

RULEMAKING NOTICE FORM

Notice
Number

2015-179

Rule Number

He-P 4035

<p>1. Agency Name & Address:</p> <p>NH Dept. of Health & Human Services Division of Public Health Services Radiological Health Section (RHS) 29 Hazen Drive Concord, NH 03301</p>	<p>2. RSA Authority: <u>RSA 125-F:5, IV & V</u></p> <p>3. Federal Authority: <u>Section 274 of the Atomic Energy Act of 1954 as amended</u></p> <p>4. Type of Action:</p> <p>Adoption _____</p> <p>Amendment _____</p> <p>Repeal _____</p> <p>Readoption _____</p> <p>Readoption w/amendment <u>X</u></p>
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5. Short Title: **Use of Byproduct Materials in the Healing Arts**

6. (a) Summary of what the rule says and of any proposed amendments:

The proposed rule, He-P 4035, replaces an interim rule which is scheduled to expire on January 18, 2016. The proposed rule is being amended to update, clarify and more specifically state requirements for the use of radionuclides in the healing arts in order for the Department of Health and Human Services' Radiological Health Section (DHHS/RHS) to be consistent and in compliance with Nuclear Regulatory Commission (NRC) regulation requirements.

The proposed He-P 4035 includes updates and clarification of definitions, states requirements for the possession and use of byproduct materials, sealed sources, and devices used to treat patients or human research subjects, and includes NRC mandated updates regulating the possession of byproduct material in certain quantities. The proposed rule describes qualifications, supervision, training options, and documentation required for those who use byproduct material in the healing arts, including training for use with and without written directives, and updated qualifications for a radiation safety officer, and a nuclear pharmacist. The rule defines medical events, clarifies and specifies notification after a medical event, and clarifies requirements for releasing patients who were treated with byproduct material. The rule clarifies and updates calibration requirements for certain teletherapy, and dosimetry units, and states requirements for other devices using byproduct material in the treatment and diagnosis of patients, including the requirements for calibration, survey and safety records. The proposed rule states requirements for medical uses of byproduct material including diagnostic, therapeutic uses, positron emission tomography (PET), and training for use of radioactive drugs. The rule also clarifies the as low as reasonably achievable (ALARA) principle to control the release and dosage of byproduct materials. The rule updates and clarifies requirements for decay in storage and provision of mobile medical services. Some of the NRC mandated updates have resulted in sections of the rule being deleted. Some deleted section numbers have been renamed and reused, and other sections reserved.

6. (b) Brief description of the groups affected:

Those affected by the rule include those who produce, prepare, compound, use and are trained to use byproduct material for medical purposes and in the healing arts. The rule also affects the issuance of licenses authorizing the medical use of byproduct material which provides for the radiation safety of workers, and the safety of patients, human research subjects and the general public.

6. (c) Specific section or sections of state statute or federal statute or regulation which the rule is intended to implement:

RULE	STATE OR FEDERAL REGULATION IMPLEMENTED
He-P 4035	Section 274 of the AEA of 1954, as amended, and Title 10, Code of Federal Regulations (CFR), Part 35
He-P 4035.01	10 CFR 35.1
He-P 4035.02	10 CFR 35.1
He-P 4035.03	10 CFR 35.2
He-P 4035.04	10 CFR 35.11, 35.6
He-P 4035.05	10 CFR 35.12, 35.13
He-P 4035.06	10 CFR 35.14
He-P 4035.07	10 CFR 35.24, 35.26, 35.2026
He-P 4035.08	10 CFR 35.24
He-P 4035.09	10 CFR 35.24
He-P 4035.10	10 CFR 35.24, 35.2024
He-P 4035.11	10 CFR 35.27
He-P 4035.12	10 CFR 35.80, 35.2080
He-P 4035.13	10 CFR 35.40, 35.41, 35.100, 35.2040, 35.2041
He-P 4035.14	10 CFR 35.3045
He-P 4035.15	10 CFR 35.49
He-P 4035.16	10 CFR 35.60, 35.2060
He-P 4035.17	10 CFR 35.60, 35.2060
He-P 4035.18	10 CFR 35.61, 35.2061
He-P 4035.19	10 CFR 35.63, 35.2063
He-P 4035.20	10 CFR 35.65
He-P 4035.21	10 CFR 35.67, 35.2067, 35.3067
He-P 4035.22 Reserved	
He-P 4035.23	10 CFR 35.69
He-P 4035.24	10 CFR 35.70, 35.2070
He-P 4035.25	10 CFR 35.75, 35.2075
He-P 4035.26	10 CFR 35.80, 2080
He-P 4035.27	10 CFR 35.100
He-P 4035.28	10 CFR 35.92, 35.2092
He-P 4035.29	10 CFR 35.1000
He-P 4035.30 Reserved	

