements of He-P 4019.04 of these regulations:

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(a) A licensee shall provide radiation safety instruction to personnel caring for patients or human research subjects that have received therapy with a radioactive drug, and cannot be released

in accordance with He-P 4035.42. The training must be provided initially and at least annually. The instruction must be appropriate to the personnel's assigned duties and include the following:

(1) Patient or human research subject control;

(2) Visitor control to include the following:

a. Routine visitation to hospitalized individuals in accordance with He-P 4020.13 of these regulations;

b. Contamination control;

c. Waste control;

d. Notification of the RSO, or his or her designee, and the authorized user if the patient or the human research subject dies or has a medical emergency.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with He-P 4035.103.

He-P 4035.54 Safety Precautions.

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(a) For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with He-P 4035.42, a licensee shall:

(1) Place the patient or the human research subject either in:

a. A private room with a private sanitary facility; or

b. A room, with a private sanitary facility, with another individual who also has received similar radiopharmaceutical therapy and who cannot be released in accordance with He-P 4035.42; and

(2) Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room; and

(3) Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle such material and items as radioactive waste.

(b) The Radiation Safety Officer, or his or her designee, and the authorized user shall be notified immediately if the hospitalized patient dies or has a medical emergency. The licensee shall

also notify the Agency in accordance with He-P 4035.120, if it is possible that any individual could receive exposures in excess of He-P 4020.13 of these regulations as a result of the deceased's body.

He-P 4035.55 Training for Use of Unsealed Byproduct Material for which a Written Directive is Required. Except as provided in He-P 4035.28, the licensee shall require an authorized user of byproduct material for the uses authorized under He-P 4035.52 to be a physician who:

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(a) Is certified by a medical specialty board whose certification process includes all of the requirements of He-P 4035.55(b) and whose certification has been recognized by an Agreement State, the Licensing State certification for NARM or the Nuclear Regulatory Commission; or

(b)

(1) Has successfully 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, that includes:

a. 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 radioactive material for medical use; and

5. Radiation biology; and

b. Work experience, under the supervision of an authorized user who meets the requirements in He-P 4035.55 or equivalent Agreement State, or Nuclear Regulatory Commission requirements. A supervising authorized user, who meets the requirements of He-P 4035.55(b) must have experience in administering dosages in the same dosage category or categories listed in He-P 4035.55(b)(2) as the individual requesting authorized user status. The work experience must involve:

1. Ordering, receiving, and unpacking byproduct materials safely and performing the related radiation surveys;

2. Calibrating instruments used to determine the activity of dosages, and performing checks for porper operation of survey meters;

3. Calculating, measuring, and safely preparing patient or human research subject dosages;

4. Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

5. Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;

6. Administrating dosages to patients or human research subjects; and

7. Eluting generator systems, measuring and testing the eluant for radiochemical purity, and processing the eluant with reagent kits to prepare labeled radioactive drugs containing byproduct material; and

(2) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of 3 cases in each of the following categories for which the individual is requesting authorized user status. This experience may be obtained concurrently with the supervised work experience required by He-P 4035.55(b)(1)b:

a. Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;

b. Oral administration of greater than 1.22 gigabecquerels (33 millicures) of sodium iodide I-131. Experience with at least 3 cases in category (b) also satisfies the requirement in category (a);

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

d. Parenteral administration of any other radionuclide; and

(3) Has obtained written certification, signed by a preceptor authorized user, who meets the requirements in He-P 4035.55 or equivalent Agreement State, or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements He-P 4035.55(b)(1) and He-P 4035.55(b)(2) and has achieved a level of competency sufficient to independently function as an authorized user for the medical uses authorized under He-P 4035.55. The preceptor authorized user who meets the requirements of He-P 4035.55(b) must have experience in administering dosages in the same dosage category or categories listed in He-P 4035.55(b)(2) as the individual requesting authorized user status.

He-P 4035.56 Training for the Oral Administration of Sodium Iodide I-131 in Quantities Less than or Equal to 1.22 Gigabecquerels (33 millicuries) for which a Written Directive is Required. Except as provided in He-P 4035.28, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities less than or equal to 1.22 gigabecquerels (33 millicuries), for which a written directive is required, to be a physician who:

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(a) Is certified by a medical specialty board whose certification process includes all of the requirements of He-P 4035.56(c) and whose certification has been recognized by Licensing States Certification for NARM or the Nuclear Regulatory Commission, or

(b) Is an authorized user under He-P 4035.55(a), He-P 4035.55(b), for uses listed in He-P 4035.55(b)(2)a. or b., He-P 4035.57 or equivalent Agreement State, Licensing State or Nuclear Regulatory requirements; or

(c)

(1) Has successfully completed 80 hours of classrooom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive, that includes:

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

(2) Has work experience, under the supervision of an authorized user who meets the requirements in He-P 4035.55(a), He-P 4035.55(b), He-P 4035.56, He-P 4035.57, or equivalent Agreement State, or Nuclear Regulatory Commission requirements. A supervising authorized user, who meets the requirements of He-P 4035.55(b), must have experience in administering dosages as specified in He-P 4035.55(b)(2)a or He-P 4035.55(b)(2)b. The work experience must involve:

a. Ordering, receiving, and unpacking byproduct 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. 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 He-P 4035.56(c)(1) and He-P 4035.56(c)(2) and has achieved a level of competency sufficient to independently function as an authorized user for the medical uses of unsealed byproduct material using sodium iodide I-131 in activities less than or equal to 1.22 gigabecquerels (33 millicuries). The written certification must be signed by a preceptor authorized user who meets the requirements of He-P 4035.55(a), He-P 4035.55(b), He-P 4035.56, or He-P 4035.57, or equivalent Agreement State or Nuclear Regulatory Commission requirements. A preceptor authorized user who meets the requirements of He-P 4035.55(b) must have experience in administering dosages as specified in He-P 4035.55(b)(2)a and/or b.

He-P 4035.57 Training for the Oral Administration of Sodium Iodide I-131 in Quantities Greater than 1.22 Gigabecquerels (33 millicuries) for which a Written Directive is Required. Except as provided in He-P 4035.28, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities greater than 1.22 gigabecquerels (33 millicuries), to be a physician who:

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(a) Is certified by a medical specialty board whose certification process includes all of the requirements of He-P 4035.56(c) and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission, or

(b) Is an authorized user under He-P 4035.55(a), He-P 4035.55(b) for uses listed in He-P 4035.55(b)(2)b., or equivalent Agreement State, Licensing State, or Nuclear Regulatory Commission 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:

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

(2) Has work experience, under the supervision of an authorized user who meets the requirements in He-P 4035.55(a), He-P 4035.55(b), He-P 4035.57, or equivalent

Agreement State, or Nuclear Regulatory Commission requirements. A supervising authorized user, who meets the requirements of He-P 4035.55(b) must have experience in administering dosages as specified in He-P 4035.55(b)(2)b. The work experience must involve:

a. Ordering, receiving, and unpacking byproduct 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. Administering dosages to patients or human 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 He-P 4035.57(c)(1) and He-P 4035.57(c)(2) and has achieved a level of competency sufficient to independently function as an authorized user for medical uses of unsealed byproduct material using sodium iodide I-1331 in activities greater than 1.22 gigabecquerels (33 millicuries). The written certification must be signed by a preceptor authorized user, who meets the requirements of He-P 4035.55(b), He-P 4035.57, or equivalent Agreement State or Nuclear Regulatory Commission requirements. A preceptor authorized user who meets the requirements of He-P 4035.55(b) must have experience in administering dosages as specified in He-P 4035.55(b)(2)b.

He-P 4035.~~35~~58 Use of ~~Radiopharmaceuticals —~~Sealed Sources for Manual ~~Therapy~~Brachytherapy. A licensee ~~may~~ shall use ~~any radioactive material in a radiopharmaceutical and~~ only brachytherapy sources for ~~a~~ therapeutic medical uses:

(a) ~~Which has been granted acceptance or approval by the FDA.~~As approved in the Sealed Sources and Device Registry; or

(b) ~~Which has been prepared and compounded in accordance with the rules of the state Board of Pharmacy by an authorized nuclear pharmacist, an authorized user physician who meets the requirements of He-P 4035.64, or an individual supervised by either pursuant to He-P 4035.11.~~In

research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of He-P 4035.22(a) are met.

He-P 4035.59 Surveys After Source Implant and Removal.

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(a) Immediately after implanting sources in a patient or a human research subject, the licensee shall perform a survey to locate and account for all sources that have not been implanted.

(b) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

(c) A licensee shall retain a record of the surveys in accordance with He-P 4035.104.

He-P 4035.60 Brachytherapy Sources Inventory.

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(a) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

(b) Promptly after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

(c) A licensee shall maintain a record of the brachytherapy source accountability in accordance with He-P 4035.105.

