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

REVISION NOTE:

Doc. #6942, effective 2-1-99, repealed Parts He-P 2030, 2031, 2032, 2033, 2034, 2035, 2042 and 2093 relative to Radiation and Radioactive Material and adopted new rules to replace them and renumbered them as He-P 4030, 4031, 4032, 4033, 4034, 4035, 4093 and 4096.

He-P 4035.01 Purpose. This part shall establish requirements and provisions for the medical production, preparation, compounding and, use of byproduct material in the healing arts and for issuance of licenses authorizing the medical use of this material which provide for the radiation safety of workers, the general public, patients, and human research subjects.

He-P 4035.02 Scope.

(a) The requirements and provisions of this part shall be in addition to, and not in substitution for, other parts in this chapter.

(b) The requirements and provisions of He-P 4019 through He-P 4023, He-P 4030, He-P 4037, He-P 4070, He-P 4071, and the Nuclear Regulatory Commission requirements pursuant to 10 CFR 37, apply to applicants and licensees subject to He-P 4035 unless specifically exempted.

He-P 4035.03 Definitions.

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

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

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

(1) Meets the requirements in He-P 4035.70 and He-P 4035.73; or

(2) Is identified as an authorized medical physicist or teletherapy physicist on:

a. A specific medical use license issued by DHHS/RHS, or an agreement state, or the Nuclear Regulatory Commission;

b. A medical use permit issued by an Nuclear Regulatory Commission master material licensee;

c. A permit issued by DHHS/RHS, or an agreement state, or the Nuclear Regulatory Commission broad scope medical use licensee; or

d. A permit issued by a Nuclear Regulatory Commission master license broad scope medical use permittee.

(d) "Authorized nuclear pharmacist" means a person who is a "licensed pharmacist" as defined in RSA 318:1, VII, and who:

(1) Meets the requirements in He-P 4035.73, He-P 4035.74, and NH Pharmacy Board Administrative Rule (Ph) 405.03; or

(2) Is identified as an authorized nuclear pharmacist on:

a. A specific license issued by DHHS/RHS, or an agreement state, or the Nuclear Regulatory Commission that authorizes medical use, or the practice of nuclear pharmacy;

b. A permit issued by a Nuclear Regulatory Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

c. A permit issued by DHHS/RHS, or an agreement state, or the Nuclear Regulatory Commission broad scope medical use licensee, that authorizes medical use or the practice of nuclear pharmacy;

d. A permit issued by a Nuclear Regulatory Commission master material license broad scope medical use permittee, that authorizes medical use or the practice of nuclear pharmacy; or

(3) Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

(4) Is designated as an authorized nuclear pharmacist in accordance with the He-P 4035.74(b)(3), or by an equivalent agreement state regulation, or by the Nuclear Regulatory Commission pursuant to 10 CFR 32.72(b)(4).

(e) "Authorized user" means a physician, dentist, or podiatrist who:

(1) Meets the applicable requirements for an authorized user as listed in in He-P 4035.59, He-P 4035.63, He-P 4035.64, He-P 4035.65, He-P 4035.66, He-P 4035.68, or He-P 4035.69; He-P 4035.73, or

(2) Is identified as an authorized user on:

a. A DHHS/RHS, or an agreement state, or Nuclear Regulatory Commission license that authorizes the medical use of byproduct material;

b. A permit issued by a Nuclear Regulatory Commission master material licensee that is authorized to permit the medical use of byproduct material;

c. A permit issued by DHHS/RHS, or an agreement state, or the Nuclear Regulatory Commission specific licensee of broad scope who is authorized to permit the medical use of byproduct material; or

d. A permit issued by the Nuclear Regulatory Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

(f) "Brachytherapy" means a method of radiation therapy in which 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.

(g) "Brachytherapy source" means a radioactive 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 a few centimeters.

(h) "Client's address" means the area of use or a temporary job site for the purpose of providing mobile medical service in accordance with He-P 4035.12 and He-P 4035.26.

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

(j) "Dentist" means an individual licensed to practice dentistry in New Hampshire, another state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(k) "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 byproduct material, dosage, and route of administration, or in the case of sealed sources, the procedure.

(l) "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 point or surface where the dose is prescribed.

(m) "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 point or surface where the dose is prescribed.

(n) "Management" means the chief executive officer, or other individual having the authority to manage, direct, or administer the applicant or licensee's activities, or those persons' delegate or delegates.

(o) "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 implanted directly into the tissue volume.

(p) "Medical event" means an event that meets the criteria in He-P 4035.14(b).

(q) "Medical institution" means an organization in which more than one medical discipline is practiced.

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

(s) "Medium dose-rate remote afterloader" (MDR) means a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads) per hour, but less than or equal to 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

(t) "Mobile medical service" means the transportation of byproduct material to, and its medical use at, the client's address.

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

(v) "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.

(w) "Podiatrist" means an individual licensed to practice podiatry in New Hampshire, another state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(x) "Positron emission tomography (PET) radionuclide production facility" means a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

(y) “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, or a radiation safety officer.

(z) “Prescribed dosage” means the specific activity or range of activity of unsealed byproduct material as documented:

(1) In a written directive; or

(2) In accordance with the directions of the authorized user for procedures pursuant to He-P 4035.27 and He-P 4035.31.

(aa) “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;

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

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

(ab) “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.

(ac) “Radiation Safety Officer” means an individual who:

(1) Meets the requirements in He-P 4035.61 and He-P 4035.73; or

(2) Is identified as a radiation safety officer on a specific medical use license issued by DHHS/RHS, or an agreement state, or the Nuclear Regulatory Commission, or a medical use permit issued by a Nuclear Regulatory Commission master material licensee.

(ad) “Radiation therapist” means an individual who is an authorized user, or 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.

(ae) “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.

(af) “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.

(ag) “Sealed source” means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

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

(ai) “Stereotactic radiosurgery” means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

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

(ak) “Teletherapy” means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

(al) Teletherapy physicist” means an individual identified as the qualified medical physicist on a DHHS/RHS license.

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

(an) “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.

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

(ap) “Unit dosage” means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

(aq) “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 4035.13.

He-P 4035.04 License Required.

(a) No person shall manufacture, produce, prepare, compound, acquire, receive, possess, use, or transfer byproduct material for medical use except in accordance with a specific license issued by DHHS/RHS, or an agreement state, or the Nuclear Regulatory Commission, or as allowed in He-P 4035.04(b) or (c).

(b) A person shall receive, possess, use, or transfer byproduct material in accordance with He-P 4035 under the supervision of an authorized user as provided in He-P 4035.11 unless prohibited by license condition.

(c) A person shall prepare unsealed 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, unless prohibited by license condition.

(d) A person shall conduct research involving human subjects using byproduct materials specified on a license for the uses authorized on the license provided that:

(1) The research is conducted, funded, supported, or regulated by a federal agency which has implemented the Federal Policy for the Protection of Human Subjects; or

(2) The licensee has:

a. Applied for and received approval of a specific amendment to its license prior to conducting such research; and

b. Obtained informed consent from the human subjects and has obtained 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.

(e) Nothing in He-P 4035.04(d) relieves licensees from complying with other requirements in He-P 4035.

He-P 4035.05 License Amendments. A licensee possessing a license in accordance with He-P 4030 shall receive a license amendment before:

(a) Receiving, preparing, or using byproduct material for a method or type of medical use not permitted by the license issued under He-P 4035;

(b) Permitting anyone to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist, under the license;

(c) Changing a radiation safety officer;

(d) Permitting an authorized user or an individual qualified to be a radiation safety officer under He-P 4035.61 and He-P 4035.73 to:

(1) Function as a temporary radiation safety officer; and

(2) Perform the functions of a radiation safety officer in accordance with He-P 4035.10(c);

(e) Receiving byproduct material that is in excess of the licensed amount of radionuclide, or a different form, or a different radionuclide than is authorized on the license;

(f) Adding to or changing the areas of use or address or addresses of use identified in the application or on the license;

(g) Changing statements, representations, and procedures which are incorporated into the license;

(h) Revising procedures required by He-P 4035.50 and He-P 4035.55, if those revisions reduce radiation safety; and

(i) Releasing licensed facilities for unrestricted use;

(j) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in He-P 4030.15; or

(k) The licensee's mailing address changes.

He-P 4035.06 Notifications. A licensee shall notify the DHHS/RHS in writing within 30 days when an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist permanently discontinues performance of duties under the license, or has a name change, or has appointed a temporary radiation safety officer as provided in He-P 4035.10(c).

He-P 4035.07 ALARA Program.

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

(b) To satisfy the requirement of He-P 4035.07(a) above:

(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(c) above shall include summaries of the types and amounts of radioactive material used, occupational dose reports, and continuing education and training for all personnel who work with or in the vicinity of radioactive material.

(e) The purpose of the review required in He-P 4035.07(c) above shall ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive 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 4035.09(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 requirements are as follows:

(1) A licensee shall revise its ALARA program without DHHS/RHS approval if:

a. The revision does not require a license amendment;

b. The revision is in compliance with the rules 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 ALARA program change for 5 years. The record shall include:

a. A copy of the old and new procedures;

b. The effective date of the change; and

c. The signature of the licensee management that reviewed and approved the change.

He-P 4035.08 Radiation Safety Officer.

(a) A licensee shall appoint a radiation safety officer who, with the approval of DHHS/RHS, 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 byproduct material program.