He-P 4035.31	10 CFR 35.200
He-P 4035.32	10 CFR 35.204, 35.2204
He-P 4035.33	RHS
He-P 4035.34 Reserved	
He-P 4035.35	10 CFR 35.300
He-P 4035.36	10 CFR 35.410, 35.2310
He-P 4035.37	10 CFR 35.315
He-P 4035.38	10 CFR , 35.3047
He-P 4035.39	10 CFR 35.500
He-P 4035.40	10 CFR 35.457
He-P 4035.41	10 CFR 35.400
He-P 4035.42	10 CFR 35.410, 35.2310
He-P 4035.43	10 CFR 35.415
He-P 4035.44	10 CFR 35.406, 35.2406
He-P 4035.45	10 CFR 35.404, 35.604, 35.2404
He-P 4035.46	10 CFR 35.432, 35.2432
He-P 4035.47	10 CFR 35.600
He-P 4035.48	10 CFR 35.605, 35.2605
He-P 4035.49	10 CFR 35.12, 35.13
He-P 4035.50	10 CFR 35.610, 35.2310, 35.2610
He-P 4035.51	10 CFR 35.615
He-P 4035.52	10 CFR 35.647
He-P 4035.53	10 CFR 35.630, 35.2630
He-P 4035.54	10 CFR 35.632, 35.632, 35.633, 35.635
He-P 4035.55	10 CFR 35.642, 35.643, 35.645, 35.2642, 35.2643, 35.2645
He-P 4035.56	10 CFR 35.652, 35.2652
He-P 4035.57	10 CFR 35.657
He-P 4035.58 Reserved	10 CFR 35.643
He-P 4035.59	10 CFR 35.690
He-P 4035.60	10 CFR 35.655, 35.2655
He-P 4035.61	10 CFR 35.50
He-P 4035.62 Reserved	10 CFR 35.901
He-P 4035.63	10 CFR 35.190
He-P 4035.64	10 CFR 35.290
He-P 4035.65	10 CFR 35.390
He-P 4035.66	10 CFR 35.392, 35.394, 35.396
He-P 4035.67	10 CFR 35.433, 35.491
He-P 4035.68	10 CFR 35.590
He-P 4035.69	10 CFR 35.490
He-P 4035.70	10 CFR 35.51
He-P 4035.71	10 CFR 35.57
He-P 4035.72 Reserved	10 CFR 35.971
He-P 4035.73	10 CFR 35.59
He-P 4035.74	10 CFR 35.44
He-P 4035.75 Reserved	

7. Contact person for copies and questions including requests to accommodate persons with disabilities:

Name: **Catherine Bernhard** Title: **Rules Coordinator**
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TTY/TDD Access: Relay NH 1-800-735-2964 or dial 711 (in NH)

The proposed rules may be viewed and downloaded at:

<http://www.dhhs.nh.gov/oos/aru/comment.htm>

8. Deadline for submission of materials in writing or, if practicable for the agency, in the electronic format specified: **Monday, November 30, 2015**

Fax

E-mail

Other format (specify):

9. Public hearing scheduled for:

Date and Time: **Thursday, November 19, 2015 at 1:45 P.M.**

Place: [**DHHS/DES Auditorium, 29 Hazen Drive, Concord, NH**](#)

10. Fiscal Impact Statement (Prepared by Legislative Budget Assistant)

FIS # **15:192**, dated **10/21/15**

1. Comparison of the costs of the proposed rule(s) to the existing rule(s):

When compared to the existing rules, the proposed rules may increase costs to independently owned businesses by an indeterminable amount.

2. Cite the Federal mandate. Identify the impact of state funds:

The proposed rules update the qualification requirements for medical use of byproduct material to be consistent with Nuclear Regulatory Commission regulations, specifically 10 C.F.R. part 35. The State of New Hampshire is an agreement state with the NRC, pursuant to section 274b of the Atomic Energy Act of 1954, as amended. As such, the State of New Hampshire is required to have a program in place that is adequate and compatible with federal regulations, which the proposed rules address. There is no effect on state funds associated with any of the proposed rules.

3. Cost and benefits of the proposed rule(s):

To the extent a state citizen or independently owned business is a licensee, they may have an increase in costs related to additional training if their qualifications do not meet the new requirements contained in the proposed rules.

A. To State general or State special funds:

None.

B. To State citizens and political subdivisions:

See 3 above. No impact on political subdivisions.

C. To Independently owned businesses:

11. Statement Relative to Part I, Article 28-a of the N.H. Constitution:

The proposed rules modify an existing program or responsibility, but do not mandate any fees, duties or expenditures on the political subdivisions of the state, and therefore do not violate Part I, Article 28-a of the N.H. Constitution See 3 above.

Readopt with amendment He-P 4035, effective 7/22/15 (Document # 10897), to read as follows:

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

He-P 4035.01 Purpose. This part shall establish requirements and provisions for the medical production, preparation, compounding and, use of ~~radionuclides~~ byproduct material in the healing arts and for issuance of licenses authorizing the medical use of this material which provide for the ~~protection of the public health and safety~~ 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, ~~and~~ 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 ~~radioactive~~ byproduct material may be produced, prepared, received, used, or stored.

(b) “Area of use” means a portion of ~~a physical structure~~ an address of use that has been set aside for the purpose of producing, preparing, receiving, using, or storing ~~radioactive~~ 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.

~~(ed) “Authorized nuclear pharmacist” means a person who is a “licensed pharmacist” as defined in RSA 318:1, VII, and who: who is a qualified nuclear pharmacist under Ph 405.03 and who is identified as an authorized nuclear pharmacist on a DHHS/BRH license that authorizes the use of radioactive material in the practice of nuclear pharmacy.~~

(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;

~~a.~~ 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 4035.05(b)(3), or by an equivalent agreement state regulation, or by the Nuclear Regulatory Commission pursuant to 10 CFR 32.72(b)(4).