He-P 4035.~~36~~ 61 Safety Instruction ~~for Use of Radiopharmaceuticals for Therapy~~. In addition to the requirements of He-P 4019.04 of these regulations:

(a) The licensee shall provide radiation safety instruction, initally and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and who cannot be released in accordance with He-P 4035.42. Instructions must be commensurate with the duties of the personnel and shall include the following:

~~(a) A licensee shall provide oral and written radiation safety instruction for all personnel caring for patients or human research subjects undergoing radiopharmaceutical therapy.~~

(1) ~~Patient or human research subject control~~Size and appearance of brachytherapy sources;

(2) ~~Visitor control~~Safe handling and shielding instructions;

(3) ~~Contamination~~ Patient or human research subject control;

(4) ~~Waste control;~~ Visitor control, including both:

a. Routine visitation of hospitalized individuals in accordance with He-P 4020.13 of these regulations; and

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~~a.~~b. Visitation authorized in accordance with He-P 4020.14 of these regulations; and

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(5) Notification of the Radiation Safety Officer, or his or her designee, ~~or~~ and an authorized user ~~in case of the patient's or human research subject's death or medical emergency; and~~if the patient or the human research subject dies or has a medical emergency. The licensee shall also notify the Agency in accordance with He-P 4035.120, if it is possible that any individual could receive exposures in excess of 5 millisievert (500 mrem) as a result of the deceased's body.

(b) A licensee shall retain a record individuals receiving instruction in accordance with He-P 4035.107.

~~(6) Training for workers as required by He-P 4019.~~

~~(d) A licensee shall keep a record of:~~

~~(1) Individuals receiving instruction required by He-P 4035.36(a);~~

~~(2) A description of the instruction;~~

~~(3) The date of instruction; and~~

~~(4) The name of the individual who gave the instruction.~~

~~(e) The record required in He-P 4035.36(d) shall be maintained for inspection by the DHHS/BRH for 3 years.~~

~~Source. (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07~~

~~New: #8959, eff 8-7-07~~

He-P 4035.~~37~~62 Safety Precautions for ~~Use of Radiopharmaceuticals for Therapy~~Patients or Human Research Subjects Receiving Brachytherapy.

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(a) ~~—~~For each patient or human research subject receiving ~~radiopharmaceutical therapy~~brachytherapy and ~~hospitalized for compliance with~~cannot be released under He-P 4035.~~25~~42, a licensee shall:

(1) ~~Provide a private room with a private sanitary facility~~Not place the patient or human research subject in the same room as an individual who is not receiving brachytherapy;

(2) ~~Post~~ Visibly post the patient's or human research subject's ~~door~~ room with a

"~~Caution:~~ Radioactive Material" sign and note on the door or ~~on~~ in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

(b) ~~For each non-hospitalized patient or human research subject receiving radiopharmaceutical therapy, the licensee shall instruct the patient or human research subject and, where appropriate, the patient's or human research subject's family, orally and in writing concerning radiation safety precautions that will help to keep radiation doses to the household members and the public as low as reasonably achievable.~~ A licensee shall have emergency response equipment available near each treatment room to respond to a source that inadvertently becomes:

(1) Dislodged from the patient; or

(2) Lodged within the patient following removal of the source applicators.

(c) The Radiation Safety Officer, or his or her designee, and the authorized user shall be notified immediately if the hospitalized patient or human research subject dies or has a medical emergency.

He-P 4035.63 Calibration Measurements of Brachytherapy Sealed Sources.

(a) Prior to the first medical use of a brachytherapy sealed source on or after January 1, 2014, a licensee shall perform the following:

(1) Determine the source output or activity using a dosimetry system that meets the requirements of He-P 4035.77(a):

(2) Determine source position accuracy within applicators; and

(3) Use published protocols accepted by nationally recognized bodies to meet the requirements of He-P 4035.63(a)(1) and He-P 4035.63(a)(2).

(b) A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with He-P 4035.63(a).

(c) A licensee shall mathematically correct the outputs or activities determined in He-P 4035.63(a) of this section for physical decay at intervals consistent with 1.0 percent physical decay.

(d) An authorized medical physicist shall perform or review the calculation measurements made pursuant to He-P 4035.63(a), He-P 4035.63(b), or He-P 4035.63(c).

(e) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined in accordance with paragraphs He-P 4035.63(a), He-P 4035.63(b), and He-P 4035.63(c).

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(f) A licensee shall retain a record of each calibration in accordance with He-P 4035.106.

(g) A licensee shall retain a record of decay calculations requried by He-P 4035.63(e) in accordance with He-P 4035.107.

He-P 4035.64 Therapy-related Computer Systems. The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

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(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays; and

(d) The accuracy of the software used to determine radioactive-source positions from radiographic images.

He-P 4035.65 Possession of Survey Instruments. A licensee authorized to use manual brachytherapy sources shall possess a portable radiation detection survey instrument capable of detecting dose ratees over the range of 1 microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10 microsieverts (1 mrem) per hour to 10 millisieverts (1000 mrem) per hour. The instruments shall be operable and calibrated in accordance with He-P 4035.35.

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~~He-P 4035.38 Possession of Survey Instruments for Use of Radiopharmaceuticals for Therapy.~~

~~(a) A licensee authorized to use radioactive material for radiopharmaceutical therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 1 microsievert (0.1 mrem) per hour to 1,000 microsievert (100 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (1 mrem) per hour to 10 millisieverts (1,000 mrems) per hour.~~

~~(b) The survey instruments shall be operable and calibrated in accordance with He-P 4035.18.~~

~~Source: (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07~~

~~New: #8959, eff 8-7-07~~

He-P 4035.66 Training for Use of Manual Brachytherapy Sources. Except as provided in He-P 4035.28, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under He-P 4035.58 to be a physician who:

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(a) Is certified by a medical specialty board whose certification process includes all of the requirements in He-P 4035.66(b) and whose certification has been recognized by an Agreement State, or the Licensing State certification for NARM, or the Nuclear Regulatory Commission; or

(b)

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

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; and

4. Radiation biology; and

b. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in He-P 4035.66 or equivalent Agreement State, or Nuclear Regulatory Commission requirements at a medical institution, involving:

1. Ordering, receiving, and unpacking byproduct materials safely and performing the related radiation surveys;

2. Checking survey meters for proper operation;

3. Preparing, implanting, and removing brachytherapy sources;

4. Maintaining running inventories of material on hand;

5. Using administrative controls to prevent a medical event involving the use of byproduct material;

6. Using emergency procedures to control byproduct material; and

(2) Three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in He-P 4035.66 or equivalent Agreement State or Nuclear Regulatory Commission 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 He-P 4035.66(b)(1)b; and

(3) Has obtained written certification, signed by a preceptor authorized user, who meets the requirements in He-P 4035.66 or equivalent Agreement State or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in He-P 4035.66(b)(1) and He-P 4035.66(b)(2) and has achieved a level of competency sufficient to independently function as an authorized user of manual brachytherapy sources for the medical uses authorized under He-P 4035.58.

He-P 4035.67 Training for Ophthalmic Use of Strontium-90. Except as provided in He-P 4035.28, the licensee shall require an authorized user of a strontium-90 source for ophthalmic uses authorized under He-P 4035.58 to be a physician who:

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(a) Is an authorized user under He-P 4035.66, Licensing State certification for NARM, equivalent Agreement State, or Nuclear Regulatory Commission 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:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity; and,

d. Radiation biology; and,

(2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user who meets the requirements of He-P 4035.66 or He-P 4035.67, and that includes the use of strontium-90 for the ophthalmic treatment of five individuals that includes:

a. Examination of each individual to be treated;

b. Calculation of the dose to be administered;

c. Administration of the dose; and,

d. 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 requiremnts in He-P 4035.66 or He-P 4035.67 or equivalent Agreement State or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in paragraphs (1) and (2) of this section and has achieved a level of competency sufficient to independently function as an authorized user of strontium-90 for ophthalmic use.

He-P 4035.~~39~~ 68 Use of Sealed Sources for Diagnosis. A licensee shall use ~~the following sealed sources in accordance with the manufacturer's radiation safety and handling instructions~~only only sealed sources for diagnostic medical uses:

~~(a) Iodine-125 as a sealed source in a device for bone mineral analysis;~~

~~(b) Americium-241 as a sealed source in a device for bone mineral analysis;~~

~~(c) Gadolinium-153 as a sealed source in a device for bone mineral analysis or in a portable device for imaging; and~~

~~(d) Iodine-125 as a sealed source in a portable device for imaging.~~

(a) Approved in the Sealed Source and Device Registry; and,

(b) Handled in accordance with the manufacturer's radiation safety instructions.

He-P 4035.69 ,Training for Use of Sealed Sources for Diagnosis. Except as provided in He-P 4035.28, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under He-P 4035.68 to be a physician, dentist, or podiatrist who:

(a) Is certified by a specialty board whose certification process includes all of the requirements in He-P 4035.69(b) and whose certification has been recognized by an Agreement State, the Licensing State certification for NARM, or the Nuclear Regulatory Commission; or

(b) Has had 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device that includes:

(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.