(c) The radiation safety officer shall:

(1) Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, medical events, and other deviations from approved radiation safety practices, and implement corrective actions as necessary;

(2) Implement written policy and procedures for:

a. Authorizing the purchase of byproduct material;

b. Receiving and opening packages of byproduct material;

c. Storing byproduct material;

d. Keeping an inventory record of byproduct material;

e. Using byproduct material safely;

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

g. Performing periodic radiation surveys;

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

i. Disposing of byproduct material;

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

k. Keeping a copy of all records and reports required by DHHS/RHS, 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 DHHS/RHS 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 4035.09 Radiation Safety Committee.

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

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

(1) Membership shall consist of at least four 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 Radiation Safety Committee shall meet at least once each calendar quarter;

(3) To establish a quorum and to conduct business, one-half of the Radiation Safety 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(c); and

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

(c) To oversee the use of licensed material, the Radiation Safety 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 medical 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 DHHS/RHS 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 4035.10 Statement of Authorities and Responsibilities.

(a) In addition to the radiation protection program requirements of He-P 4020.04, a licensee's management shall approve in writing as set forth in He-P 4030.01(c) the following:

(1) Requests for a license application, renewal, amendment or other documentation before submittal to DHHS/RHS;

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

(3) Radiation protection program changes that do not require a license amendment and are permitted under He-P 4035.07(h);

(b) A licensee's management shall appoint a radiation safety officer, 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;

(c) For up to 10 days each year, a licensee may permit an authorized user, or an individual qualified to be a radiation safety officer under He-P 4035.61 and He-P 4035.71, to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer, as provided in He-P 4035.10(g), if the licensee takes the actions required in He-P 4035.10(b), (e), (g), and (h) and notifies DHHS/RHS in accordance with He-P 4035.05(d);

(d) A licensee may simultaneously appoint more than one temporary radiation safety officer in accordance with He-P 4035.10(c), if needed, to ensure that the licensee has a temporary radiation safety officer who satisfies the requirements to be a radiation safety officer for each of the different types of uses of byproduct material permitted by the license;

(e) A licensee shall establish the authority, duties, and responsibilities of the radiation safety officer in writing;

(f) Licensees that are authorized for two or more different types of uses of byproduct material under rules governing the uses of unsealed byproduct materials, manual brachytherapy, and photon emitting remote afterloader units, teletherapy units, and gamma stereotactic units shall establish a radiation safety committee to oversee all uses of byproduct material permitted by the license;

(g) 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.

(h) A licensee shall retain a record of actions taken under He-P 4035.10(a)-(c), He-P 4035.10(b), and He-P 4035.10(e). A license shall retain a record of actions for 5 years.

(1) The record shall include a summary of the actions taken and a signature of licensee management. The licensee shall retain a copy of authority, duties, and responsibilities of the radiation safety officer as required by He-P 4035.10(e);

(2) The record shall include a signed copy of each radiation safety officer's agreement to be responsible for implementing the radiation safety program, as required by He-P 4035.10(b) and (c), for the duration of the license; and

(3) The records shall include the signature of the radiation safety officer and the licensee management.

He-P 4035.11 Supervision.

(a) A licensee who 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 4035.04 shall:

(1) In addition to the requirements in He-P 4019.04, instruct the supervised individual in licensee's written radiation protection procedures, written directive procedures, He-P 4019 through He-P 4023, and the license conditions with respect to the use of byproduct material;

(2) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of byproduct material, written radiation protection procedures established by the licensee, written directive procedures, He-P 4019 through He-P 4023, and the license conditions with respect to the use of byproduct material;

(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 under state regulations and specifically trained to administer radionuclides or radiation to patients or human research subjects.

(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 4035.04(c), shall:

(1) In addition to the requirements in He-P 4019.04, instruct the supervised individual in the preparation of byproduct material for medical use, as appropriate to that individual's involvement with byproduct material; and;

(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 established by the licensee, the written directive procedures, the applicable sections of He-P 4019 through He-P 4023, and the license conditions; and

(3) Follow the written radiation safety and quality management procedures established by the licensee.

(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 4035.04(a) through (c) shall be responsible for the acts and omissions of the supervised individual.

He-P 4035.12 Mobile Medical Service Administrative Requirements.

(a) DHHS/RHS shall license mobile medical 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 medicine service shall be licensed by DHHS/RHS if the client receives or possesses byproduct material to be used by a mobile medical service.

(c) Mobile medical service licensees shall obtain a letter signed by the management of each client for which services are rendered that permits the use of byproduct material at the client's address and clearly delineates the authority and responsibility of the licensee and the client. Each letter shall be retained 3 years after the last provision of service.

(d) 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 location for use by the mobile medicine service.

(e) A mobile medical service shall not have 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 byproduct material.

(f) 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 medical service shall inform a responsible individual, such as a representative of management, 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 are being administered.

He-P 4035.13 Quality Management Program and Written Directives.

(a) Each licensee shall establish and maintain a written quality management program to provide assurance that byproduct material or radiation therefrom shall be administered as directed by the 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 shall be prepared as required in He-P 4035.13(b)(4) below;

(2) That, prior to each administration, the patient or human research subject's identity shall be 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, gamma stereotactic radiosurgery, and therapeutic treatment with radiation from byproduct material shall be in accordance with the respective written directives;

(4) That each administration shall be in accordance with the written directive. The written directive shall be dated and signed by an authorized user. The written directive shall contain the patient or human research subject's name and the following information:

a. For any administration of quantities greater than 1.11 megabecquerel (30 microcuries) of sodium iodide I-131: the dosage;

b. For an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;

c. For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

d. For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

e. For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

f. For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

1. Before implantation: treatment site, the radionuclide, and dose; and

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

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

(6) For any administration requiring a written directive that the licensee shall:

a. Develop, implement, and maintain written procedures to provide high confidence that the patient's or human research subject's identity is verified before each administration; and each administration is in accordance with the written directive;

b. Verify the identity of the individual, the administration is in accordance with the treatment plan, if applicable, and the written directive;

c. Check both manual and computer-generated dose calculations;

d. Verify that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by He-P 4035.47; and

e. Retain a copy of the procedures for the duration of the license.

(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 dosage of unsealed byproduct material, 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(d) would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive shall be documented immediately in the patient's record and a written directive shall be signed by the authorized user 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 medical events 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(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 written directive as required in He-P 4035.13(b)(4) 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 DHHS/RHS a quality management program as part of the application for a license and implement the program upon issuance of the license by DHHS/RHS.

(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 DHHS/RHS.

He-P 4035.14 Records, Notifications, and Reports of Medical Events.

(a) For a medical event, the licensee shall:

(1) Notify DHHS/RHS by telephone no later than 24 hours after discovery of the medical event;

(2) Submit a written report to DHHS/RHS within 15 days after discovery of the medical event:

a. The written report 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, if any, on the patient or human research subject;

6. What improvements are needed to prevent recurrence;

7. Actions taken to prevent recurrence;

8. Certification that the licensee notified the patient or human research subject, or the patient's responsible relative or guardian, and if not, why not; and

9. 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's, or human research subject's responsible relative or guardian, of the medical event 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 medical event, because of any delay in notification; and

(6) Within 15 days after discovery of the medical event furnish a statement of whether the patient or human research subject was notified that a written report to the patient or human research subject by sending:

a. A copy of the report that was submitted to DHHS/RHS; 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 DHHS/RHS can be obtained from the licensee.

(7) Send copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event. The annotated report shall include:

a. Name of the individual who is the subject of the event; and

b. Identification number or if no other identification number is available, the social security number of the individual who is the subject of the event.

(b) Each licensee shall report any medical event to DHHS/RHS, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in:

(1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage 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

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 containing byproduct material;

b. An administration of a radioactive drug containing byproduct 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; or

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 the skin or an organ or tissue and 50 percent or more 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); or

(4) An 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 record required in He-P 4035.14(b) shall contain:

(1) The names of all individuals involved;

(2) The patient or human research subject's social security number or identification number if one has been assigned;

(3) A brief description of the medical event, why it occurred, the effect on the patient or human research subject;

(4) What improvements are needed to prevent recurrence; and

(5) The actions taken to prevent recurrence.

(d) Aside from the notification requirement, nothing in He-P 4035.14(a) through (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.

(e) Each licensee shall retain a record of each medical event for 5 years.

He-P 4035.15 Suppliers for Sealed Sources or Devices for Medical Use. A licensee shall use for medical use only:

(a) Sealed sources, or devices 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-P 4032.06, or He-P 4032.07 or the equivalent regulations of an agreement state, or the Nuclear Regulatory Commission; and

(b) Sealed sources, or devices non-commercially transferred from a DHHS/RHS licensee, or an agreement state medical use licensee, or a Nuclear Regulatory Commission Part 35 licensee; and

(c) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to He-P 4030, or the equivalent regulations of another agreement state, or the Nuclear Regulatory Commission.

He-P 4035.16 Quality Control of Diagnostic Equipment.

(a) Each licensee shall establish written quality control procedures for all diagnostic equipment used for radionuclide studies.

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

(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) For direct measurements performed in accordance with He-P 4035.19, a medical use licensee shall possess and use instrumentation to measure the activity of unsealed byproduct materials before it is administered to each patient or human research subject.

(b) A licensee shall calibrate the instrumentation required in He-P 4035.17(a) in accordance with nationally recognized standards or the manufacturer's instructions.

(c) A licensee shall retain a record of each instrument calibration for 3 years. The records shall include:

(1) The model and serial number of the instrument;

(2) The date of the calibration;

(3) The results of the calibration; and

(4) The name of the individual who performed the calibration.