~~(de) “Authorized user” means a physician, dentist, or podiatrist, as licensed or permitted by the appropriate state authority, who is identified on a DHHS/BRH license that authorizes the medical use of radioactive material, who:~~

(1) Meets the applicable requirements for an authorized user as listed 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.

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

(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.

(fi) “Dedicated check source” means a radioactive source that is used to ~~assure~~ 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.

(gk) “Diagnostic clinical procedures manual” means a collection of written procedures that describes each method, and other instructions and precautions, by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the ~~radiopharmaceutical~~ 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.

(hn) “Management” means the chief executive officer, or ~~equivalent position, or that individual’s designee~~ other individual having the authority to manage, direct, or administer the 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).

(iq) “Medical institution” means an organization in which several medical disciplines are practiced.

(jr) “Medical use” means the intentional internal or external administration of ~~radioactive~~ byproduct material, or the radiation ~~therefrom~~ byproduct material to patients or human research subjects under the supervision of an authorized user.

(s) “Medium dose-rate 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.

~~(k) “Misadministration” means the administration of:~~

~~(1) A radiopharmaceutical dosage greater than 1.11 megabecquerels (30 μ Ci) of either sodium iodide I-125 or I-131:~~

~~a. Involving the wrong patient or human research subject or wrong radiopharmaceutical; or~~

~~b. When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 1.11 megabecquerels (30 μ Ci);~~

~~(2) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:~~

~~a. Involving the wrong patient or human research subject, wrong radiopharmaceutical, or wrong route of administration; or~~

~~b. When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage;~~

~~(3) A gamma stereotactic radiosurgery radiation dose:~~

~~a. Involving the wrong patient or human research subject or wrong treatment site; or~~

~~b. When the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;~~

~~(4) A teletherapy radiation dose:~~

~~a. Involving the wrong patient or human research subject, wrong mode of treatment, or wrong treatment site;~~

~~b. When the treatment consists of 3 or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;~~

~~c. When the calculated weekly administered dose exceeds the weekly prescribed dose by 30 percent or more of the weekly prescribed dose; or~~

~~d. When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose;~~

~~(5) A brachytherapy radiation dose:~~

~~a. Involving the wrong patient or human research subject, wrong radionuclide, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);~~

~~b. Involving a sealed source that is leaking;~~

~~c. When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or~~

~~d. When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose; or~~

~~(6) A diagnostic radiopharmaceutical dosage, other than quantities greater than 1.11 megabecquerels (30 μ Ci) of either sodium iodide I-125 or I-131, both:~~

~~a. Involving the wrong patient or human research subject, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and~~

~~b. When the dose to the patient or human research subject exceeds 50 millisieverts (5 rem) effective dose equivalent or 500 millisieverts (50 rem) dose equivalent to any individual organ.~~

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

~~(m) "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 unit 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.~~

~~(nz) "Prescribed dosage" means the quantity of radiopharmaceutical activity specific activity or range of activity of unsealed byproduct material as documented:~~

~~(1) In a written directive; or~~

~~(2) Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures In accordance with the directions of the authorized user for procedures pursuant to He-P 4035.27 and He-P 4035.31.~~

~~(oaa) "Prescribed dose" means:~~

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

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

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

(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 ~~R~~radiation ~~S~~safety ~~O~~fficer on a specific medical use license issued by DHHS/RHS, or an agreement ~~S~~state, or the Nuclear Regulatory Commission, or a medical use permit issued by a ~~U.S.~~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.

~~(p) "Recordable event" means the administration of:~~

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

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

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

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

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

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

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

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

~~(s)~~ “Teletherapy” means ~~therapeutic irradiation in which the source of radiation is at a distance from the body.~~

~~(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)~~ “Type of use” means use of byproduct material under He-P 4035.27, He-P 4035.29, He-P 4035.31, He-P 4035.35, He-P 4035.39, He-P 4035.41, or He-P 4035.47.

~~(aq)~~ “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.

~~(tar)~~ “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.

~~an order in writing for a specific patient or human research subject, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in (t)(6) below, containing the following information:~~

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

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

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

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

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

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

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

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

He-P 4035.04 License Required.

(a) No person shall manufacture, produce, prepare, compound, acquire, receive, possess, use, or transfer radioactive-byproduct material for medical use except in accordance with a specific license issued pursuant to He-P 4030 and He-P 4032 by DHHS/RHS, or an agreement state, or the Nuclear Regulatory Commission, or as allowed in He-P 4035.04(b) or (c).

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

(c) An individual may-shall prepare unsealed radioactive-byproduct material for medical use in accordance with He-P 4035 under the supervision of an authorized nuclear pharmacist, or authorized user as provided in He-P 4035.11, unless prohibited by license condition.