~~He-P 4035.40 Availability of Survey Instruments for Use of Sealed Sources for Diagnosis.~~

~~(a) A licensee authorized to use radioactive material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range 1 microsievert (0.1 mrem) per hour to 1,000 microsieverts (100 mrems) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (1 mrem) per hour to 10 microsieverts (1,000 mrems) per hour.~~

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~~(b) The survey instrument shall be operable and calibrated in accordance with He-P 4035.18.~~

~~Source: (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07~~

~~New: #8959, eff 8-7-07~~

He-P 4035.70 Other Medical Uses of Byproduct Material or Radiation From Byproduct Material. A licensee may use byproduct material or a radiation source approved for medical use that is not specifically addressed in Part He-P 4035 if:

(a) The applicant or licensee has submitted the information required by He-P 4035.08(b), He-P 4035.08(c), and He-P 4035.08(d); and

(b) The applicant or licensee has received written approval from the Nuclear Regulatory Commission, and Agreement State, or Licensing State in a license and uses the material in accordance with the regulations and specific conditions the Nuclear Regulatory Commission, Agreement State, or Licensing State considers necessary for the medical use of the material.

He-P 4035.71 Use of Sealed Sources in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit. A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic units for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry; or

(b) In research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of He-P 4035.22(a) are met.

He-P 4035.72 Surveys of Patients and Human Research Subjects Treated with a Remote Afterloader Unit.

(a) Before releasing a patient or a human research subject from licensee control, a licensee shall make a survey of the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe, shielded position.

(b) A licensee shall retain a record of the surveys in accordance with He-P 4035.104.

~~He-P 4035.41 Use of Sources for Brachytherapy. A licensee shall use the following sources in accordance with the manufacturer's radiation safety and handling instructions:~~

~~(a) Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;~~

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~~(b) Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;~~

~~(c) Gold-198 as a sealed source in seeds for interstitial treatment of cancer;~~

~~(d) Iodine-125 as a sealed source in seeds for interstitial treatment of cancer;~~

~~(e) Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;~~

~~(f) Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions; and~~

~~(g) Palladium-103 as a sealed source in seeds for the interstitial treatment of cancer.~~

~~Source: (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07~~

~~New: #8959, eff 8-7-07~~

He-P 4035.73 Training for Use of Remote Afterload Units, teletherapy units, and Gamma Stereotactic Radiosurgery Units. Except as provided in He-P 4035.28, the licensee shall require an authorized user of a sealed source for a use authorized under He-P 4035.71 to be a physician who:

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(a) Is certified by a medical specialty board whose certification process includes all of the requirements in HeP 4035.73(b) and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission or a Licensing State certification for NARM; 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:

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; and

4. Radiation biology; and

(2) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in He-P 4035.73 or equivalent Agreement State or Nuclear Regulatory Commission 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

(3) Three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in He-P 4035.73 or equivalent Agreement State or Nuclear Regulatory Commission requirements, as part of the 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 He-P 4035.73(b)(2); and

(4) Has obtained written certification, signed by a preceptor authorized user, who meets the requirements in He-P 4035.73, equivalent Agreement State or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in He-P 4035.73(b)(1) and He-P 4035.73(b)(2) and has achieved a level of competency sufficient to independently function as an authorized user of the therapeutic medical unit for which the individual is requesting authorized user status.

He-P 4035.74 Installation, Maintenance, Adjustment, and Repair.

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(a) Only a person specifically licensed by the Agency, the Nuclear Regulatory Commission or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(b) Except for low dose-rate remote afterloader units, only a person specifically licensed by the Agency, an Agreement State, Licensing State, or the Nuclear Regulatory Commission shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

(c) For a low dose-rate remote afterloader unit, only a person specifically licensed by the Agency, an Agreement State, Licensing State or the Nuclear Regulatory Commission, or an

authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

(d) A licensee shall retain a record of the installation, maintenance, adjustment and repair done on remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with He-P 4035.108.

He-P 4035.75 Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

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(a) A licensee shall:

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(1) Secure the unit, the console, the consule keys, and the treatment room when not in use or unattended;

(2) Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

(3) Prevent dual operation of more than one radiation producing device in a treatment room, if applicable; and

(4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. This procedure must include:

a. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

b. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

c. The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(b) A copy of the procedures required by He-P 4035.75(a)(4) must be physically located at the unit console.

(c) A licensee shall post instructions at the unit console to inform the operator of:

(1) The location of the procedures required by He-P 4035.75(a)(4); and

(2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(d) A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as apropriate to the individual's assigned duties, in:

(1) The procedures identified in He-P 4035.75(a)(4); and

(2) The operating procedures for the unit.

(e) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(f) A licensee shall retain a record of individuals receiving instruction required by He-P 4035.75(d), in accordance with He-P 4035.103.

He-P 4035.76 Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

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(a) A licensee shall control access to the treatment room by a door at each entrance.

(b) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will:

(1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(2) Cause the source(s) to be shielded promptly when an entrance door is opened; and

(3) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

(c) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(d) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(e) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

(f) In addition to the requirements specified in He-P 4035.76(a) through He-P 4035.76(e), a licensee shall:

(1) For low dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units, require:

a. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

b. An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

(2) For high dose-rate remote afterloader units, require:

a. An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

b. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physcially present during continuation of all patient treatments involving the unit.

(3) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(4) Notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible, if the patient or human research subject has a medical emergency and, immediately, if the patient dies.

(g) A licensee shall have emergency response equipment available near each treatment room, to respond to a source that inadvertently:

(1) Remains in the unshielded position; or

(2) Lodges within the patient following completion of the treatment.

~~He-P 4035.44 Brachytherapy Sources Inventory.~~

~~(a) Each time brachytherapy sources are returned to an area of storage from an area of use, the licensee shall immediately count or otherwise verify the number returned to ensure that all sources taken from the storage area have been returned.~~

~~(b) A licensee shall make a record of brachytherapy source utilization which includes:~~

~~(1) The names of the individuals permitted to handle the sources;~~

~~(2) The number and activity of sources removed from storage, the room number of use or patient's or human research subject's name, the time and date they were removed from storage, the number and activity of sources in storage after the removal, and the initials of the individual who removed the sources from storage; and~~

~~(3) The number and activity of sources returned to storage, the room number of use or patient's or human research subject's name, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.~~

~~(c) Immediately after implanting sources in a patient or human research subject and immediately after removal of sources from a patient or human research subject, the licensee shall make a radiation survey of the patient or human research subject and the area of use to confirm that no sources have been misplaced.~~

~~(d) The licensee shall make a record of each survey.~~

~~(e) A licensee shall maintain the records required in He-P 4035.44(b) and (d) for 3 years.~~

~~Source: (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07~~

~~New: #8959, eff 8-7-07~~

He-P 4035.77 Dosimetry Equipment.

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(a) Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met:

(1) The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies, or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous four years; 18 to 30 months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated with the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must have indicated that the

calibration factor of the licensee's system had not changed by more than two percent. The licensee may not use the intercomparision result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

(b) The licensee shall have available for use a dosimetry system for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with He-P 4035.77(a). This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in He-P 4035.77(a).

(c) The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with He-P 4035.109.

~~He-P 4035.50 Safety Instruction for Sealed Source Teletherapy.~~

~~(a) A licensee shall post written instructions at the teletherapy unit console.~~

~~(b) The instructions required in He-P 4035.50(a) shall inform the operator of:~~

~~(1) The procedure to be followed to ensure that only the patient or human research subject is in the treatment room before turning the primary beam of radiation "on" to begin a treatment or after a door interlock interruption;~~

~~(2) The procedure to be followed if the operator is unable to turn the primary beam of radiation "off" with controls outside the treatment room or any other abnormal operation occurs; and~~

~~(3) The names and telephone numbers of the authorized users and Radiation Safety Officer to be immediately contacted if the teletherapy unit or console operates abnormally.~~

~~(c) A licensee shall provide instruction in the topics identified in He-P 4035.50(a) to all individuals who operate a teletherapy unit and shall provide appropriate refresher training to individuals at intervals not to exceed one year.~~

~~(d) A licensee shall maintain a record of individuals receiving instruction required by He-P 4035.50(c), a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for 3 years.~~

~~Source: (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07~~

New. #8959, eff 8-7-07

He-P 4035.51 Safety Precautions for Sealed Source Teletherapy.

(a) A licensee shall control access to the teletherapy room by a door at each entrance.

(b) A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that shall:

(1) Prevent the operator from turning the primary beam of radiation "on" unless each treatment room entrance door is closed;

(2) Turn the beam of radiation "off" immediately when an entrance door is opened; and

(3) Prevent the primary beam of radiation from being turned "on" following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.

(c) A licensee shall equip each entrance to the teletherapy room with a beam condition indicator light.

(d) A licensee shall have in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.

(e) Each radiation monitor shall be capable of providing visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source.

(f) The visible indicator of high radiation levels shall be observable by an individual entering the teletherapy room.

(g) Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit.

(h) A radiation monitor shall be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients or human research subjects.

(i) A licensee shall retain for 3 years a record of the check required He-P 4035.51(h) including the date of the check, notation that the monitor indicates when the source is exposed, and the initials of the individual who performed the check.

(j) If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism.

(k) The radiation monitoring instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use.

(l) The licensee shall keep a record of the instrument checks as described in He-P 4035.51(i).

(m) A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

(n) A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient or human research subject from the teletherapy unit console during irradiation.

Source. (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New: #8959, eff 8-7-07

He-P 4035.52 Possession of Survey Instrument for Use of Sealed Source Teletherapy.

(a) A licensee authorized to use radioactive material in a teletherapy unit shall possess either a portable radiation detection survey instrument capable of detecting dose rates over the range 1 microsievert (0.1 mrem) per hour to 1,000 microsieverts (100 mrems) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (1 mrem) per hour to 10 millisieverts (1,000 mrems) per hour.