(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 microcuries) 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 370 kilobecquerels (10 microcuries) for radium-226 and 1.85 megabecquerels (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 370 kilobecquerels (10 microcuries) 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 370 kilobecquerels (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) above 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 name of the individual who performed the test.

He-P 4035.18 Calibration of Survey Instruments.

(a) A licensee shall calibrate the survey instruments used to show compliance with He-P 4020 before first use, at intervals not to exceed 12 months, and following repair that affects the calibration.

(b) To satisfy the requirements of He-P 4035.18(a), the licensee shall:

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

(2) Calibrate 2 separated readings on each scale or decade that will be used to show compliance; and

(3) Clearly mark the date of calibration on the instrument.

(c) To satisfy the requirements of He-P 4035.18(b), the licensee shall use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is less 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(a) for 3 years.

(f) Each calibration record shall include:

(1) The model and serial number of the instrument;

(2) The date of the calibration;

(3) The results of the calibration; and

(4) The name of the individual who performed the calibration.

(g) To meet the requirements of He-P 4035.18(a) – (c), the licensee may obtain the services of individuals licensed by DHHS/RHS, or an agreement state, or the Nuclear Regulatory Commission to perform calibrations of survey instruments.

He-P 4035.19 Assay of Dosages of Unsealed Byproduct Material for Medical Use. A licensee shall meet the following requirements for determination of dosages of unsealed byproduct material:

(a) A licensee shall determine and record the activity of each dosage prior to medical use;

(b) For a unit dosage, this determination shall be made by:

(1) Direct measurement of radioactivity; or

(2) A decay correction, based on the activity or activity concentration determined by:

a. A manufacturer or preparer licensed under He-P 4032.05, or the equivalent agreement state requirements, or the Nuclear Regulatory Commission;

b. A DHHS/RHS, or an agreement state or a Nuclear Regulatory Commission 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

c. A PET radioactive drug producer licensed under He-P 4032.05, an equivalent agreement state, or Nuclear Regulatory Commission requirements;

(c) For other than unit dosages, this determination shall be made by:

(1) Direct measurement of radioactivity; and either

(2) Combination of measurement of radioactivity and mathematical calculations; or

(3) Combination of volumetric measurements and mathematical calculations, based on the measurement made by:

a. A manufacturer or preparer licensed under He-P 4032.05, or an equivalent agreement state, or the Nuclear Regulatory Commission requirements; or

b. A PET radioactive drug producer licensed under He-P 4032.05, an equivalent agreement state, or Nuclear Regulatory Commission requirements;

(d) Unless otherwise directed by the authorized user, a licensee shall not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent; and

(e) A licensee shall retain a record of the dosage determination required by He-P 4035.19 for 3 years. The record shall include:

(1) The radiopharmaceutical;

(2) The patient's or human research subject's name, or identification number if one has been assigned;

(3) The prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 megabecquerels (30 microcuries);

(4) The date and time of the dosage determination; and

(5) The name of the individual who determined the dosage.

He-P 4035.20 Authorization for Calibration, Transmission, and Reference Sources. Any person authorized by He-P 4035.04 for medical use of byproduct material may receive, possess, and use the following byproduct material for check, calibration, transmission, and reference use:

(a) Sealed sources that do not exceed 1.11 gigabecquerels (30 millicuries) each that are:

(1) Manufactured and distributed by persons specifically licensed pursuant to He-P 4032, or equivalent provisions of an agreement state, or the Nuclear Regulatory Commission; or

(2) Redistributed by persons specifically licensed to redistribute the sealed sources manufactured and distributed by a person licensed pursuant to He-P 4032, or equivalent provisions of an agreement state, or the Nuclear Regulatory Commission;

(b) Any byproduct material with a half-life of 120 days or less in individual amounts not to exceed 555 megabecquerels (15 millicuries);

(c) Any byproduct material with a half-life greater than 120 days in individual amounts not to exceed 7.4 megabecquerels (200 microcuries) each or 1000 times the quantities listed in He-P 4092.01; and

(d) Technetium-99m in individual amounts as needed.

He-P 4035.21 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 DHHS/RHS; 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 ensure 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 DHHS/RHS, or another agreement state or the Nuclear Regulatory Commission in the Sealed Source and Device Registry.

(c) To satisfy the leak test requirements of He-P 4035.21(b), the licensee shall ensure that:

(1) Leak tests are capable of detecting the presence of 185 becquerels (0.005 microcurie) of radioactive material on the test sample;

(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.

(d) A licensee shall retain leak test records for 3 years.

(e) The leak test records shall contain:

(1) The model number;

(2) Serial number, if assigned, of each source tested;

(3) The identity of each source radionuclide;

(4) The estimated activity of each source radionuclide;

(5) The measured activity of each test sample expressed in becquerels (microcuries);

(6) The date of the test; and

(7) The name of the individual who performed the test.

(f) If the leak test reveals the presence of 185 becquerels (0.005 microcurie) 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 4023; and

(2) File a report with DHHS/RHS within 5 days of receiving the leak test results describing the equipment involved, the test results, and the action taken.

(g) A licensee:

(1) Shall not be required to perform a leak test on the following sources:

a. Sources containing only byproduct material with a half-life of less than 30 days;

b. Sources containing only byproduct material as a gas;

c. Sources containing 3.7 megabecquerels (100 microcuries) or less of beta or gamma-emitting material or 370 kilobecquerels (10 microcuries) or less of alpha-emitting material;

d. Seeds of iridium-192 encased in nylon ribbon; and

e. Sources stored and not being used; but

(2) Shall test each such source in (g)(1) above for leakage before any use or transfer unless it has been tested for leakage within 6 months before the date of use or transfer.

(h) A licensee in possession of a sealed source or brachytherapy source, except for gamma stereotactic radiosurgery sources, shall conduct a physical inventory of all such sources in its possession at intervals not to exceed 6 months.

(i) The licensee shall retain each sealed source inventory record for 3 years.

(j) The sealed source inventory records shall contain:

(1) The model number of each source;

(2) The serial number, if one has been assigned;

(3) The identity of each source radionuclide;

(4) The estimated activity of each source radionuclide;

(5) The location of each source;

(6) The date of the inventory; and

(7) The name of the individual who performed the inventory.

(k) A licensee in possession of a sealed source or brachytherapy source shall survey with a radiation survey instrument at intervals not to exceed 3 months all areas where such sources are stored.

(l) The survey required in He-P 4035.21(k) shall not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

(m) A licensee shall retain a record of each survey required in He-P 4035.21(k) for 3 years.

(n) The record required in He-P 4035.21(m) above shall include:

(1) The date of the survey;

(2) A sketch of each area that was surveyed;

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

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

(5) The name of the individual who performed the survey.

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He-P 4035.23 Syringe and Vial Shields and Labels.

(a) Each syringe and vial that contains unsealed byproduct material shall be labeled to identify the radioactive drug.

(b) Each syringe shield and vial shield shall also be labeled unless the label on the syringe or vial is visible when shielded.

He-P 4035.24 Surveys for Ambient Radiation Exposure Rate.

(a) In addition to the surveys required by He-P 4021, a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where unsealed byproduct material requiring a written directive are prepared for use or administered.

(b) A licensee shall not need to perform the surveys required by He-P 4035.24(a) above in the area(s) where patients or human research subjects are confined when they cannot be released under He-P 4035.25.

(c) A licensee shall retain a record of each survey required by He-P 4035.24(a) for 3 years.

(d) The survey record required in He-P 4035.24(a) shall include:

(1) The date of the survey;

(2) A sketch of each area surveyed;

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

(4) The name of the individual who performed the survey.

He-P 4035.25 Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material.

(a) A licensee shall authorize the release from its control any individual who has been administered unsealed byproduct material if:

(1) The total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem); or

(2) The calculated doses, based on methods and tables of activities described in NUREG-1556 (Vol. 9), “Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Medical Use Licenses” show that the released individual is not likely to cause doses exceeding 5 millisieverts (0.5 rem).

(b) A licensee shall provide instructions to the released individual, or the individual's parent or guardian, instructions, including written instructions, on actions recommended to maintain doses as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 millisievert (0.1 rem).

(c) If the total effective dose equivalent to a nursing infant or child could exceed 1 millisievert (0.1 rem), assuming there are no interruption of breast-feeding, the instructions shall also include:

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

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

(d) A licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with He-P 4035.25(f)(1).

(e) The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with He-P 4035.25(f)(2).

(f) Records of the released individuals containing unsealed byproduct material or implants containing byproduct material:

(1) A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with He-P 4035.25, if the total effective dose equivalent is calculated by:

a. Using the retained activity rather than the activity administered;

b. Using an occupancy factor less than 0.25 at 1 meter;

c. Using the biological or effective half-life; or

d. Considering the shielding by tissue.

(2) A licensee shall retain a record that the instructions required by He-P 4035.25(b) and (c) were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 millisieverts (0.5 rem); and

(3) The records required by He-P 4035.25(f)(1) and (f)(2) above shall be retained for 3 years after the date of release of the individual.

He-P 4035.26 Provision of Mobile Medical Service.

(a) A licensee providing mobile medical service shall:

(1) Obtain a letter signed by the management of each client for which services are rendered that permits the use of byproduct material at the client’s address and clearly delineates the authority and responsibility of the licensee and the client;

(2) Check the 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 required by He-P 4035.26 shall include a constancy check;

(3) Check the survey instruments for proper operation with a dedicated check source before use at each client’s address; and

(4) Before leaving a client's address, complete a survey all areas of use to ensure compliance with the requirements of He-P 4020 through He-P 4022.