(d) A licensee may-shall conduct research involving human subjects using radioactive-byproduct materials specified on its license for the uses authorized on its 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 shall apply for a license in accordance with He-P 4030 and receive a license amendment before:

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

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

(c) Before ~~changing a R~~radiation ~~S~~safety ~~O~~fficer ~~or Teletherapy Physicist~~;

(d) Before ~~The licensee permits an authorized user or an individual qualified to be a radiation safety officer under He-P 4035.61 and He-P 4035.73 to: receiving radioactive material in excess of the amount authorized on the license;~~

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

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

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

(f) Before adding to or changing the areas of use or address or addresses of use identified in the application or on the license including areas in accordance with He-P 4035.27 or He-P 4035.31, if the addition or change includes addition of, or relocation of, either an area where PET radionuclides are produced, or a PET radioactive drug delivery line from PET radionuclide/PET radioactive drug production area; and

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

(h) Before ~~revising procedures required by He-P 4035.50 and He-P 4035.55, as applicable, where such revisions reduce radiation safety; and~~

(i) Before ~~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 4035.15; or

(k) The licensee's mailing address changes.

He-P 4035.06 Notifications. A licensee shall notify the DHHS/~~BRHRHS~~ in writing within 30 days when an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist, ~~Radiation Safety Officer, or Teletherapy Physicist,~~ permanently discontinues performance of duties under the license, or has a name change.

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, ~~R~~radiation ~~S~~safety ~~O~~fficer, 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 ~~R~~radiation ~~S~~safety ~~O~~fficer.

(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 ~~R~~radiation ~~S~~safety ~~O~~fficer 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 ~~R~~radiation ~~S~~safety ~~O~~fficer brief management once each year on the radiation safety program;

(3) Personnel exposure investigational levels as established in accordance with He-P ~~40204035.09~~(c)(8) that, when exceeded, will initiate an investigation by the ~~r~~Radiation ~~S~~safety ~~O~~fficer of the cause of the exposure; and

(4) Personnel exposure action levels that, when exceeded, will initiate a prompt investigation by the Radiation Ssafety 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 Ssafety Officer who, with the approval of ~~the~~ DHHS/~~BRH~~RHS, will be responsible for implementing the radiation safety program.

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

(c) The Radiation Ssafety Officer shall:

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

(2) Implement written policy and procedures for:

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

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

c. Storing ~~radioactive-byproduct~~ material;

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

- e. Using ~~radioactive~~-byproduct material safely;
- f. Taking emergency action if control of ~~radioactive~~-byproduct material is lost;
- g. Performing periodic radiation surveys;
- h. Performing checks of survey instruments and other safety equipment;
- i. Disposing of ~~radioactive~~-byproduct material;
- j. Training personnel who work in, or frequent areas where ~~radioactive~~-byproduct material is used or stored; and
- k. Keeping a copy of all records and reports required by ~~the~~-DHHS/~~BRH~~-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 ~~the~~ DHHS/~~BRH~~-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 ~~radioactive~~-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 three individuals, as follows:

- a. An authorized user of each type of use permitted by the license;
- b. The ~~R~~-radiation ~~S~~-safety ~~O~~-fficer;
- c. A representative of the nursing service; and
- d. A representative of management who is neither an authorized user nor a ~~R~~-radiation ~~S~~-safety ~~O~~-fficer.
- e. Other members may be included on the ~~R~~-radiation ~~S~~-safety ~~C~~-ommittee 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 ~~R~~-radiation ~~S~~-safety ~~O~~-fficer 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 ~~the~~ DHHS/~~BRH~~ 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 Rradiation Ssafety Officer, or ~~Teletherapy~~ Mmedical 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 Rradiation Ssafety Officer and the management representative, or disapprove procedures and radiation safety program changes prior to submittal to ~~the~~ DHHS/~~BRH~~ RHS for licensing action;

(5) Review quarterly, with the assistance of the Rradiation Ssafety Officer, occupational radiation exposure records of all personnel working with ~~radioactive~~ byproduct material;

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

(7) Review annually, with the assistance of the Rradiation Ssafety Officer, the ~~radioactive~~ 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 Rradiation Ssafety 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 610 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 4035.73, 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 4035.06(b);

(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), 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), for the duration of the license; and

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

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

~~(1) Identify radiation safety problems;~~

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

~~(3) Verify implementation of corrective actions.~~

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

He-P 4035.11 Supervision.

(a) A licensee who permits the receipt, possession, ~~production, preparation, compounding,~~ use, or transfer of radioactive 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; Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material and in the licensee's written quality management program;

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

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

(4) Require that only those individuals permitted under state and local regulations and specifically trained, and designated by the authorized user, be permitted 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:~~

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

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

(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; and,~~

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

(c) A licensee shall require the supervising authorized nuclear pharmacist or physician who is an authorized user to periodically review the work of the supervised individual as it pertains to preparing ~~radioactive-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)~~ ~~supervises an individual~~ shall be responsible for the acts and omissions of the supervised individual.

He-P 4035.12 ~~Mobile Nuclear~~-Medicine Service Administrative Requirements.

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

- (1) Uptake, dilution and excretion;
- (2) Imaging and localization;
- (3) Sealed sources in diagnosis; and
- (4) Certain in-vitro clinical or laboratory testing.