(b) The survey instruments shall be operable and calibrated in accordance with He-P 4035.18.

Source. (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New: #8959, eff 8-7-07

He-P 4035.53 Dosimetry Equipment for Sealed Source Teletherapy.

(a) A licensee shall have a calibrated dosimetry system available for use.

(b) To satisfy the requirement in He-P 4035.53(a), one of the following two conditions shall be met:

(1) The system shall have been calibrated by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The calibration shall have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

(2) The system shall have been calibrated within the previous 4 years and 18 to 30

months after the calibration, intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine.

(c) The intercomparison meeting required in He-P 4035.53(b)(2) shall be sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine.

(d) The results of a calibration intercomparison meeting shall have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent.

(e) The licensee shall not use an intercomparison result to change the calibration factor.

(f) When intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt-60 source.

(g) When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.

(h) The licensee shall have available a dosimetry system for spot-check measurements.

(i) The system required in He-P 4035.53(g) may be compared with a system that has been calibrated in accordance with He-P 4035.53(a) through (g) which shall:

(1) Have been performed within the previous year and after each servicing that may have affected system calibration; and

(2) Be the same system used to meet the requirement in He-P 4035.53 (a) through (g).

(j) The licensee shall maintain a record of each calibration, intercomparison, and comparison for the duration of the license.

(k) For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by He-P 4035.53(a) through (i), the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine.

Source. (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New. #8959, eff 8-7-07

He-P 4035.~~54~~78 Full Calibration Measurements ~~for Use of Sealed Source Teletherapy~~on Teletherapy Units.

(a) ~~–~~A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit ~~as follows~~:

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions:

a. Whenever spot-check measurements indicate that the output differs by more than 5~~%~~ percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

b. ~~–~~Following replacement of the source or following reinstallation of the teletherapy unit in a new location; and

c. Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding one year.

(b) ~~–~~To satisfy the requirement of He-P 4035.~~54~~78(a), full calibration measurements shall include determination of:

(1) The output within +/-3 percent for the range of field sizes and for the distance or range of distances used for medical use;

(2) The coincidence of the radiation field and the field indicated by the light beam-localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer accuracy and linearity over the range of use;

(5) "On-off" error; and

(6) The accuracy of all distance measuring and localization devices in medical use.

(c) A licensee shall use the dosimetry system described in He-P 4035.~~53~~77(a) to measure the output for one set of exposure conditions~~, and the~~. The remaining radiation measurements required in He-P 4035.~~54~~78(b)(1) ~~shall then~~may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by He-P 4035.~~54~~78(a) in accordance with ~~the measurements required for annual calibration by "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40," Medical Physics, Vol. 21, No. 4, 1994, pp. 581-618.~~published protocols accepted by nationally recognized bodies.

(e) A licensee shall correct mathematically the outputs determined in He-P 4035.~~54~~78(b)(1) for physical decay for intervals not exceeding one month for cobalt-60 ~~and intervals not exceeding~~ , 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other radionuclides.

(f) Full calibration measurements required by He-P 4035.~~54~~78(a) and physical decay corrections required by He-P 4035.~~54~~78(e) shall be performed by ~~a teletherapy~~the authorized medical physicist. ~~physicist named on the licensee's license or authorized by a license issued by the NRC or an Agreement State to perform such services.~~

(g) A licensee shall maintain a record of each calibration ~~for the duration of the license~~in accordance with He-P 4035.110.

He-P 4035.79 Full Calibration Measurements on Remote Afterloader Units.

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(a) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions:

a. Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

b. Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

(4) At intervals not exceeding 1 year for low dose-rate afterloader units.

(b) To satisfy the requirement of He-P 4035.79(a), full calibration measurements must include, as applicable, determination of:

(1) The output within +/- 5 percent;

(2) Source positioning accuracy to within +/- 1 millimeter;

(3) Source retraction with backup battery upon power failure;

(4) Length of the source transfer tubes;

(5) Timer accuracy and linearity over the typical range of use;

(6) Length of the applicators; and

(7) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(c) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in He-P 4035.79(b), a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one quarter.

(d) A licensee shall use the dosimetry system described in He-P 4035.77(a) to measure the output.

(e) A licensee shall make full calibration measurements required by He-P 4035.79(a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(f) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with He-P 4035.79(a) through He-P 4035.79(e).

(g) A licensee shall mathematically correct the outputs determined in He-P 4035.79(b)(1) for physical decay at intervals consistent with 1 percent physical decay.

(h) Full calibration measurements required by He-P 4035.79(a) and physical decay corrections required by He-P 4035.79(g) must be performed by the authorized medical physicist.

(i) A licensee shall retain a record of each calibration in accordance with He-P 4035.110.

He-P 4035.80 Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units.

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(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions:

a. Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

b. Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

c. Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

(3) At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(b) To satisfy the requirements of He-P 4035.80(a), full calibration measurements must include determination of:

(1) The output within +/- 3 percent;

(2) Relative helmet factors;

(3) Isocenter coincidence;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error;

(6) Trunnion centricity;

(7) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(8) Helmet microswitches;

(9) Emergency timing circuits; and

(10) Stereotactic frames and localizing devices (trunnions).

(c) A licensee shall use the dosimetry system described in He-P 4035.77(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in He-P 4035.80(b)(1) may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by He-P 4035.80(a) in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in He-P 4035.80(b)(1) at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(f) Full calibration measurements required by He-P 4035.80(a) and physical decay corrections required by He-P 4035.80(e) must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with He-P 4035.110.

He-P 4035.~~55~~ 81 Periodic Spot-Checks for ~~Use of Sealed Source~~ Teletherapy Units.

(a) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit ~~at intervals not to exceed one month~~once in each calendar month that include the determination of~~.~~:

~~(b) To satisfy the requirement of He-P 4035.55(a), spot-checks shall include determination of:~~

(1) Timer constancy and timer linearity over the range of use;

(2) "On-off" error;

(3) The coincidence of the radiation field and the field indicated by the light beam-localizing device;

(4) The accuracy of all distance measuring and localization devices used for medical use;

(5) The output for ~~1~~ one typical set of operating conditions measured with the dosimetry systsem described in He-P 4035.77(b); and

(6) The difference between the measurement made in He-P 4035.~~55~~81(~~b~~a)(5) and the anticipated output, expressed as a percentage of the anticipated output (*i.e.*, the value obtained at last full calibration corrected mathematically for physical decay).

(~~c~~b) A licensee shall perform ~~spot-checks~~measurements required by He-P 4035.~~55~~81(a) in accordance with procedures established by the ~~teletherapy~~ authorized medical physicist. That individaul need not actually perform the spot-check measurements.

(~~d~~c) A licensee shall have the ~~teletherapy~~ authorized medical physicist review the results of each output spot-check within 15 days.

~~(e) The teletherapy~~ The authorized medical physicist shall promptly notify the licensee in writing of the results of each ~~output~~ spot-check.

~~(f) The licensee shall keep a copy of each written notification for 3 years.~~

(~~e~~d) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility ~~at intervals not to exceed one month~~once in each calendar month and after each source installation to assure proper operation of~~:~~:

~~(h) To satisfy the requirement of He-P 4035.55(g), safety spot-checks shall assure proper operation of:~~

(1) Electrical interlocks at each teletherapy room entrance;

(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel, and operation of the beam "on-off" mechanism);

(3) ~~Beam condition~~Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) Viewing and intercom systems;

(5) Treatment room doors from inside and outside the treatment room; and

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned "off".

(~~i~~c) ~~A licensee shall lock the control console in the "off" position if any door interlock malfunctions until the interlock system is repaired or unless use is specifically authorized by the DHHS/BRH.~~If the results of the checks required in He-P 4035.81(d) indicate the malfunction of any system, a license shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

~~(j) A licensee shall not use and shall promptly repair any system identified in He-P 4035.55(h) that is not operating properly.~~

(~~k~~f) A licensee shall maintain a record of each spot-check required by He-P 4035.~~55~~81(a) and He-P 4035.81(~~g~~d) ~~for 3 years~~in accordance with He-P 4035.111.

~~(l) The record shall include:~~

~~(1) The date of the spot-check;~~

~~(2) The manufacturer's name, model number, and serial number for both the teletherapy unit and source;~~

~~(3) The manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit;~~

~~(4) The measured timer accuracy;~~

~~(5) The calculated "on-off" error;~~

~~(6) A determination of the coincidence of the radiation field and the field indicated by the light beam-localizing device;~~

~~(7) The measured timer accuracy for a typical treatment time;~~

~~(8) The calculated "on-off" error, the estimated accuracy of each distance measuring or localization device;~~

~~(9) The difference between the anticipated output and the measured output;~~

~~(10) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors; and~~

~~(11) The signature of the individual who performed the periodic spot-check.~~

~~Source. (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07~~

~~New: #8959, eff 8-7-07~~

He-P 4035.82 Periodic Spot-Checks for Remote Afterloader Units.

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(a) A licensee authorized to use remote afterloader units for medical use shall perform spot-checks of each remote afterloader facility and on each unit:

(1) At the beginning of each day of use of a high dose-rate, medium dose-rate or pulsed dose-rate remote afterloader unit;

(2) Prior to each patient treatment with a low dose-rate remote afterloader unit; and

(3) After each source installation.