(b) A mobile medical service shall not have byproduct material delivered from the manufacturer or the distributor to the client's address 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.

(c) A licensee providing mobile medical services shall retain a copy of the letter required in He-P 4035.26(a)(1) and the record of each survey required in He-P 4035.26(a)(4) for 3 years. The records shall include:

(1) The copy of the letter that clearly delineates the authority and responsibility of the licensee and the client; and

(2) For each survey done, the following:

a. The date of the survey;

b. The results of the survey;

c. The instrument used to make the survey; and

d. The name of the individual who performed the survey.

He-P 4035.27 Use of Unsealed Byproduct Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive is Not Required.

(a) Except for quantities that require a written directive under He-P 4035.13(b)(4), a licensee may use any unsealed byproduct material prepared for medical use for uptake, dilution, or excretion studies that is:

(1) Obtained from:

a. A manufacturer or preparer licensed under He-P 4032.06, or an equivalent agreement state, or the Nuclear Regulatory Commission requirements;

b. A PET radioactive drug producer licensed under He-P 4030.10(p), or an equivalent agreement state, or the Nuclear Regulatory Commission requirements.

(2) Prepared by, excluding production of PET radionuclides:

a. An authorized nuclear pharmacist;

b. A physician who is an authorized user and who meets the requirements specified in He-P 4035.64, or He-P 4035.65 and He-P 4035.64(c)(1)b.7;

c. An individual under the supervision, as specified in He-P 4035.11, of the authorized nuclear pharmacist in He-P 4035.27(a)(2)a. or the physician who is an authorized user in He-P 4035.27(a)(2)b.; or

(3) Obtained from and prepared by a DHHS/RHS, or an agreement state, or the Nuclear Regulatory Commission 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

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

He-P 4035.28 Decay-In-Storage.

(a) A licensee may hold byproduct material for decay-in-storage if the material has a physical half-life of less than or equal to 120 days.

(b) Before disposal without regard to its activity, a licensee shall hold byproduct material for decay-in-storage and shall be exempt from the waste disposal requirements of He-P 4023 if the licensee:

(1) Monitors byproduct material at the surface before disposal 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;

(2) Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers; and

(3) Manages as biomedical waste after they have been released from the licensee.

(c) For licensed material disposed in accordance with He-P 4035.28(b), the licensee shall retain a record of each disposal for 3 years.

(d) The disposal record shall include:

(1) The date of the disposal;

(2) The date on which the byproduct material was placed in storage;

(3) The model and serial number of the survey instrument used;

(4) The background radiation level;

(5) The radiation level measured at the surface of each waste container; and

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

He-P 4035.29 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 which is not specifically addressed in He-P 4035 if:

(a) The applicant or licensee has submitted the information required by He-P 4030; and

(b) The applicant or licensee has received written approval from DHHS/RHS in a license or license amendment and uses the material in accordance with the regulations and specific conditions DHHS/RHS considers necessary for the medical use of the material.

He-P 4035.30 RESERVED

He-P 4035.31 Use of Unsealed Byproduct Material for Imaging and Localization Studies for Which a Written Directive Is Not Required. Except for quantities that require a written directive under He-P 4035.13(b)(4), a licensee may use any unsealed byproduct material prepared for medical use for imaging and localization studies that is:

(a) Obtained from:

(1) A manufacturer or preparer licensed under He-P 4032.05, equivalent agreement state, or Nuclear Regulatory Commission requirements; or

(2) A PET radioactive drug producer licensed under He-P 4032.05(a), equivalent agreement state, or Nuclear Regulatory Commission requirements; or

(b) Prepared by, excluding production of PET radionuclides:

(1) An authorized nuclear pharmacist;

(2) An authorized user physician who meets the requirements of He-P 4035.64 or He-P 4035.64(c)(1)b.7 and He-P 4035.65; or

(3) An individual under the supervision, as specified in He-P 4035.11, of the authorized nuclear pharmacist in He-P 4035.31(b)(1) or the physician who is an authorized user in He-P 4035.31(b)(2);

(c) Obtained from and prepared by DHHS/RHS, another agreement state, or a Nuclear Regulatory Commission 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 for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

He-P 4035.32 Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations.

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

(1) More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m); or

(2) More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride); or more than 0.2 microcurie of strontium-85 per megabequerel of rubidium-82 chloride injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82 chloride).

(b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with He-P 4035.32(a).

(c) A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with He-P 4035.32(a).

(d) If a licensee is required to measure the molybdenum-99 concentration or strontium-82 and strontium-85 concentrations, the licensee shall retain a record of each measurement. A licensee shall maintain the record for 3 years. The record shall include:

(1) For each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (or microcuries of molybdenum per millicurie of technetium), the time and date of the measurement, and the name of the individual who made the measurement; or

(2) For each measured elution of rubidium-82, the ratio of the measures expressed as kilobecquerel of strontium-82 per megabecquerel of rubidium-82 (or microcuries of strontium-82 per millicurie of rubidium) and kilobecquerel of strontium-85 per megabecquerel of rubidium-82 (or microcuries of strontium-85 per millicurie of rubidium), the time and date of the measurement, and the name of the individual who made the measurement.

He-P 4035.33 Control of Aerosols and Gases.

(a) A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed in He-P 4020.05 and He-P 4020.13.

(b) The system in (a) above 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.

(c) A licensee shall only administer radioactive gases in rooms that are at negative pressure with respect to surrounding rooms.

(d) Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in He-P 4020.05.

(e) The calculation required in He-P 4035.33(d) shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

(f) A licensee shall post the time calculated in He-P 4035.33(d) and (e) at the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.

(g) A licensee shall check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed six months.

(h) Records of the checks and measurements required in He-P 4035.33(g) shall be maintained for 3 years.

(i) A copy of the calculations required in He-P 4035.33(d) and (e) shall be recorded and retained for the duration of the license.

He-P 4035.34 RESERVED

He-P 4035.35 Use of Unsealed Byproduct Material—Written Directive Required. A licensee shall use any unsealed byproduct material prepared for medical use and for which a written directive is required that is:

(a) Obtained from one of the following:

(1) A manufacturer or preparer licensed under He-P 4032.06, or the requirements of an equivalent agreement state, or the Nuclear Regulatory Commission; or

(2) A PET radioactive drug producer licensed under He-P 4030.07(k), or an equivalent agreement state, or the Nuclear Regulatory Commission requirements; or

(b) Excluding production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified under He-P 4035.64 or He-P 4035.65; or

(3) An individual under the supervision, as specified in He-P 4035.11, of the authorized nuclear pharmacist in He-P 4035.35(b)(1) or the physician who is an authorized user in He-P 4035.35(b)(2); or

(c) Obtained from and prepared by a DHHS/RHS licensee, or an equivalent agreement state, or a Nuclear Regulatory Commission licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Is prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

He-P 4035.36 Safety Instruction for Use of Unsealed Byproduct Material—Written Directive Required.

(a) A licensee shall provide oral and written radiation safety instruction for all personnel caring for patients or human research subjects who cannot be released under He-P 4035.25.

(b) Refresher training shall be provided at intervals not to exceed 1 year.

(c) To satisfy the requirements of He-P 4035.36(a), the instruction shall describe the licensee's procedures for:

(1) Patient or human research subject control;

(2) Visitor control, including:

a. Routine visitation to hospitalized individuals in accordance with He-P 4020.13(a)(1); and

b. Visitation authorized in accordance with He-P 4020.13(c);

(3) Contamination control;

(4) Waste control;

(5) Notification of the radiation safety officer, or his or her designee, and an authorized user in case of the patient's or human research subject's death or medical emergency; and

(6) Training, which shall be commensurate with the duties of the personnel, 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 DHHS/RHS for 3 years.

He-P 4035.37 Safety Precautions for Use of Unsealed Byproduct Material—Written Directive Required.

(a) For each patient or human research subject who cannot be released under He-P 4035.25, a licensee shall:

(1) Provide a private room, or share with another individual who also cannot be released under He-P 4035.25, with a private sanitary facility;

(2) Post the patient's or human research subject's door with a "Caution: Radioactive Material" sign and note on the door or on 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;

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

(b) The radiation safety officer, or his or her designee, and an authorized user shall be notified immediately if the patient or human research subject dies or has a medical emergency.

He-P 4035.38 Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child.

(a) A licensee shall report any dose to an embryo/fetus, that is greater than 50 millisieverts (5 rem) dose equivalent that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

(b) A license shall report any dose to a nursing child that is a result of an administration of byproduct material to a breast-feeding individual that:

(1) Is greater than 50 millisieverts (5 rem) total effective dose equivalent; or

(2) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(c) The licensee shall notify by telephone DHHS/RHS no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in He-P 4035.38(a) or He-P 4035.38(b).

(d) The licensee shall submit a written report to DHHS/RHS within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in He-P 4035.38(a) or He-P 4035.38(b). The written report shall include:

(1) The licensee's name;

(2) The name of the prescribing physician;

(3) A brief description of the event;

(4) Why the event occurred;

(5) The effect, if any, on the embryo/fetus or the nursing child;

(6) What actions, if any, have been taken or are planned to prevent recurrence;

(7) Certification that the licensee notified the pregnant individual or mother (or the mother's child's responsible relative or guardian), and if not, why not; and

(8) The report shall not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(e) The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under He-P 4035.38(a) or He-P 4035.38(b), unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee shall:

(1) Not be required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter;

(2) Not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification;

(3) Notify the mother's or child's responsible relative or guardian instead of the mother;

(4) Inform the mother, or the mother's or child's responsible relative or guardian, if a verbal notification is made, that a written description of the event can be obtained from the licensee upon request; and

(5) Provide such a written description if requested.