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

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

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

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

(g) A mobile ~~nuclear~~-medicine service shall inform a responsible individual, such as a representative of management, ~~or~~ a registered nurse in charge of the patient, or the registered nurse in charge of the nursing unit, who is on site at each client's address of use at the time that radiopharmaceuticals 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 ~~radioactive-byproduct~~ material or radiation therefrom ~~shall~~will 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~~is prepared ~~for~~as required in He-P 4035.13(b)(4) below:

~~a. Any teletherapy radiation dose;~~

~~b. Any gamma stereotactic radiosurgery radiation dose;~~

~~c. Any brachytherapy radiation dose;~~

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

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

(2) That, prior to each administration, the patient or human research subject's identity ~~is~~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, ~~and~~ 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, ~~and~~. 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

~~a.~~ 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 ~~is~~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 ~~radiopharmaceutical~~ 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 ~~is~~shall be documented immediately in the patient's record and a written directive ~~is prepared~~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 ~~misadministrations~~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 ~~administered radiation dose or radiopharmaceutical dosage where a~~ written directive ~~is~~is required in He-P 4035.13(b)(~~14~~) in an auditable form, for 3 years after the date of administration.

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

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

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

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

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

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

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; actions taken to prevent recurrence;
7. ~~Whether-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
8. If the patient or human research subject was notified, what information was provided to the patient or human research subject; and

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

(3) Notify the referring physician and also notify the patient's, or human research subject's, ~~or th responsible at individual's responsible relative or guardian~~, of the ~~misadministration~~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 ~~misadministration~~medical event, because of any delay in notification; and
- (6) Within 15 days after discovery of the medical event ~~F~~urnish, ~~within 15 days after discovery of the misadministration~~a statement of whether if 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 ~~the~~ DHHS/~~BRH~~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 ~~the~~ DHHS/~~BRH~~RHS can be obtained from the licensee.
- (b) Each licensee shall ~~retain a record of each misadministration for 5 years~~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 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 the names of all individuals involved, the patient's or human research subject's social security number or identification number if one has been assigned, a brief description of the ~~misadministration~~medical event, why it occurred, the effect on the patient or human research subject, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

(d) Aside from the notification requirement, nothing in He-P 4035.14(a) ~~—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) ~~Radioactive material~~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 another ~~A~~ agreement Sstate, ~~a Licensing State~~ or the ~~U.S.~~ 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
~~Reagent kits, radiopharmaceuticals, and/or radiobiologies that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the U.S. Department of Health and Human Services, Food and Drug Administration (FDA); or~~

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

~~(d)~~ Teletherapy ~~and brachytherapy~~ sources manufactured and distributed in accordance with a license issued pursuant to He-P 4030, or the equivalent regulations of another ~~A~~ agreement Sstate, ~~a Licensing 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 ~~the~~ DHHS/~~BRHRHS~~.

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

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

~~(a) A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity administered to each patient or human research subject. 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) In the case where the ionization type dose calibrator required in He-P 4035.17(a) cannot be used effectively to verify the administered activity, the licensee shall use an alternative method. 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) Any alternative method to the use of a dose calibrator shall be approved by the DHHS/BRH. 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 or human research subject.

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

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

(1) At the beginning of each day of use, check each dose calibrator for constancy on a frequently used setting with a dedicated check source of not less than 1.85 megabecquerels (50 ~~µCi~~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) ~~(370 kilobecquerels)~~ and the highest dosage that will be assayed;

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

(5) Keep a record of the geometry dependence tests required in (g)(4) above for the duration of the use of the dose calibrator.

(h) A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 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 signature name of the individual who performed the test.

He-P 4035.18 Calibration and Check of Survey Instruments.

(a) A licensee shall ensure that calibrate the survey instruments used to show compliance with He-P 4035-4020 have been calibrated before first use, annually, 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) For each scale that shall be calibrated, calibrate 2 readings separated by at least 50% of scale rating~~Calibrate 2 separated readings on each scale or decade that will be used to show compliance; and

(3) Conspicuously note on the instrument ~~the apparent dose rate from a dedicated check source as determined at the time of calibration, and~~ the date of calibration.

(c) To satisfy the requirements of He-P 4035.18(b), the licensee shall ~~consider a point as calibrated if:~~use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is less than 20 percent.

~~(1) The indicated dose rate differs from the calculated dose rate by not more than 10 percent; and~~

~~(2) The indicated exposure rate differs from the calculated exposure rate by not more than 20 percent if a correction chart or graph is conspicuously attached to the instrument.~~

(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) A description of the calibration procedure~~The model and serial number of the instrument;

~~(2) A description of the source used~~The date of the calibration;

(3) The ~~certified dose rates from the source~~results of the calibration; and

(4) The ~~rates indicated by the instrument being calibrated;~~name of the individual who performed the calibration.

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

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

~~(7) The date of calibration.~~

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

~~(h) Records of calibrations which contain information required by He-P 4035.18(e) and (f) shall be maintained by the licensee.~~

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

(a) ~~Assay, before medical use, the activity of each radiopharmaceutical dosage that contains more than 370 kilobecquerels (10 μ Ci) of a photon-emitting radionuclide;~~ 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.~~

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

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

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

~~(c) Retain a record of the assays or calibrations required by He P 4035.19(a) and (b) for 3 years;~~
and

~~(d) The records required in He P 4035.19(c) shall contain the:~~

~~(1) Radiopharmaceutical, or the radionuclide administered;~~

~~(2) Patient's or human research subject's name, and identification number if one has been assigned;~~