(b) The licensee shall have the authorized medical physicist establish written procedures for performing the spot-checks required in He-P 4035.82(a). The authorized medical physicist need not actually perform the spot-check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check.

(d) To satisfy the requirements of He-P 4035.82(a), spot-checks must, at a minimum, assure proper operation of:

(1) Electrical interlocks at each remote afterloader unit room entrance;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems in each high dose-rate, medium dose-rate and

pulsed dose-rate remote afterloader facility;

(4) Emergency response equipment;

(5) Radiation monitors used to indicate the source position;

(6) Timer accuracy;

(7) Clock (date and time) in the unit's computer; and

(8) Decayed source(s) activity in the unit's computer.

(e) If the results of the checks required in He-P 4035.82(d) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each check required by He-P 4035.82(d) in accordance with He-P 4035.112.

He-P 4035.83 Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.

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(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:

(1) Monthly;

(2) At the beginning of each day of use; and

(3) After each source installation.

(b) The licensee shall have the authorized medical physicist:

(1) Establish written procedures for performing the spot-checks required in He-P 4035.83(a); and

(2) Review the results of each spot-check required by He-P 4035.83(a)(1) within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements. The authorized medical physicist shall notify the licensee as soon as possible, in writing, of the results of the spot check.

(c) To satisfy the requirements of He-P 4035.83(a)(1), spot-checks must, at a minimum:

(1) Assure proper operation of:

a. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

b. Helmet microswitches;

c. Emergency timing circuits; and

d. Stereotactic frames and localizing devices (trunnions).

(2) Determine:

a. The output for one typical set of operating conditions measured with the dosimetry system described in He-P 4035.77(b);

b. The difference between the measurement made in He-P 4035.83(c)(2)a and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

c. Source output against computer calculation;

d. Timer accuracy and linearity over the range of use;

e. On-off error; and

f. Trunnion centricity.

(d) To satisfy the requirements of He-P 4035.83(a)(2) and He-P 4035.83(a)(3), spot-checks must assure proper operation of:

(1) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(2) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Timer termination;

(5) Radiation monitors used to indicate room exposures; and

(6) Emergency off buttons.

(e) A licensee shall arrange for prompt repair of any system identification in He-P 4035.83(c) that is not operating properly.

(f) If the results of the checks required in He-P 4035.83(d) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(g) A licensee shall retain a record of each check required by He-P 4035.83(c) and He-P 4035.83(d) in accordance with He-P 4035.113.

He-P4035.84 Additional Technical Requirements for Mobile Remote Afterloader Units.

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(a) A licensee providing mobile remote afterloader service shall:

(1) Check survey instruments for consistent response before medical use at each address of use or on each day of use, whichever is more frequent; and

(2) Account for all sources before departure from a client's address of use.

(b) In addition to the periodic spot-checks required by He-P 4035.82, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of:

(1) Electrical interlocks on treatment area access points;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Applicators, source transfer tubes, and transfer tube-applicator interfaces;

(5) Radiation monitors used to indicate room exposures;

(6) Source positioning (accuracy); and

(7) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

(c) In addition to the requirements for checks in He-P 4035.84(b), a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(d) If the results of the checks required in He-P 4035.84(b) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(e) A licensee shall retain a record of each check required by He-P 4035.84(b) in accordance with He-P 4035.114.

He-P 4035.~~56~~ 85 Radiation Surveys ~~for Teletherapy Facilities~~.

(a) In addition to the survey requirements in He-P 4022.01 of these regulations, a person licensed pursuant to Part He-P 4035 shall perform surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry.

(b) The licensee shall make the survey required by He-P 4035.85(a) at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(c) A licensee shall retain a record of the radiation surveys required by He-P 4035.85(a) in accordance with He-P 4035.115.

~~(a) Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by He-P 4035.49, the licensee shall perform radiation surveys with an operable radiation measurement survey instrument calibrated in accordance with He-P 4035.18 to verify that:~~

~~(1) The maximum and average radiation levels at one meter from the teletherapy source with the source in the "off" position and the collimators set for a normal treatment field do not exceed 100 microsieverts (10 mrems) per hour and 20 microsieverts (2 mrems) per hour, respectively; and~~

~~(2) With the teletherapy source in the "on" position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that:~~

~~a. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in He-P 4020.05; and~~

~~b. Radiation levels in unrestricted areas do not exceed the limits specified in He-P 4020.13.~~

~~(b) If the results of the surveys required in He-P 4035.56(a) indicate any radiation levels in excess of the respective limit specified in that paragraph, the licensee shall lock the control in the "off" position and not use the unit:~~

~~(1) Except as may be necessary to repair, replace, or test the teletherapy unit, the teletherapy unit shielding, or the treatment room shielding; or~~

~~(2) Until the licensee has received a specific exemption from the DHHS/BRH.~~

~~(c) A licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license.~~

~~(d) The record required in He-P 4035.56(c) shall include:~~

~~(1) The date of the measurements;~~

~~(2) The reason the survey is required;~~

~~(3) The manufacturer's name, model number and serial number of the teletherapy unit;~~

~~(4) The source, and the instrument used to measure radiation levels;~~

~~(5) Each dose rate measured around the teletherapy source while in the "off" position and the average of all measurements;~~

~~(6) A plan of the areas surrounding the treatment room that were surveyed;~~

~~(7) The measured dose rate at several points in each area expressed in microsieverts (mrems) per hour;~~

~~(8) The calculated maximum level of radiation over a period of one week for each restricted and unrestricted area; and~~

~~(9) The signature of the Radiation Safety Officer.~~

~~Source: (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07~~

~~New: #8959, eff 8-7-07~~

He-P 4035.86 Five-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units.

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(a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Agency, and Agreement State, a Licensing State or the Nuclear Regulatory Commission.

(c) A licensee shall keep a record of the inspection and servicing in accordance with He-P 4035.116.

He-P 4035.87 Therapy-Related Computer Systems. The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

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(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plot and graphic displays;

(d) The accuracy of the software used to determine radioactive source positions from radiographic images; and

(e) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

He-P 4035.88 Possession of Survey Instruments. A licensee authorized to use radioactive material in remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10 microsieverts (1 mrem) per hour to 10 millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with He-P 4035.35.

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He-P 4035.89 Records of Authority and Responsibilities for Radiation Protection Programs.

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(a) A licensee shall retain a record of actions taken by the licensee's management in accordance with He-P 4035.15(a) for 5 years. The record must include a summary of the actions taken and a signature of license management.

(b) The licensee shall retain a current copy of the authorities, duties and responsibilities of the Radiation Safety Officer as required by He-P 4035.15(d), and a signed copy of the Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by He-P 4035.15(b). The record must include the signature of the Radiation Safety Officer and licensee management.

(c) The minutes of each Radiation Safety Committee meeting held in accordance with He-P 4035.15(g) shall include:

(1) The date of the meeting;

(2) Members present;

(3) Members absent; and

(4) Summary of deliberations and discussions.

He-P 4035.90 Records of Radiation Protection Program Safety Changes. A licensee shall

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retain a record of each radiation protection program change made in accordance with He-P 4035.17(h) for 5 years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

He-P 4035.91 Records of Written Directives. A licensee shall retain a copy of each written directive as required by He-P 4035.20 for 3 years.

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He-P 4035.92 Records of Medical Events. A licensee shall retain a record of medical events reported in accordance with He-P 4035.117 for 3 years. The record must contain the licensee's name; names of the individuals involved; the Social Security Number or other identification number, if one has been assigned, of the individual who is the subject of the medical event; a brief description of the event; why it occurred; the effect, if any, on the individual; the actions, if any, taken, or planned, to prevent recurrence; and, whether the licensee notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

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He-P 4035.93 Records of Calibrations of Instruments Used to Measure the Activity of Unsealed Byproduct Material. A licensee shall maintain a record of instrument calibrations required by He-P 4035.34 for 3 years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

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He-P 4035.94 Records of Survey Instrument Calibrations. A licensee shall maintain a record of survey instrument calibrations required by He-P 4035.35 for 3 years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

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He-P 4035.95 Records of Dosages of Unsealed Byproduct Material for Medical Use. A licensee shall maintain a record of dosage determinations required by He-P 4035.36 for 3 years. The record must contain the radioactive drug; the patient's or human research subject's name or identification number if one has been assigned; prescribed dosage; the determined dosage, or a notation that the total activity is less than 1.1 megabecquerel (30 µCi); the date and time of the dosage determination; and the name of the individual who determined the dosage.

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He-P 4035.96 Records of Possession of Sealed Sources and Brachytherapy Sources. A licensee shall retain a record of the semi-annual physical inventory of sealed sources and brachytherapy sources required by He-P 4035.38(d) for 3 years. The inventory record must contain the model number of each source, and serial number if one has been assigned; the identity of each source radionuclide and its nominal activity; the location of each source; and the name of the individual who performed the inventory.

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He-P 4035.97 Records of Surveys for Ambient Radiation Exposure Rate. A licensee shall retain a record of each survey required by He-P 4035.41 for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

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He-P 4035.98 Records of the Release of Individuals Containing Radioactive Drugs or Implants Containing Radioactive Material.