(f) In the report, a licensee shall:

(1) Annotate a copy of the report provided to DHHS/RHS with the following:

a. Name of the pregnant individual or the nursing child who is the subject of the event; and

b. Identification number or if no other identification number is available, the social security number of the individual who is the subject of the event.; and

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

He-P 4035.39 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:

(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.

He-P 4035.40 Therapy-related Computer Systems. The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing shall include, as applicable, verification of:

(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 sealed source positions from radiographic images.

He-P 4035.41 Use of Sources for Manual Brachytherapy. A licensee shall use only brachytherapy sources for therapeutic medical use:

(a) As approved in the Sealed Source and Device Registry; or

(b) In research, in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of He-P 4035.15(a) are met.

He-P 4035.42 Safety Instruction for Use of Brachytherapy Sources.

(a) The licensee shall provide radiation safety instruction (commensurate with the duties of the personnel) initially to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under He-P 4035.25.

(b) Refresher training shall be provided at intervals not to exceed one year.

(c) To satisfy He-P 4035.42(a), the instruction shall describe:

(1) The size and appearance of the brachytherapy sources;

(2) The safe handling and shielding instructions;

(3) The procedures for patient or human research subject control;

(4) The procedures for visitor control; including:

a. Routine visitation of hospitalized individuals in accordance with He-P 4020.13(a)(1); and

b. Visitation authorized in accordance with He-P 4020.13(c);

(5) The procedures for notification of the radiation safety officer, or his or her designee, and an authorized user if the patient or human research subject dies or has a medical emergency; and

(6) The training for workers as required by He-P 4019.

(d) A licensee shall maintain a record of individuals receiving instruction required by He-P 4035.42(a), a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for 3 years.

He-P 4035.43 Safety Precautions for Use of Brachytherapy Sources.

(a) For each patient or human research subject receiving brachytherapy and cannot be released under He-P 4035.25, a licensee shall:

(1) Not place the patient or human research subject in the same room with a patient who is not receiving brachytherapy unless the licensee can demonstrate compliance with the radiation dose limits for individual members of the public as specified in He-P 4020.13 at a distance of one meter from the implant;

(2) Post the patient's or human research subject's door with a "Caution: Radioactive Materials" sign and note on the door or 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;

(3) Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the radiation safety officer;

(4) Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with He-P 4020, He-P 4021, and He P 4022.

(5) Retain for 3 years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in microsieverts (mrems) per hour, the instrument used to make the survey, and the initials of the individual who made the survey; and

(6) Before authorizing the release of a patient or human research subject administered a permanent implant, 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 keep the radiation dose to household members and the public as low as reasonably achievable.

(b) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:

(1) Dislodged from the patient; and

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

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

He-P 4035.44 Brachytherapy Sources Accountability.

(a) A licensee shall:

(1) Maintain accountability at all times for all brachytherapy sources in storage or use; and

(2) As soon as possible after removing sources from a patient or a human research subject, return brachytherapy sources to a secure storage area.

(b) A licensee shall maintain a record of brachytherapy source accountability for 3 years.

(1) For temporary implants, the record shall include:

a. 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 the source(s) from storage, and the location of use; and

b. The number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned the source(s) to storage.

(2) For permanent implants the record shall include:

a. The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed the source(s) from storage;

b. The number and activity of sources not implanted, the date the source(s) were returned to storage, and the name of the individual who returned the source(s) to storage; and

c. The name and activity of sources permanently implanted in the patient or human research subject.

He-P 4035.45 Surveys After Source Implant/Removal and Surveys of Individuals Treated With a Remote Afterloader Unit.

(a) Immediately after implanting sources in a patient or a human research subject, the licensee shall make 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) Before releasing a patient or a human research subject from license control, a licensee shall survey 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.

(d) A licensee shall maintain a record of patient or human research subject surveys which demonstrate compliance with He-P 4035.45(a) through (c) for 3 years, including the date and the results of the survey, the survey instrument used, and the name of the individual who made the survey.

He-P 4035.46 Calibration Measurements of Brachytherapy Sources.

(a) Before the first medical use of a brachytherapy source, a licensee shall have:

(1) Determined the source output or activity using a dosimetry system that meets the requirements of He-P 4035.53(b);

(2) Determined source positioning accuracy within applicators; and

(3) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of He-P 4035.46(a)(1) and (a)(2); or

(4) Used 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 4035.46(a).

(b) A licensee shall mathematically correct the outputs or activities determined by He-P 4035.46(a) for physical decay at intervals consistent with 1 percent physical decay.

(c) A licensee shall retain a record of each calibration of brachytherapy source for 3 years after the last use of the Source. The record shall include:

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

(3) The source output or activity;

(4) The source positioning accuracy within the applicators; and

(5) The name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration.

He-P 4035.47 Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Units, or Gamma Stereotactic Radiosurgery Units. A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry; or

(b) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of He-P 4035.15(a) are met.

He-P 4035.48 Installation, Maintenance, Adjustment, and Repair of Remote Afterloader Units, Teletherapy Units, or Gamma Ster**e**otactic Radiosurgery Units.

(a) Only a person specifically licensed by DHHS/RHS, or an agreement state, or the Nuclear Regulatory Commission 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 DHHS/RHS, or an agreement 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 DHHS/RHS, an agreement 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 of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units for 3 years. Each record shall include:

(1) The date;

(2) The description of the service; and

(3) The name(s) of the individual(s) who performed the work.

He-P 4035.49 Amendments for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units. In addition to the requirements specified in He-P 4035.05, a licensee shall apply for and receive a license amendment before:

(a) Making any change in the treatment room shielding;

(b) Making any change in the location of the remote afterloader unit, the teletherapy unit, or the gamma stereotactic radiosurgery unit within the treatment room;

(c) Using the remote afterloader unit, the teletherapy unit, or the gamma stereotactic radiosurgery unit in a manner that could result in increased radiation levels in areas outside the therapy treatment room;

(d) Relocating the remote afterloader unit, the teletherapy unit, or the gamma stereotactic radiosurgery unit; or

(e) Allowing an individual not listed on the licensee's license to perform the duties of the authorized medical physicist.

He-P 4035.50 Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

(a) A licensee shall:

(1) Secure the unit, the console, the console 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. The procedures shall 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 4035.50(a)(4) shall be physically located at the unit console.

(c) A licensee shall post instructions at the console to inform the operator of:

(1) The location of the procedures required by He-P 4035.50(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 annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties. The instructions shall include:

(1) The procedures identified in He-P 4035.50(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 annually.

(f) A licensee shall retain a record of individuals receiving instruction required by He-P 4035.50(d) for 3 years. The record shall include:

(1) A list of the topics covered;

(2) The date of the instruction;

(3) The name(s) of the attendee(s); and

(4) The name(s) of the individual(s) who provided the instruction.

(g) A licensee shall retain a copy of the procedures required by He-P 4035.50(a)(4) and (d)(2) until the licensee no longer possesses the remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

He-P 4035.51 Safety Precautions for Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units.

(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 shall:

(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 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 beam "on-off" control is reset at the console.

(c) A licensee shall require any individual entering the treatment room to ensure, 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 4035.51(a) through(e), a licensee shall:

(1) For medium dose-rate and pulsed dose-rate remote afterloader units, shall 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 treatment 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;

(2) For high dose-rate remote afterloader units, shall 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 physically 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; and

(4) Notify the radiation safety officer, or his/her designee, and an authorized user immediately if the patient or human research subject has a medical emergency or dies.

(g) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:

(1) Remaining in the unshielded position; or

(2) Lodged within the patient following completion of the treatment.

He-P 4035.52 Technical Requirements for Mobile Remote Afterloader.

(a) A licensee providing mobile remote afterloader service shall:

(1) Check survey instruments 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 4035.55(i) through (n), 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 shall 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 exposure;

(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 4035.52(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 4035.52(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 4035.52(b) for 3 years. The record shall 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 source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy; and

(5) The name and the signature of the individual who performed the check.

He-P 4035.53 Dosimetry Equipment.

(a) Except for low dose-rate afterloader sources where the source output or activity is determined by the manufacturer, 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 using a system or source traceable to the National Institute of Standards and Technology and published protocols accepted by nationally recognized bodies; 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 sealed sources for teletherapy 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.

(g) The licensee shall have a dosimetry system available for use for spot-check output measurements, if applicable. To satisfy this requirement:

(1) The system shall be compared with a system that has been calibrated in accordance with He-P 4035.53(a) through (f);

(2) The comparison shall have been performed within the previous year and after each servicing that may have affected system calibration; and

(3) The spot-check system shall be the same system used to meet the requirements in He-P 4035.53(a) through (f).

(h) The licensee shall retain a record of each calibration, intercomparison, and comparison of its dosimetry equipment for the duration of the license. For each calibration, intercomparison, or comparison, the record shall 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 4035.53(a) through (g);

(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 4035.54 Full Calibration Measurements on Teletherapy Units, Remote Afterloader Units, and Gamma Stereotactic Radiosurgery 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(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 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(a) through (f) to measure the output for one set of exposure conditions, and the remaining radiation measurements required in He-P 4035.54(b)(1) shall then 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(a) in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall correct mathematically the outputs determined in He-P 4035.54(b)(1) for physical decay for intervals not exceeding one month for cobalt-60, intervals not exceeding 6 months for cesium-137, or at intervals consistent with one percent decay for all other nuclides.