~~(3) Prescribed dosage and measured activity of the dosage at the time of assay, or a notation that the total activity was determined by a calibration traceable to a national standard;~~

~~(4) Date and time of the assay or calibration and the date and time of the administration; and~~

~~(5) Initials of the individual who performed the assay or documentation of the supplier's participation in the measurement quality assurance program specified in He P 4035.19(b).~~

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

(a) Sealed sources ~~manufactured and distributed by persons specifically licensed pursuant to He P 4032 or equivalent provisions of the U.S. Nuclear Regulatory Commission, Agreement State, or Licensing State and that do not exceed 555-1.11 megabeequerels-gigabecquerels (15-30 mCimillicuries) 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 ~~radioactive-byproduct~~ material with a half-life of ~~100-120~~ days or less in individual amounts not to exceed 555 megabecquerels (15 ~~mCi~~ millicuries);

(c) Any ~~radioactive-byproduct~~ material with a half-life greater than ~~100-120~~ days in individual amounts not to exceed 7.4 megabecquerels (200 ~~µCi~~ microcuries) each or 1000 times the quantities listed in He-P 4092.01; and

(d) Technetium-99m in individual amounts ~~not to exceed 1.85 gigabecquerels (50 mCi) 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 ~~the~~ DHHS/~~BRHRHS~~; and

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

(b) A licensee in possession of a sealed source shall ~~assure~~ 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 ~~the~~ DHHS/~~BRHRHS~~, or another ~~A~~ agreement ~~S~~ state, ~~a~~ Licensing ~~State~~, or the ~~U.S.~~ Nuclear Regulatory Commission in the Sealed Source and Device Registry.

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

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

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

(3) Test samples are taken when the device containing the source is in the “off” position.

(d) A licensee shall retain leak test records for ~~5~~ 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 (~~μCi~~microcuries);
 - (6) ~~A description of the method used to measure each test sample~~The date of the test; and
 - (7) The ~~date of the test; and~~name of the individual who performed the test.
 - (8) ~~The signature of the Radiation Safety Officer.~~
- (f) If the leak test reveals the presence of 185 becquerels (0.005 ~~μCi~~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 ~~the~~DHHS/BRH-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 ~~radioactive byproduct~~ material with a ~~half life~~half-life of less than 30 days;
 - b. Sources containing only ~~radioactive byproduct~~ material as a gas;
 - c. Sources containing 3.7 megabecquerels (100 ~~μCi~~microcuries) or less of beta or ~~photon~~gamma-emitting material or 370 kilobecquerels (10 ~~μCi~~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 3-6 months.
- (i) The licensee shall retain each sealed source inventory record for 5-3 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 ~~signature of the Radiation Safety Officer~~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 ~~signature of the Radiation Safety Officer~~name of the individual who performed the survey.

He-P 4035.22 ~~Syringe Shields and Labels.~~Reserved.

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

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

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

He-P 4035.23 Vial Shields and Labels.

~~(a) A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield. Each syringe and vial that contains unsealed byproduct material shall be labeled to identify the radioactive drug.~~

~~(b) A licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical with the radiopharmaceutical name or its abbreviation. 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 Dose-Exposure Rate and Contamination.

~~(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 radiopharmaceuticals-unsealed byproduct material requiring a written directive are prepared for use or administered.~~

~~(b) A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored 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 conduct the surveys required by He-P 4035.25(a) and (b) so as to be able to measure dose rates as low as 1.0 microsievert (0.1 mrem) per hour.~~

~~(d) A licensee shall:~~

~~(1) Establish dose rate action levels for the surveys required by He-P 4035.24(a) and (b); and~~

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

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

~~(f) A licensee shall conduct the surveys required by He-P 4035.24(e) so as to be able to detect contamination as required by He-P 4021.21.~~

~~(g) A licensee shall:~~

~~(1) Establish removable contamination action levels for the surveys required by He-P 4035.24(e); and~~

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

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

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

~~(53) The serial number and the model number of the instrument used to make the survey or analyze the samples; and~~

~~(64) The initials-name of the individual who performed the survey.~~

He-P 4035.25 Release of ~~Patients or Human Research Subjects~~Individuals Containing Radiopharmaceuticals—Unsealed Byproduct Material or Permanent Implants Containing Byproduct Material.

~~(a) A licensee shall not authorize release from confinement for medical care any patient or human research subject administered a radiopharmaceutical until either;~~shall authorize the release from its control of any individual who has been administered unsealed byproduct material if:

~~(1) The dose rate from the patient or human research subject is less than 50 microsieverts (5 mrem) per hour at a distance of one meter; or~~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 activity in the patient or human research subject is less than 1.11 gigabecquerel (30 mCi);~~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” available as a PDF document @www.nrc.gov/reading-rr,NRC Library, show that the released individual is not likely to cause doses exceeding 5 millisieverts (0.5 rem).

~~(b) A licensee shall not authorize release from confinement for medical care any patient or human research subject administered a permanent implant until the dose rate from the patient or human research subject is less than 50 microsieverts (5 mrem) per hour at a distance of 1 meter. 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 ~~Mobile Nuclear Medicine Service Technical Requirements~~ Provision of Mobile Medical Service.

(a) A licensee providing mobile ~~nuclear medicine~~ 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, including:

- 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.