(a) A licensee shall retain a record, signed by the authorized user, of the basis for authorizing the release of an individual, for 3 years after the date of release.

(b) A licensee shall retain a record, for 3 years after the date of release, that the instructions required by He-P 4035.42(b) were provided to a breastfeeding woman if the radiation dose to the infant or child from continued breastfeeding could result in a total effective dose equivalent exceeding 1 millisievert (0.1 rem).

He-P 4035.99 Records of Administrative and Technical Requirements that Apply to the Provision of Mobile Services.

(a) A licensee shall retain a copy of the letter(s) that permits the use of byproduct material at a client's address of use, as required by He-P 4035.09(b), for 3 years after the last provision of service.

(b) A licensee shall retain the record of each survey required by He-P 4035.43(f) for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

He-P 4035.100 Records of Decay-in-Storage. A licensee shall maintain records of the disposal of licensed materials, as required by He-P 4035.45, for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

He-P 4035.101 Records of Radionuclide Purity. A licensee shall maintain a record of the radionuclide contaminant concentration tests required by He-P 4035.50 for 3 years. The record must include, for each measured elution of radionuclide used to prepared a radioactive drug, the ratio of the measures expressed as kilobecquerel of contaminant per megabecquerel of desired radionuclide (micocuries/millicurie), or microgram of contaminant per megabecquerel of desired radionuclide (microgram/millicurie), the time and date of the measurement, and the name of the individual who made the measurement.

He-P 4035.102 Records of Training. A licensee shall maintain records of training required by He-P 4035.27 for 3 years after the last date an individual was authorized to act as a nuclear medicine technologist or radiation therapist at the licensee's facility.

He-P 4035.103 Records of Safety Instruction and Training. A licensee shall maintain a record of safety instructions and training required by He-P 4035.53, He-P 4035.61 and He-P 4035.75 for 3 years. The record must include a list of the topics covered, the date of the instruction or training, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

He-P 4035.104 Records of Radiation Surveys of Patients and Human Research Subjects. A licensee shall maintain a record of the surveys required by He-P 4035.59 and He-P 4035.72 for 3

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years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

He-P 4035.105 Records of Brachytherapy Source Inventory.

(a) A licensee shall maintain a record of brachytherapy source accountability required by He-P 4035.60 for 3 years.

(b) For temporary implants, the record must include:

(1) The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and

(2) The number and activity of sources not implanted, the time and date they were returned to storage, and the name of the individual who returned them to storage.

(c) For permanent implants, the record must include:

(1) The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

(2) The number and activity of sources returned to storage, the date they were returned to storage, and the name of the individual who returned them to storage; and

(3) The number and activity of sources permanently implanted in the patient or human research subject.

He-P 4035.106 Records of Calibration Measurements on Brachytherapy Sources. A licensee shall maintain a record of the calibrations on brachytherapy sources required by He-P 4035.63 for 3 years after the last use of the source. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source; the source output or activity; source positioning accuracy within applicators; and the signature of the authorized medical physicist.

He-P 4035.107 Records of Decay of Strontium-90 Sources for Ophthalmic Treatments. The licensee shall maintain a record of the activity of a strontium-90 source required by He-P 4035.63 for the life of the source. The record must include the date and initial activity of the source as determined under He-P 4035.63, and for each decay calculation, the date, and source activity and the signature of the authorized medical physicist.

He-P 4035.108 Records of Installation, Maintenance, Adjustment, and Repair. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by He-P 4035.74 for 3 years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

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He-P 4035.109 Records of Dosimetry Equipment.

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(a) A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment dose in accordance with He-P 4035.77 for the duration of the license.

(b) For each calibration, intercomparison, or comparison, the record must include:

(1) The date;

(2) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by He-P 4035.77(a) and He-P 4035.77(b);

(3) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

(4) The names of the individuals who performed the calibration, intercomparison, or comparison.

He-P 4035.110 Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery Full Calibrations.

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(a) A licensee shall maintain a record of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations required by He-P 4035.78, He-P 4035.79 and He-P 4035.80 for 3 years.

(b) The record must include:

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number for the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and instruments used to calibrate the unit;

(3) The results and assessments of the full calibrations;

(4) The results of the autoradiograph required for low dose-rate remote afterloader units; and

(5) The signature of the authorized medical physicist who performed the full calibration.

He-P 4035.111 Records of Periodic Spot-Checks for Teletherapy Units.

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(a) A licensee shall retain a record of each periodic spot-check for teletherapy units required by He-P 4035.78 for 3 years.

(b) The record must include:

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

(3) An assessment of timer linearity and constancy;

(4) The calculated on-off error;

(5) A determination of the coincidence of the radiation field and the field indicated by the light-beam localizing device;

(6) The determined accuracy of each distance measuring and localization device;

(7) The difference between the anticipated output and the measured output;

(8) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and

(9) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

He-P 4035.112 Records of Periodic Spot-Checks for Remote Afterloader Units.

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(a) A licensee shall retain a record of each spot-check for remote afterloader units required by He-P 4035.82 for 3 years.

(b) The record must include, as applicable:

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

(3) An assessment of timer accuracy;

(4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and

(5) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

He-P 4035.113 Records of Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.

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(a) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by He-P 4035.83 for 3 years.

(b) The record must include:

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

(3) An assessment of timer linearity and accuracy;

(4) The calculated on-off error;

(5) A determination of trunnion centricity;

(6) The difference between the anticipated output and the measured output;

(7) An assessment of source output against computer calculations;

(8) Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and the intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and

(9) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

He-P 4035.114 Records of Additional Technical Requirements for Mobile Remote Afterloader Units.

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(a) A licensee shall retain a record of each check for mobile remote afterloader units required by He-P 4035.84 for 3 years.

(b) The record must include:

(1) The date of the check;

(2) The manufacturer's name, model number, and serial number of the remote afterloader unit;

(3) Notations accounting for all sources before the licensee departs from a facility;

(4) Notations indicating the operability of each entrance door electrical interlock; radiation monitors, source exposure indicator lights, viewing and intercom system, applicators and source transfer tubes, and source positioning accuracy; and

(5) The signature of the individual who performed the check.

He-P 4035.115 Records of Surveys of Therapeutic Treatment Units.

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(a) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with He-P 4035.85 for the duration of use of the unit.

(b) The record must include:

(1) The date of the measurements;

(2) The manufacturer's name, model number, and serial number of the treatment unit, source, and instrument used to measure radiation levels;

(3) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

(4) The signature of the individual who performed the test.

He-P4035.116 Records of 5-Year Inspection for Teletherapy and Gamma Stereotactic Surgery Units.

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(a) A licensee shall maintain a record of the 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by He-P 4035.86 for the duration of use of the unit.

(b) The record must contain:

(1) The inspector's radioactive materials license number;

(2) The date of inspection;

(3) The manufacturer's name and model number and serial number of both the treatment unit and source;

(4) A list of components inspected and serviced, and the type of service; and

(5) The signature of the inspector.

He-P 4035.117 Reports and Notifications of Medical Events.

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(a) Other than events that result from intervention by a patient or human research subject, a licensee shall report any event in which the administration of byproduct material or radiation from

byproduct material results in:

(1) A dose that differs from the prescribed dose by more than 0.05 Sievert (5 rem) effective dose equivalent, 0.5 Sievert (50 rem) to an organ or tissue, or 0.5 Sievert (50 rem) shallow dose equivalent to the skin; and either

a. The total dose delivered differs from the prescribed dose by 20 percent or more;

b. The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

c. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

(2) A dose that exceeds 0.05 Sievert (5 rem) effective dose equivalent, 0.5 Sievert (50 rem) to an organ or tissue, or 0.5 Sievert (50 rem) shallow dose equivalent to the skin from any of the following:

a. An administration of a wrong radioactive drug;

b. An administration of a radioactive drug containing radioactive material by the wrong route of administration;

c. An administration of a dose or dosage to the wrong individual or human research subject;

d. An administration of a dose or dosage delivered by the wrong mode of treatment;

e. A leaking sealed source.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sievert (50 rem) to an organ or tissue and 50 percent of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

(b) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results, or will result in, unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(c) The licensee shall notify the Agency by telephone no later than the next calendar day after the discovery of the medical event.

(d) The licensee shall submit a written report to the Agency within 15 days after discovery of the medical event.

(1) The written report must include:

a. The licensee's name;

b. The name of the prescribing physician;

c. A brief description of the event;

d. Why the event occurred;

e. The effect, if any, on the individual(s) who received the administration;

f. Actions, if any, that have been taken, or are planned, to prevent recurrence;

g. Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and, if not, why not.

(2) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(e) The licensee shall provide notification of the medical event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

(g) A licensee shall retain a record of a medical event in accordance with He-P 4035.92. A copy of the record required under He-P 4035.92 shall be provided to the referring physician if other than the licensee, within 15 days after discovery of the medical event.

He-P 4035.118 Reports of Leaking Sources. A licensee shall file a report with the Agency within 5 days if a leakage test required by He-P 4035.38 reveals the presence of 185 Becquerel (0.005 μCi) or more of removable contamination. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the

results of the test; the date of the test; and the action taken.

He-P 4035.119 Reports of Patient Departure Prior to Authorized Release.