(f) Full calibration measurements required by He-P 4035.54(a) and physical decay corrections required by He-P 4035.54(e) shall be performed by an authorized medical physicist.

(g) 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 3 months 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 remote afterloader units.

(h) To satisfy the requirement of He-P 4035.54(g), full calibration measurements shall 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.

(i) A licensee shall use the dosimetry system described in He-P 4035.53(b) to measure the output.

(j) A licensee shall make full calibration measurements required in He-P 4035.54(g) in accordance with published protocols accepted by nationally recognized bodies.

(k) In addition to the requirements for full calibration for low dose-rate remote afterloaders in He-P 4035.54(h), a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding 3 months.

(l) For low dose-rate remote afterloader units, a licensee shall use measurements provided by the source manufacturer that are made in accordance with He-P 4035.54(g) through (k).

(m) A licensee shall mathematically correct the outputs determined in He-P 4035.54(h)(1) for physical decay at intervals consistent with 1 percent physical decay.

(n) Full calibration measurements required by He-P 4035.53(g) and physical decay corrections required by He-P 4035.54(m) shall be performed by the authorized medical physicist.

(o) 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.

(p) To satisfy the requirement of He-P 4035.54(o), full calibration measurements shall 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).

(q) A licensee shall use the dosimetry system described in He-P 4035.53(b) to measure the output for one set of exposure conditions. The remaining radiation measurements required in He-P 4035.54(p)(1) shall be made using a dosimetry system that indicates relative dose rates.

(r) A licensee shall make full calibration measurements required by He-P 4035.54(o) in accordance with published protocols accepted by nationally recognized bodies.

(s) A licensee shall mathematically correct the outputs determined in He-P 4035.54(p)(1) at interval not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(t) Full calibration measurements required by He-P 4035.54(o) and physical decay corrections by He-P 4035.54(s) shall be performed by the authorized medical physicist.

(u) A licensee shall maintain a record of each calibration of teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit for 3 years.

(v) The record in (u) above shall include the date of the calibration, the manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and the instruments used to calibrated the unit(s); the results and an assessment of the full calibrations; the results of the autograph required for low dose-rate remote afterloader units; and the signature of the authorized medical physicist who performed the full calibration.

He-P 4035.55 Periodic Spot-Checks for Teletherapy Units, Remote Afterloader Units, and Gamma Stereotactic Radiosurgery 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 that include determination of:

(1) Timer accuracy 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 typical set of operating conditions measured with the dosimetry system described in He-P 4035.53(b); and

(6) The difference between the measurement made in He-P 4035.55(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).

(b) A licensee shall perform spot-checks required by He-P 4035.55(a) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each output spot-check within 15 days. The authorized medical physicist shall promptly notify the licensee in writing of the results of each output spot-check.

(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, and after each source installation, to ensure 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) 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".

(e) A licensee shall lock the control console in the "off" position if it indicates the malfunction of any system, and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall maintain a record of each spot-check required by He-P 4035.55(a) and (d) for 3 years.

(g) 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 linearity and constancy;

(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 determined accuracy of each distance measuring or localization device;

(8) The difference between the anticipated output and the measured output;

(9) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, the viewing and intercom system and doors; and

(11) 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.

(h) A licensee shall retain a copy of the procedures required by He-P 4035.55(b) until the licensee no longer possesses the teletherapy unit.

(i) A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit:

(1) Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate afterloader unit on a given day;

(2) Before each patient treatment with a low dose-rate remote afterloader unit; and

(3) After each source installation.

(j) A licensee shall perform the measurements required by He-P 4035.55(i) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(k) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall promptly notify the licensee in writing of the results of each spot-check.

(l) To satisfy the requirements of He-P 4035.55(i), spot-checks shall, at a minimum, ensure 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) Decay source(s) activity in the unit's computer.

(m) If the results of the checks required in He-P 4035.55(l) 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 malfunction system.

(n) A licensee shall retain a record of each check required by He-P 4035.55(l) for 3 years. The record shall 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.

(o) A licensee shall retain a copy of the procedures required by He-P 4035.55(j) until the licensee no longer possesses the remote afterloader unit.

(p) 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) Before the first use of the unit on a given day; and

(3) After each source installation.

(q) A licensee shall:

(1) Perform the measurements required by He-P 4035.55(p) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(2) Have the authorized medical physicist review the results of each spot-check with 15 days. The authorized medical physicist shall promptly notify the licensee in writing of the results of each spot-check.

(r) To satisfy the requirements of He-P 4035.55(p)(1), spot-checks shall, at a minimum:

(1) Ensure 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 4035.53(b);

b. The difference between the measurement made in He-P 4035.55(r)(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.

(s) To satisfy the requirements of He-P 4035.55(p)(2) and (p)(3), spot-checks shall ensure 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) Emergency "off" buttons;

(6) Radiation monitors used to indicate room exposures.

(t) A licensee shall arrange for repair of any system identified in He-P 4035.55(r) that is not operating as soon as possible.

(u) If the results of the checks required in He-P 4035.55(s) 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.

(v) A licensee shall retain a record of each check required by He-P 4035.55(r) and (s) for 3 years. The record shall 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 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.

(w) A licensee shall retain a copy of the procedures required by He-P 4035.55(q) until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

He-P 4035.56 Radiation Surveys for Therapy Facilities.

(a) In addition to the survey requirements in He-P 4022.01, a licensee shall make 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 do not exceed the levels stated in the Sealed Source and Device Registry.

(b) The licensee shall make the survey required by He-P 4035.56(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 of treatment units made in accordance with He-P 4035.56(a) for the duration of use of the unit. The record shall 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 name and the signature of the individual who performed the test.

He-P 4035.57 Therapy-related Computer Systems. The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing shall include, as applicable, verification of:

(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;

(d) The accuracy of the software used to determine sealed 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 4035.58 RESERVED

He-P 4035.59 Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units. Except as provided in He-P 4035.71, the licensee shall require an authorized user of a sealed source for use authorized under He-P 4035.47 to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the DHHS/RHS, an agreement state, or the Nuclear Regulatory Commission and who meets the requirements in He-P 4035.59(b)(3) and (c). To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

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

(1) 200 hours of classroom and laboratory training in the following areas:

a. Radiation physics and instrumentation;

b. Radiation protection;

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

d. Radiation biology; and

(2) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in He-P 4035.59, He-P 4035.71, equivalent agreement state, or the 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) Have completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in He-P 4035.59, He-P 4035.71, 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 Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by He-P 4035.59(b)(1)b.; and

(4) Have obtained written attestation that the individual has satisfactorily completed the requirements in He-P 4035.59(a)(1) or He-P 4035.59(b)(1) and (b)(2), and He-P 4035.59(c), and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation shall be signed by a preceptor authorized user who meets the requirements in He-P 4035.59, He-P 4035.71, equivalent agreement state, or the Nuclear Regulatory Commission requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status.

(c) All authorized users described in (a) and (b) above, shall have received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

He-P 4035.60 Five Year Inspection of Teletherapy and Gamma Stereotactic Radiosurgery Units.

(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 ensure proper functioning of the source exposure mechanism.

(b) This inspection and servicing shall only be performed by persons specifically licensed to do so by DHHS/RHS, an agreement state, or the Nuclear Regulatory Commission.

(c) A licensee shall maintain a record of the inspection and servicing for the duration of use of the unit.

(d) The record required in He-P 4035.60(c) shall contain:

(1) The inspector’s name;

(2) The inspector's radioactive materials license number;

(3) The date of inspection;

(4) The manufacturer's name and model number and serial number for both the treatment unit and source;

(5) A list of components inspected;

(6) A list of components serviced and the type of service;

(7) A list of components replaced; and

(8) The signature of the inspector.

He-P 4035.61 Radiation Safety Officer Training. Except as provided in He-P 4035.71, the licensee shall require an individual fulfilling the responsibilities of the radiation safety officer as provided in He-P 4035.08 to be an individual who is certified by a specialty board whose certification process has been recognized by DHHS/RHS, or an agreement state, or the Nuclear Regulatory Commission, and which meets the requirements in He-P 4035.61.

(a) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

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

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

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

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

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

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

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

(b) In order to meet the qualifications of the individual fulfilling the responsibilities of the radiation safety officer as provided in He-P 4035.08, an individual who is not certified by a specialty board meeting the requirements of (a) above, shall have completed a structured educational program consisting of:

(1) 200 hours of classroom and laboratory training in the following areas:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurements of radioactivity;

d. Radiation biology;

e. Radiation dosimetry; and

(2) One year of full-time radiation safety experience under the supervision of the individual identified as the radiation safety officer on a DHHS/RHS, or agreement state, or Nuclear Regulatory Commission license, or permit issued by a Nuclear Regulatory Commission master material license that authorized similar type(s) of use(s) of byproduct material involving the following:

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

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

c. Securing and controlling byproduct material;

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

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

f. Using emergency procedures to control byproduct material; and

g. Disposing of byproduct material; or

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

(4) Be 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.

(c) All individuals with qualifications as set forth in (a), or (b) above, shall obtain a written attestation, signed by a preceptor radiation safety officer, that the individual has satisfactorily completed the requirements in He-P 4035.61(a)(1) and (a)(2) and He-P 4035.61(d), or He-P 4035.61(a)(4), and (a)(5) or He-P 4035.61(b)(1) and (b)(2), He-P 4035.61(b)(3) or He-P 4035.61(b)(4), and has achieved a level of

radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use license; and

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

He-P 4035.62 RESERVED

He-P 4035.63 Training for Uptake, Dilution, or Excretion Studies.