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

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

~~(c) Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at an area of use;~~

~~(d) In addition to complying with He-P 4035.17 and He-P 4035.18, check survey instruments and dose calibrators for constancy and response, and check all other transported equipment for proper function before medical use at each area of use (e) Carry a survey meter calibrated in accordance with He-P 4035.18 in each vehicle that is being used to transport radioactive material;~~

~~(f) Before leaving a client area of use, survey all areas of radiopharmaceutical use with a radiation detection survey instrument to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed;~~

~~(g) Retain a record of each survey required by He-P 4035.26(f) for 3 years, including:~~

- ~~(1) The date of the survey;~~
- ~~(2) A plan of each area that was surveyed;~~
- ~~(3) The measured dose rate at several points in each area of use expressed in microsieverts (mrem) per hour;~~
- ~~(4) Any removable contamination expressed in becquerels (dpm) per 100 square centimeters;~~
- ~~(5) The model and serial number of the instrument used to make the survey; and~~
- ~~(6) The initials of the individual who performed the survey; and~~

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

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

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

~~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.~~

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

He-P 4035.28 Decay-In-Storage.

(a) A licensee may hold radioactive byproduct material for decay-in-storage if the material has a physical half-life of less than 65 or equal to 120 days, ~~or, if the DHHS/BRH has approved it, material of longer half life.~~

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

~~(1) Holds radioactive material for decay a minimum of 10 half live~~

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

~~(23)~~ Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers; and

~~(44)~~ ~~Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal~~Manages as biomedical waste after they have been released from the licensee.

(c) For radioactive-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 radioactive-byproduct material was placed in storage;

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

(4) The background ~~dose rate~~radiation level;

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

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

He-P 4035.29 Use of Radiopharmaceuticals for Uptake, Dilution, or Excretion Studies. ~~A licensee may use any radioactive material in a radiopharmaceutical for a diagnostic use involving measurements of uptake, dilution, or excretion.~~ 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.

~~(a) Which has been granted acceptance or approval by the U.S. Food and Drug Administration; or~~

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

He-P 4035.30 Possession of Survey Instrument for Use of Radiopharmaceuticals for Uptake, Dilution, or Excretion Studies -Reserved.

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

~~(b) The instrument in (a) above shall be operable and calibrated in accordance with He P 4035.18.~~

He-P 4035.31 Use of Radiopharmaceuticals, Generators, and Reagent Kits-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(k), 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.

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

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

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

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

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

He-P 4035.32 ~~Radionuclide Contaminants 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 (0.004 microcurie of molybdenum-99 per 0.027 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 0.0005 microcurie of strontium-85 per 0.027 millicurie of rubidium-82 chloride injection (0.005 microcurie of strontium-85 per 0.0027 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), 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.~~

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

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

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

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

~~(b) A licensee preparing radiopharmaceuticals from radionuclide generators shall measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for the generator system, to determine compliance with the limits specified in He-P 4035.32(a).~~

~~(c) A licensee who must measure radionuclide contaminant concentration shall retain a record of each measurement for 3 years.~~

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

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

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

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

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

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

~~(e) A licensee shall report immediately to the DHHS/BRH each occurrence of radionuclide contaminant concentration exceeding the limits specified in He-P 4035.32(a).~~

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 Possession of Survey Instruments for Use of Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and Localization Studies.~~ Reserved.

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

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

~~He-P 4035.35 Use of Radiopharmaceuticals for Therapy. A licensee may use any radioactive material in a radiopharmaceutical and for a therapeutic use.~~ 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) Prepared by, excluding (a) above, is 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 DHHS/RHS, 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.

~~(a) Which has been granted acceptance or approval by the FDA; or~~

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

~~He-P 4035.36 Safety Instruction for Use of Radiopharmaceuticals for Therapy 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 ~~undergoing radiopharmaceutical therapy~~ 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 ~~R~~adiation ~~S~~safety ~~O~~fficer, 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 for workers 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 ~~the~~ DHHS/~~BRH~~ RHS for 3 years.

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

(a) For each patient or human research subject ~~receiving radiopharmaceutical therapy and hospitalized for compliance with~~ 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) 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 administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of He P 4020, He P 4021, and He P 4022 and retain for 3 years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in microsieverts (mrem) per hour, the instrument used to make the survey, and the initials of the individual who made the survey;~~

(5) 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 and with no interposed shielding, or handle these materials and items as radioactive waste.;

~~(6) Instruct the patient or human research subject and, where appropriate, the patient's or human research subject's family, orally and in writing concerning radiation safety precautions that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient or human research subject;~~

~~(7) Survey the patient's or human research subject's room and private sanitary facility for removable contamination with a radiation detection survey instrument to ensure that the removable contamination is less than 3.33 becquerels (200 dpm) per 100 square centimeters before assigning another patient or human research subject to the room;~~

~~(8) Measure the thyroid burden of each individual who helped prepare or administer a dosage of Iodine 131 within 3 days after administering the dosage; and~~

~~(9) Retain for the period required by He P 4021.07 a record of each thyroid burden measurement, date of measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.~~

~~(b) For each non hospitalized patient or human research subject receiving radiopharmaceutical therapy, the licensee shall instruct the patient or human research subject and, where appropriate, the patient's or human research subject's family, orally and in writing concerning radiation safety precautions that will help to keep radiation doses to the household members and the public as low as reasonably achievable.~~

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

He-P 4035.38 Possession of Survey Instruments for Use of Radiopharmaceuticals for Therapy. 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 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. Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child 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.