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(a) The licensee shall notify the Agency by telephone immediately upon discovery that a patient or human research subject has departed from the licensee's facility without authorization under He-P 4035.42(a).

(b) The licensee shall submit a written report to the Agency within 30 days after discovery of the unauthorized departure. The written report must include:

(1) The licensee's name;

(2) The date and time of the unauthorized departure;

(3) The projected date and time when release would have occurred;

(4) The address of the patient's or human research subject's home or anticipated destination following departure;

(5) The radionuclide, chemical and physical form and calculated activity at the time of release;

(6) The apparent reason(s) for the departure prior to authorized release; and

(7) A description of any changes in the licensee's patient release criteria or patient instructions that are designed to avoid a recurrence of such an event.

He-P 4035.120 Notification of Deceased Patients or Human Research Subjects Containing Byproduct Material.

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(a) The licensee shall notify the Agency by telephone immediately upon discovery that a patient or human research subject containing byproduct material has died, and it is possible that any individual could receive exposures in excess of He-P 4035.42(a)(1) of these regulations as a result of the deceased's body.

(b) The licensee shall submit a written report to the Agency within 30 days after discovery that the patient or human research subject referenced in He-P 4035.42(a)(1) or He-P 4035.42(e)(1) has died. The written report must include:

(1) The licensee's name;

(2) The date of death;

(3) The radionuclide, chemical and physical form and calculated activity at time of death; and

(4) The name(s) (or titles) and address(es) of known individual who might have received exposures exceeding 5 millisieverts (500 mrem).~~He-P 4035.61 Radiation Safety Officer Training. Except as provided in He-P 4035.62, an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in He-P 4035.08 shall:~~

~~(a) Be certified by the:~~

~~(1) American Board of Health Physics in Comprehensive Health Physics;~~

~~(2) American Board of Radiology;~~

~~(3) American Board of Nuclear Medicine;~~

~~(4) American Board of Science in Nuclear Medicine;~~

~~(5) The American Board of Medical Physicists in Radiation Oncology Physics;~~

~~(6) Board of Pharmaceutical Specialties in Nuclear Pharmacy;~~

~~(7) Royal College of Physicians and Surgeons of Canada in Nuclear Medicine;~~

~~(8) American Osteopathic Board of Radiology; or~~

~~(9) American Osteopathic Board of Nuclear Medicine;~~

~~(b) Meet the following requirements:~~

~~(1) Have had 200 hours of classroom and laboratory training covering:~~

~~a. Radiation physics and instrumentation;~~

~~b. Radiation protection;~~

~~c. Mathematics pertaining to the use and measurement of radioactivity;~~

~~d. Radiation biology; and~~

~~e. Radiopharmaceutical chemistry; and~~

~~(2) Have had one year of full-time experience in radiation safety at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on an DHHS/BRH, Agreement State, Licensing State, or U.S. Nuclear Regulatory Commission license that authorizes the medical use of radioactive material; or~~

(e) Be an authorized user for those radioactive material uses that come within the Radiation Safety Officer's responsibilities.

Source. (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New. #8959, eff 8-7-07

He-P 4035.62 Training for Experienced Radiation Safety Officer. An individual identified as a Radiation Safety Officer on an DHHS/BRH, Agreement State, Licensing State, or U.S. Nuclear Regulatory Commission license on October 1, 1986 who oversees only the use of radioactive material for which the licensee was authorized on that date need not comply with the training requirements of He-P 4035.61.

Source. (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New. #8959, eff 8-7-07

He-P 4035.63 Training for Uptake, Dilution, or Excretion Studies.

(a) Except as provided in He-P 4035.71 and He-P 4035.72, the licensee shall require the authorized user of a radiopharmaceutical listed in He-P 4035.29 to be a physician who:

(1) Is certified in:

a. Nuclear medicine by the American Board of Nuclear Medicine;

b. Diagnostic radiology by the American Board of Radiology;

c. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;

d. Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or

e. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(2) Has completed 40 hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, and 20 hours of supervised clinical experience as follows:

a. To satisfy the basic instruction requirement, 40 hours of classroom and laboratory instruction shall include:

1. Radiation physics and instrumentation;

2. Radiation protection;

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

4. Radiation biology; and

5. Radiopharmaceutical chemistry; and

b. To satisfy the requirement for 20 hours of supervised clinical experience, training must be under the supervision of an authorized user at a medical institution and shall include:

1. Examining patients or human research subjects and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;

2. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

3. Administering dosages to patients or human research subjects and using syringe radiation shields;

4. Collaborating with the authorized user in the interpretation of radionuclide test results; and

5. Patient or human research subject follow-up; or

(3) Has successfully completed a 6-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in He-P 4035.63(a)(2).

(b) Classroom and laboratory training in all the topics identified in He-P 4035.63(a)(2)a., which is not part of a residency program as in He-P 4035.63(a)(3), shall:

(1) Be obtained in a medical teaching institution; or

(2) Be approved by the Accreditation Council for Continuing Medical Education (ACCME) or the Committee on Postdoctoral Training of the American Osteopathic Association (CPTAOA).

(c) The clinical experience described in He-P 4035.63(a)(2)b. shall be supervised by a physician licensed for the full scope of diagnostic nuclear medicine procedures.

Source. (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New: #8959, eff 8-7-07

He-P 4035.64 Training for Imaging and Localization Studies.

(a) Except as provided in He-P 4035.71 and He-P 4035.72, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit specified in He-P 4035.32 to be a physician who:

(1) Is certified in:

a. Nuclear medicine by the American Board of Nuclear Medicine;

b. Diagnostic radiology by the American Board of Radiology;

c. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;

d. Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or

e. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(2) Has completed 200 hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, 500 hours of supervised work experience, and 500 hours of supervised clinical experience, as follows:

a. To satisfy the basic instruction requirement, 200 hours of classroom and laboratory training shall include:

1. Radiation physics and instrumentation;

2. Radiation protection;

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

4. Radiopharmaceutical chemistry; and

5. Radiation biology;

b. To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

2. Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

3. Calculating and safely preparing patient or human research subject dosages;

4. Using administrative controls to prevent the misadministration of radioactive material;

5. Using emergency procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

6. Eluting technetium-99m from generator systems, assaying and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and

c. To satisfy the requirement for 500 hours of supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

1. Examining patients or human research subjects and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;

2. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

3. Administering dosages to patients or human research subjects and using syringe radiation shields;

4. Collaborating with the authorized user in the interpretation of radionuclide test results; and

5. Patient or human research subject follow-up; or

(3) Has successfully completed a 6-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in He-P 4035.64(a)(2).

(b) Classroom and laboratory training in all the topics identified in He-P 4035.64(a)(2)a., which is not part of a residency program as in He-P 4035.64(a)(3), shall:

(1) Be obtained in a medical teaching institution; or

(2) Be approved by the Accreditation Council for Continuing Medical Education (ACCME) or the Committee on Postdoctoral Training of the American Osteopathic Association (CPTAOA).

(c) The clinical experience described in He-P 4035.64(a)(2)b. shall be supervised by a physician licensed for the full scope of diagnostic nuclear medicine procedures.

(d) The experience in He-P 4035.64(a)(2)a. and (a)(2)b. may be obtained concurrently.

Source. (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New: #8959, eff 8-7-07

~~He-P 4035.65 Training for Therapeutic Use of Radiopharmaceuticals. Except as provided in He-P 4035.71, the licensee shall require the authorized user of a radiopharmaceutical listed in He-P 4035.36 for therapy to be a physician who:~~

~~(a) Is certified in:~~

~~(1) Nuclear medicine by The American Board of Nuclear Medicine;~~

~~(2) Radiation oncology, therapeutic radiology, or radiology by The American Board of Radiology;~~

~~(3) Nuclear medicine or radiation oncology by the American Osteopathic Board of Radiology after 1984; or~~

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

~~(b) Has completed 80 hours of instruction in basic radionuclide handling techniques applicable to the use of therapeutic radiopharmaceuticals, and has had supervised clinical experience, as follows:~~

~~(1) To satisfy the requirement for instruction, 80 hours of classroom and laboratory training shall include:~~

~~a. Radiation physics and instrumentation;~~

~~b. Radiation protection;~~

~~c. Mathematics pertaining to the use and measurement of radioactivity; and~~

~~d. Radiation biology; and~~

~~(2) To satisfy the requirement for supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:~~

~~a. Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in ten individuals;~~

~~b. Use of soluble phosphorus-32 for the treatment of ascites, polycythemia vera, leukemia, or bone metastases in three individuals;~~

~~c. Use of iodine-131 for treatment of thyroid carcinoma in three individuals;~~

~~d. Use of colloidal chromic phosphorus-32 or of colloidal gold-198 for intracavitary treatment of malignant effusions in three individuals; and~~

e. Use of strontium-89 as strontium chloride for the treatment of pain associated with bone metastases in 3 individuals; or

(c) Has successfully completed a 6-month training program in nuclear medicine as part of a residency program that has been approved by the Accreditation Council for Graduate Medical Education (ACGME) which included classroom and laboratory training, work experience and supervised clinical experience and supervised clinical experience in all the topics identified in He-P 4035.65(b).