(a) Except as provided in He-P 4035.71, the licensee shall require the authorized user of unsealed byproduct material listed in He-P 4035.27 to be a physician, who:

(1) Is certified by a medical specialty board whose certification process has been recognized by DHHS/RHS, or an agreement state, or the Nuclear Regulatory Commission; and

(2) Has obtained a written attestation, signed by a preceptor authorized user who meets the requirements in He-P 4035.63, He-P 4035.64, He-P 4035.65, or He-P 4035.71, or the requirements of an equivalent agreement state, or the Nuclear Regulatory Commission, that state that the individual has satisfactorily completed the requirements in He-P 4035.63(a)(1) or (c)(1), or the equivalent, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under He-P 4035.27; or

(3) Is an authorized user under He-P 4035.63(c)(1), He-P 4035.64, He-P 4035.65,or an authorized user under the equivalent regulations of an agreement state, or the Nuclear Regulatory Commission requirements.

(b) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the use of unsealed byproduct material for uptake, dilution, and excretion studies as described in He-P 4035.63(c)(1)a. through He-P 4035.63(c)(1)b.6.; and,

(2) Pass an examination, administered by diplomats of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control.

(c) Except as provided in He-P 4035.71, an authorized user of unsealed byproduct material for the uses authorized under He-P 4035.27 to be a physician, who:

(1) Completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies.

a. The training and experience shall include 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 4035.63, He-P 4035.64, He-P 4035.65, He-P 4035.71, equivalent requirements of an agreement state, or the Nuclear Regulatory Commission involving:

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

2. Performing quality control procedures on 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;

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

(2) Obtained written attestation under He-P 4035.63(a)(2).

He-P 4035.64 Training for Imaging and Localization Studies.

(a) Except as provided in He-P 4035.71, the licensee shall require the authorized user of unsealed byproduct material listed in He-P 4035.31 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by DHHS/RHS, or an agreement state, or the Nuclear Regulatory Commission; and

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in He-P 4035.64, He-P 4035.71 or He-P 4035.65 and He-P 4035.64(c)(1)b.7, or the equivalent requirements of an agreement state, or the Nuclear Regulatory Commission requirements, to document that the individual has satisfactorily completed the requirements or equivalent requirements of He-P 4035.64 (b)(1) or (c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under He-P 4035.27 and He-P 4035.31; or

(3) Is an authorized user under He-P 4035.65 and meets the requirements in He-P 4035.64(c)(1)b.7, or the equivalent requirements of an agreement state, or the Nuclear Regulatory Commission requirements; or

(4) Meets the requirements in He-P 4035.64(c).

(b) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the use of unsealed byproduct material for uptake, dilution, and excretion studies as described in He-P 4035.64(c)(1)a. through (c)(1)b.7.; and,

(2) Pass an examination, administered by diplomats of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control.

(c) Except as provided in He-P 4035.71, an authorized user of unsealed byproduct material for the uses authorized under He-P 4035.31 to be a physician who:

(1) Completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience shall include:

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 4035.64, He-P 4035.71, or He-P 4035.65 and He-P 4035.64(c)(1)b.7, or the regulations of an agreement state, or the Nuclear Regulatory Commission requirements involving

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

2. Performing quality control procedures on 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;

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

7. Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the elute for radionuclide purity, and processing the elute with reagent kits to prepare labeled radioactive drugs; and

(2) Obtained a written attestation under He-P 4035.64(a)(2).

He-P 4035.65 Training for Use of Unsealed Byproduct Material for Which a Written Directive Is Required.

(a) Except as provided in He-P 4035.71(b), the licensee shall require the authorized user of unsealed byproduct material listed in He-P 4035.35 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by DHHS/RHS, or an agreement state, or the Nuclear Regulatory Commission; and

(2) Meets the requirements in He-P 4035.65(c)(2)b. and He-P 4035.65(d).

(b) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete residency training in a radiation therapy or nuclear training program or a related medical specialty. The eligible training programs are recognized as described in the Nuclear Regulatory Commission regulations at 10 CFR 35.390(a)(1). These residency training programs shall include training and experience as described in He-P 4035.65(c)(1)a. through He-P 4035.65(c)(2)a.5.; and,

(2) Pass an examination, administered by diplomats of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control and clinical use of unsealed byproduct material for which a written directive is required; or

(c) Except as provided in He-P 4035.71(b), an authorized user of unsealed byproduct material for the uses authorized under He-P 4035.35 shall be a physician who has:

(1) Completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for requiring a written directive. The training and experience shall 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;

e. Radiation biology; and

(2) Work experience, under the supervision of an authorized user who meets the requirements in He-P 4035.65 or He-P 4035.71, or the equivalent requirements of an agreement state, or the Nuclear Regulatory Commission. A supervising authorized user, who meets the requirements in He-P 4035.65, shall also have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

a. The work experience shall involve:

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

2. Performing quality control procedures on 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;

b. Dosaging shall include, 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:

1. Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodine I-131, for which a written directive is required;

2. Oral administration of greater than 1.22 gigabecquerels (33 millicurie) of sodium iodine I-131;

3. Parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or

4. Parenteral administration of any other radionuclide, for which a written directive is required; and

(d) In addition to meeting the requirements of (a) or (b) or (c) above, a licensee shall require an authorized user to obtain a written attestation that the individual has satisfactorily completed the requirements in He-P 4035.65(a)(1) and (c)(2)b. or He-P 4035.65(c) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under He-P 4035.35.

(e) The written attestation shall be signed by a preceptor authorized user who:

(1) Meets the requirements in He-P 4035.65 or He-P 4035.71, or equivalent agreement state, or Nuclear Regulatory Commission requirements; and

(2) Meets the He-P 4035.65(c), and shall have experience in administering dosages in the same dosage category or categories (i.e., He-P 4035.65(c)(2)b.) as the individual requesting authorized user status.

He-P 4035.66 Training for the Oral Administration of Sodium Iodide I-131 and for the Parenteral Administration Requiring a Written Directive.

(a) Except as provided in He-P 4035.71, the licensee shall require the authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries), to be a physician who:

(1) Is certified by a medical specialty board whose certification process includes all the requirements in He-P 4035.66(b)(1), (b)(2), and whose certification process has been recognized by DHHS/RHS, an agreement state, or the Nuclear Regulatory Commission; and

(2) Meets the requirements in He-P 4035.66(b)(3); or the equivalent requirements of an agreement state, or the Nuclear Regulatory Commission or

(3) Is an authorized user under He-P 4035.65 for uses listed in He-P 4035.65(c)(2)b.1. or the equivalent requirements of an agreement state, or the Nuclear Regulatory Commission;

(4) Is an authorized user under He-P 4035.65 for uses listed in He-P 4035.65(c)(2)b.2., and He-P 4035.66(c) and (d), or the equivalent requirements of an agreement state, or the Nuclear Regulatory Commission.

(b) Except as provided in He-P 4035.71, a physician who does not meet the requirement of He-P 4035.66(a) above shall: successfully complete 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive.

(1) The training shall 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) Have work experience, under the supervision of an authorized user who meets the requirements in He-P 4035.65, He-P 4035.66(a) and (b), He-P 4035.66(d) and (e), He-P 4035.71, or equivalent agreement state, or Nuclear Regulatory Commission requirements. A supervising authorized user who meets the requirements in He-P 4035.65(c) shall also have experience in administering dosages as specified in He-P 4035.65(c)(2)b.1. or (c)(2)b.2.

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

c. Calculating, measuring, and safely preparing patients or human research subject dosages;

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

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

f. Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Have obtained a written attestation that the physician has satisfactorily completed the requirements in He-P 4035.66(b)(1) and (b)(2), and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under He-P 4035.35.

(c) The written attestation shall be signed by a preceptor authorized user who:

1. Meets the requirements in He-P 4035.65, He-P 4035.66(a),(b), (d), (e) and, He-P 4035.71, or the equivalent requirements of an agreement state, or the Nuclear Regulatory Commission; and

2. Meets the requirements in He-P 4035.65(c); and

3. Has experience in administering dosages as specified in He-P 4035.65(c)(2)b.1. or 2.

(d) Except as provided in He-P 4035.71, the licensee shall require the authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries), to be a physician who:

(1) Is certified by a medical specialty board whose certification process includes all of the requirements in He-P 4035.66(e) and (f), and whose certification has been recognized by the DHHS/RHS, or an agreement state, or the Nuclear Regulatory Commission; and

(2) Meets the requirements in He-P 4035.66(g); or

(3) Is an authorized user under He-P 4035.65 for uses listed in He-P 4035.65(c)(2)b., or the equivalent requirements of an agreement state, or the Nuclear Regulatory Commission; or

(e) Have 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 shall include:

(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

(f) Have work experience, under the supervision of an authorized user who meets the requirements in He-P 4035.65, He-P 4035.66(d) and (e), He-P 4035.71, or equivalent agreement state, or Nuclear Regulatory Commission requirements. A supervising authorized user, who meets the requirements in He-P 4035.65(c), shall also have experience in administering dosages as specified in He-P 4035.65(c)(2)b.2. The work experience shall involve:

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

(2) Performing quality control procedures on 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 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, that include at least 3 cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;

(g) Has obtained written attestation that the individual has satisfactorily completed the requirements in He-P 4035.66(d)(1) and (d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under He-P 4035.35.

(h) The written attestation shall be signed by a preceptor authorized user who:

(1) Meets the requirements in He-P 4035.65(c); and

(2) Has experience in administering dosages as specified in He-P 4035.65(c)(2)b..

(i) Except as provided in He-P 4035.71, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who:

(1) Is an authorized user under He-P 4035.65 for uses listed in He-P 4035.65(c)(2)b.3.or (c)(2)b.4., equivalent agreement state, or the Nuclear Regulatory Commission requirements; or

(2) Is an authorized user under He-P 4035.59 or He-P 4035.69, or equivalent agreement state, or Nuclear Regulatory Commission requirements and meets the requirements in He-P 4035.66(i)(4) – (i)(6) and (j); or

(3) Is certified by a medical specialty board whose certification process has been recognized by DHHS/RHS, under He-P 4035.59 or He-P 4035.69 or an agreement state or Nuclear Regulatory Commission, and who meets the requirements in He-P 4035.66(i)(4) and (i)(5).

(4) Shall have successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required.

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

(5) Has work experience, under the supervision of an authorized user who meets the requirements in He-P 4035.65, He-P 4035.66(i) and He-P 4035.71, or the requirements of an equivalent agreement state, or the Nuclear Regulatory Commission requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in He-P 4035.65 shall have experience in administering dosages as specified in He-P 4035.65(c)(2)b. and/or (c)b. The work experience shall involve:

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

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

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

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

f. Administering dosages to patients or human research subjects involving a minimum of 3 cases involving the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

(6) Has obtained written attestation that the individual has satisfactorily completed the requirements in He-P 4035.66(i)(4) and (i)(5), and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive.

(j) The written attestation shall be signed by a preceptor authorized user who:

(1) Meets the requirements in He-P 4035.65, He-P 4035.66(i), He-P 4035.71, or equivalent agreement state, or Nuclear Regulatory Commission requirements; and

(2) Meets the requirements in He-P 4035.65, shall have experience in administering dosages as specified in He-P 4035.65(b)(2)b., and/or He-P 4035.65(b)(2)b.4.

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 an authorized user under He-P 4035.69, or equivalent requirements of an agreement state or the Nuclear Regulatory Commission; or

(2) 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, clinic, or private practice 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) In accordance with He-P 4035.67(a) above, an authorized user who is a physician shall:

(1) Obtain a written attestation, signed by a preceptor authorized user who meets the requirements in He-P 4035.67, He-P 4035.69, He-P 4035.71, or the equivalent requirements of an agreement state, or the Nuclear Regulatory Commission requirements, that the individual has completed the requirements in He-P 4035.67(a)(2); and

(2) Has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

(c) Only an authorized medical physicist shall calculate the decayed-activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay calculation shall be based on the activity determined under He-P 4035.46.

(d) A licensee shall retain a record of the activity of each strontium-90 source required by He-P 4035.67(c) for the life of the Source. The record shall include:

(1) The date and initial activity of the source as determined under He-P 4035.46; and

(2) For each decay calculation, the date and the source activity as determined under He-P 4035.67(c).

He-P 4035.68 Training for Use of Sealed Sources for Diagnosis. Except as provided in He-P 4035.71 the licensee shall require the authorized user using a diagnostic sealed source in a device specified in He-P 4035.39 to be a physician, dentist, or podiatrist who:

(a) Is certified by a specialty board whose certification process includes all the requirements in He-P 4035.68(b) and (c) and whose certification has been recognized by DHHS/RHS, an agreement state, or the Nuclear Regulatory Commission; or

(b) Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device, including training in:

(1) Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;

(2) Radiation biology; and

(3) Radiation protection.

(c) An individual who meets the requirements of (a) or (b) above shall complete training in the use of the device for the uses requested.

He-P 4035.69 Training for Use of Manual Brachytherapy Sources.

(a) Except as provided in He-P 4035.71, the licensee shall require the authorized user of a manual brachytherapy source for the uses authorized under He-P 4035.41 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the DHHS/RHS, or an agreement state, or the Nuclear Regulatory Commission. To have its certification process recognized, a specialty board shall require all candidates for certification to:

a. Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Post-Graduate Training of the American Osteopathic Association; and

b. Pass an examination, administering by diplomats of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy.

(2) Meets the requirements in He-P 4035.69(b)(4); or

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

(1) 200 hours of classroom and laboratory training in the following:

a. Radiation physics and instrumentation;

b. Radiation protection;

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

d. Radiation biology; and

(2) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in He-P 4035.69, He-P 4035.71, or equivalent agreement state, or Nuclear Regulatory Commission requirements at a medical institution, involving:

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Checking survey meters for proper operation;

c. Preparing, implanting, and removing brachytherapy sources;

d. Maintaining running inventories of material on hand;

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

f. Using emergency procedures to control byproduct material; and

(3) All physicians who meet the requirements of (b) above shall complete 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in He-P 4035.69, He-P 4035.71, or the equivalent requirements of an agreement state, or the Nuclear Regulatory Commission, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by He-P 4035.69(b)(2); and

(4) All physicians who meet the requirements of (a) or (b) above shall obtain a written attestation, signed by a preceptor authorized user who meets the requirements in He-P 4035.69, He-P 4035.71, equivalent agreement state, or the Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in He-P 4035.69(a)(1)a., or He-P 4035.69(b)(1), (b)(2), and (b)(3) and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under He-P 4035.41.

He-P 4035.70 Training for Authorized Medical Physicist. Excepted as provided in He-P 4035.71, the licensee shall require the authorized medical physicist to be an individual who:

(a) Is certified by a specialty board whose certification process has been recognized by DHHS/RHS, or an agreement state, or the Nuclear Regulatory Commission, and who meets the requirements in He-P 4035.70(b)(5) and (b)(6).

(b) To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

(2) Have 2 years of full-time practical training and/or supervised experience in medical physics:

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

b. In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements in He-P 4035.59, He-P 4035.69, or He-P 4035.71; or meet all of the requirements of (3) and (4) below:

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

(4) Have completed 1 year of full-time training in medical physics; and

a. An additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization; and

b. This training and work experience shall be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and shall include:

1. Performing sealed source leak tests and inventories;

2. Performing decay corrections;

3. Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

4. Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afteloading units as applicable; and

(5) Have obtained written attestation that the individual has satisfactorily completed the requirements in He-P 4035.70(b)(1), (b)(2) and (b)(6) or (b)(3), (b)(4) and (b)(6), and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation shall be signed by a preceptor authorized medical physicist who meets the requirements in He-P 4035.70, He-P 4035.71, or an equivalent agreement state, or the Nuclear Regulatory Commission requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(6) Have training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

(c) In addition to the requirements of (b)(1) and (b)(2) above, each candidate for certification shall pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery.

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

(a) An individual identified as:

(1) A radiation safety officer, a teletherapy or medical physicist, or a nuclear pharmacist on a DHHS/RHS, or an agreement state, or a Nuclear Regulatory Commission license or a permit, or a Nuclear Regulatory Commission broad scope license or master material license permit, or by a master material license permittee of broad scope before October 24, 2002, need not comply with the training requirements of He-P 4035.61, He-P 4035.70, or He-P 4035.74, respectively; or

(2) A radiation safety officer, an authorized medical physicist, or an authorized nuclear pharmacist on a DHHS/RHS, or an agreement state, or a Nuclear Regulatory Commission license or a permit, or the Nuclear Regulatory Commission broad scope license, or master material license permit, or a master material license permittee of broad scope, between October

24, 2002 and April 29, 2005 need not comply with the training requirements of He-P 4035.61, He-P 4035.70, or He-P 4035.74, respectively.

(b) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material:

(1) On a license issued by the DHHS/RHS, an agreement state, or the Nuclear Regulatory Commission, or a permit issued by a U.S. Nuclear Regulatory Commission master material licensee, a permit issued by the DHHS/RHS, or an agreement state, or the Nuclear Regulatory Commission broad scope licensee, or a permit issued by aNuclear Regulatory Commission master material license broad scope permittee before October 24, 2002, who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of He-P 4035 subparts equivalent to 10 CFR 35 Subparts D through H; or

(2) On a license issued by the DHHS/RHS, or an agreement state, or the Nuclear Regulatory Commission, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by a DHHS/RHS, or an agreement state, or the Nuclear Regulatory Commission broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee who performed only those medical uses for which they were authorized between October 24, 2002 and April 29, 2005, need not comply with the training requirements of He-P 4035 subparts equivalent to 10 CFR 35 Subparts D through H.

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

He-P 4035.72 RESERVED

He-P 4035.73 Recentness of Training. The training and experience of an authorized user, radiation safety officer, authorized medical physicist and authorized nuclear pharmacist specified in He-P 4035.59, He-P 4035.61, He-P 4035.63-He-P 4035.71, and He-P 4035.74 shall have been obtained within the 7 years preceding the date of application, or the individual shall have had on-going education and applicable experience since the required training and experience was completed.

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

(a) Is certified by a specialty board whose certification process has been recognized by DHHS/RHS, or an agreement state, or the Nuclear Regulatory Commission, and who meets the requirements in He-P 4035.74(b).

(b) To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

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

(3) Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

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

(c) Have met the following requirements:

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

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

1. Radiation physics and instrumentation;

2. Radiation protection;

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

4. Chemistry of byproduct material for medical use; and

5. Radiation biology; and

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

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

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

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

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

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

(d) In addition to the requirements in (b) and (c) above, all nuclear pharmacists shall obtain a written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in He-P 4035.74(b),or (c) and that the individual has achieved a level of competency sufficient to independently operate as an authorized nuclear pharmacist.

He-P 4035.75 RESERVED