Source. (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New. #8959, eff 8-7-07

He-P 4035.66 Training for Therapeutic Use of Brachytherapy Sources.

(a) Except as provided in He-P 4035.71, the licensee shall require the authorized user using a brachytherapy source specified in He-P 4035.41 for therapy to be a physician who:

(1) Is certified in:

a. Radiology or therapeutic radiology by the American Board of Radiology;
b. Radiation oncology by the American Osteopathic Board of Radiology;

c. Radiology, with a specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

d. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(2) Is in the active practice of therapeutic radiology, has completed 200 hours of instruction in basic radionuclide handling techniques applicable to the therapeutic use of brachytherapy sources and 500 hours of supervised work experience, and a minimum of 3 years of supervised clinical experience, as follows:

a. To satisfy the requirement for instruction, 200 hours of classroom and laboratory training shall include:

1. Radiation physics and instrumentation;

2. Radiation protection;

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

4. Radiation biology;

b. To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

2. Checking survey meters for proper operation;

3. Preparing, implanting, and removing sealed sources;

4. Using administrative controls to prevent the misadministration of radioactive material; and

5. Using emergency procedures to control radioactive material;

c. To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution; and

d. The supervised clinical experience in (2)c. above shall include:

1. Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;

2. Selecting the proper brachytherapy sources, dose, and method of administration;

3. Calculating the dose; and

4. Post-administration follow-up and review of case histories in collaboration with the authorized user.

(b) Classroom and laboratory training in all the topics identified in He-P 4035.66(a)(2)a., which is not part of a residency program as in He-P 4035.66(c), shall:

(1) Be obtained in a medical teaching institution; or

(2) Be approved by the Accreditation Council for Continuing Medical Education (ACCME) or the Committee on Postdoctoral Training of the American Osteopathic Association (CPTAOA).

(c) The clinical experience described in He-P 4035.66(a)(2)b. shall be supervised by a physician licensed for the full scope of therapeutic nuclear medicine procedures.

Source. (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New. #8959, eff 8-7-07

He-P 4035.67 Training for Ophthalmic Use of Strontium-90.

(a) Except as provided in He-P 4035.71, the licensee shall require the authorized user using only strontium-90 for ophthalmic radiotherapy to be a physician who:

(1) Is certified in radiology or therapeutic radiology by the American Board of Radiology; or

(2) Is in the active practice of therapeutic radiology or ophthalmology, and has completed 24 hours of instruction in basic radionuclide handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy, as follows:

a. To satisfy the requirement for instruction, the classroom and laboratory training shall include:

1. Radiation physics and instrumentation;

2. Radiation protection;

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

4. Radiation biology; and

b. To satisfy the requirement for a period of supervised clinical training in ophthalmic radiotherapy, training shall be under the supervision of an authorized user at a medical institution and shall include the use of strontium-90 for the ophthalmic treatment of 5 individuals that includes:

1. Examination of each individual to be treated;

2. Calculation of the dose to be administered;

3. Administration of the dose; and

4. Follow-up and review of each individual's case history.

(b) Classroom and laboratory training in all the topics identified in He-P 4035.67(a)(2)a., shall:

(1) Be obtained in a medical teaching institution; or

(2) Be approved by the Accreditation Council for Continuing Medical Education (ACCME).

(c) The clinical experience described in He-P 4035.67(a)(2)b. shall be supervised by a physician licensed for the use of sealed sources in therapy.

Source. (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New: #8959, eff 8-7-07

He-P 4035.68 Training for Use of Sealed Sources for Diagnosis.

(a) Except as provided in He-P 4035.71 the licensee shall require the authorized user using a sealed source in a device specified in He-P 4035.39 to be a physician, dentist, or podiatrist who:

(1) Is certified in:

a. Radiology, diagnostic radiology with special competence in nuclear radiology, or therapeutic radiology by the American Board of Radiology;

b. Nuclear medicine by the American Board of Nuclear Medicine;

c. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

d. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(2) Has completed 8 hours of instruction in basic radionuclide handling techniques specifically applicable to the use of the device, including training in:

a. Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;

b. Radiation biology; and

c. Radiation protection and training in the use of the device for the purposes authorized by the license.

(b) Classroom and laboratory training in all the topics identified in He-P 4035.68(a)(2), shall:

(1) Be obtained in a medical teaching institution; or

(2) Be approved by the Accreditation Council for Continuing Medical Education (ACCME) or the committee on Postdoctoral training of the American Osteopathic Association (CPTAOA).

(c) The clinical experience shall be supervised by a physician, dentist, or podiatrist licensed to use the devices.

Source. (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New. #8959, eff 8-7-07

He-P 4035.69 Training for Teletherapy.

(a) Except as provided in He-P 4035.71, the licensee shall require the authorized user of a sealed source specified in He-P 4035.47 in a teletherapy unit to be a physician who:

(1) Is certified in:

a. Radiology or therapeutic radiology by the American Board of Radiology;

b. Radiation oncology by the American Osteopathic Board of Radiology;

c. Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

d. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(2) Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radionuclide techniques applicable to the use of a sealed source in a teletherapy unit, 500 hours of supervised work experience, and a minimum of 3 years of supervised clinical experience, as follows:

a. To satisfy the requirement for instruction, the classroom and laboratory training shall include:

1. Radiation physics and instrumentation;

2. Radiation protection;

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

4. Radiation biology;

b. To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at an institution and shall include:

1. Review of the full calibration measurements and periodic spot checks;

2. Preparing treatment plans and calculating treatment times;

3. Using administrative controls to prevent misadministrations;

4. Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and

5. Checking and using survey meters;

c. To satisfy the requirement for a period of supervised clinical experience, training shall include 1 year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution; and

d. The supervised clinical experience in (2)c. above shall include:

1. Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;

2. Selecting the proper dose and how it is to be administered;

3. Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses as warranted by patients' or human research subjects' reaction to radiation; and

4. Post-administration follow-up and review of case histories.

(b) The classroom and laboratory training in all the topics identified in He-P 4035.69(a)(2)a. shall:

(1) Be approved by the Accreditation Council for Continuing Medical Education (ACCME; or

(2) Be approved by the Committee on Postdoctoral Training of the American Osteopathic Association (CPTAOA).

(c) The supervised work and clinical experience described in He-P 4035.69(a)(2)b. and (a)(2)c. and d., respectively, shall be supervised by a physician licensed for teletherapy procedures.

(d) The experience in He-P 4035.69(a)(2)b. – c. may be obtained concurrently.

Source. (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New: #8959, eff 8-7-07

He-P 4035.70 Training for Teletherapy Physicist.

(a) The licensee shall require the teletherapy physicist to:

(1) Be certified by the American Board of Radiology in:

a. Therapeutic radiological physics;

b. Roentgen-ray and gamma-ray physics;

c. X-ray and radium physics; or

d. Radiological physics;

(2) Be certified by the American Board of Medical Physics in radiation oncology physics; or

(3) Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full-time training in therapeutic radiological physics and also one year of full-time work experience under the supervision of a teletherapy physicist at a medical institution.

(b) To meet the requirement in He-P 4035.70(a)(3), the individual shall have performed the tasks listed in He-P 4035.21, He-P 4035.54, and He-P 4035.56 under the supervision of a teletherapy physicist during the year of work experience.

Source. (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New. #8959, eff 8-7-07

He-P 4035.71 Training for Experienced Authorized Users. Practitioners of the healing arts identified as authorized users for the human use of radioactive material on an DHHS/BRH, NRC, Agreement State, or Licensing State license on April 1, 1997 who perform only those methods of use for which they were authorized on that date need not comply with the training requirements of He-P 4035.61 through He-P 4035.73.

Source. (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New. #8959, eff 8-7-07

He-P 4035.72 Physician Training in a Three Month Program. A physician who, before July 1, 1984, began a 3-month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program, shall be exempt from the requirements of He-P 4035.63 or He-P 4035.64.

Source. (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New. #8959, eff 8-7-07

He-P 4035.73 Recentness of Training. The training and experience specified in He-P 4035.61 through He-P 4035.70 shall have been obtained within the 7 years preceding the date of application or the individual shall have had continuing applicable experience since the required training and experience was completed.

Source. (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New. #8959, eff 8-7-07

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

(a) Has current board certification as nuclear pharmacist by the Board of Pharmaceutical Specialties; or

(b) Has met the following requirements:

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

a. Didactic 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 radioactive material for medical use; and

5. Radiation biology; and

b. Supervised 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 dose calibrators, 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 mistakes in the administration of radioactive material;

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

(2) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the training in (b)(1) has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

Source. (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New: #8959, eff 8-7-07

He-P 4035.75 Training for Experienced Nuclear Pharmacist.

(a) A licensee may apply for and shall receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist.

(b) A pharmacist who has completed a structured educational program as specified in He-P 4035.74(b) before December 2, 1994, and who is working in a nuclear pharmacy shall qualify as an experienced nuclear pharmacist.

(c) An experienced nuclear pharmacist shall not need to comply with the requirements on preceptor statement of He-P 4035.74(b)(2) and recentness of training in He-P 4035.73.

Source. (See Revision Note at part heading for He-P 4035) #6942, eff 2-1-99; ss by #8800, INTERIM, eff 2-1-07, EXPIRED: 7-31-07

New: #8959, eff 8-7-07