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

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

~~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 licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.~~

~~(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 Availability of Survey Instruments for Use of Sealed Sources for DiagnosisTherapy-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; A licensee authorized to use radioactive material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range 1 microsievert (0.1 mrem) per hour to 1,000 microsieverts (100 mrems) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (1 mrem) per hour to 10 microsieverts (1,000 mrems) per hour.~~

~~(b) The survey instrument shall be operable and calibrated in accordance with He-P 4035.18-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 ~~the following sources in accordance with the manufacturer's radiation safety and handling instructions~~only brachytherapy sources for therapeutic medical use:

~~(a) Cesium 137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;As approved in the Sealed Source and Device Registry; or~~

~~(b) Cobalt 60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;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.~~

~~(c) Gold 198 as a sealed source in seeds for interstitial treatment of cancer;~~

~~(d) Iodine 125 as a sealed source in seeds for interstitial treatment of cancer;~~

~~(e) Iridium 192 as seeds encased in nylon ribbon for interstitial treatment of cancer;~~

~~(f) Strontium 90 as a sealed source in an applicator for treatment of superficial eye conditions;~~
and

~~(g) Palladium 103 as a sealed source in seeds for the interstitial treatment of cancer.~~

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

~~(a) The licensee shall provide oral and written radiation safety instruction to all personnel caring for a patient or human research subject receiving implant therapy 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 in case of a dislodged source;

(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 ~~R~~radiation ~~S~~safety ~~O~~fficer, 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 ~~implant brachy~~therapy 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 ~~radiation brachy~~therapy 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 ~~R~~radiation ~~S~~safety ~~O~~fficer;

(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.

(bc) The ~~R~~adiation ~~S~~safety ~~O~~fficer, 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 ~~Inventory~~Accountability.

~~(a) Each time brachytherapy sources are returned to an area of storage from an area of use, the licensee shall immediately count or otherwise verify the number returned to ensure that all sources taken from the storage area have been returned. 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 subject, return brachytherapy sources to a secure storage area.

~~(b) A licensee shall ~~make~~maintain a record of ~~brachytherapy source~~brachytherapy source utilization ~~accountability for 3 years~~which includes:~~

(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)~~ 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)~~ 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 ~~they~~ source(s) were returned to storage, and the name of the individual who returned ~~them~~ source(s) to storage; and

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

~~(1) The names of the individuals permitted to handle the sources;~~

~~(2) The number and activity of sources removed from storage, the room number of use or patient's or human research subject's name, the time and date they were removed from storage, the number and activity of sources in storage after the removal, and the initials of the individual who removed the sources from storage; and~~

~~(3) The number and activity of sources returned to storage, the room number of use or patient's or human research subject's name, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual~~

~~who returned the sources to storage.~~

~~(e) Immediately after implanting sources in a patient or human research subject and immediately after removal of sources from a patient or human research subject, the licensee shall make a radiation survey of the patient or human research subject and the area of use to confirm that no sources have been misplaced.~~

~~(d) The licensee shall make a record of each survey.~~

~~(e) A licensee shall maintain the records required in He P 4035.44(b) and (d) for 3 years.~~

He-P 4035.45 Release of Patients or Human Research Subjects Treated with Temporary Implants
Surveys After Source Implant/Removal and Surveys of Individuals Treated With a Remote Afterloader Unit.

(a) Immediately after removing the last temporary implant source from a patient or human research subject, the licensee shall make a radiation survey of the patient or human research subject with a radiation detection survey instrument to confirm that all sources have been removed.
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) The licensee shall not release from confinement for medical care a patient or human research subject treated by temporary implant until all sources have been removed.
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, name of the patient or human research subject, the dose rate from the patient or human research subject expressed as microsieverts (mrems) per hour and measured within 1 meter from the patient or human research subject, and the initials-name of the individual who made the survey.

He-P 4035.46 46 Possession of Survey Instruments for Use
Calibration Measurements of Brachytherapy Sources.

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

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

(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).

(c) 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.

(d) 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.

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

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

He-P 4035.47 Use of a Sealed Source in a ~~Teletherapy Unit~~Remote Afterloader unit, Teletherapy Units, or Gamma Stereotactic Radiosurgery Units. A licensee shall use ~~cobalt-60 or cesium-137~~ as a sealed source in a teletherapy unit for medical use in accordance with the manufacturer's radiation safety and operating instructions.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 Stereotactic Radiosurgery Units.~~Maintenance and Repair Restrictions for Sealed Source Teletherapy.~~ Only a person specifically licensed by the DHHS/BRH, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform teletherapy unit maintenance and repair shall install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source or maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.

(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 a Sealed Source in Teletherapy 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 ~~teletherapy remote afterloader unit, the teletherapy unit, or the gamma stereotactic radiosurgery~~ unit within the treatment room;

(c) Using the ~~teletherapy 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 ~~teletherapy therapy~~ treatment room;

(d) Relocating the ~~teletherapy 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 ~~teletherapy authorized medical~~ physicist.

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

(a) A licensee shall: ~~post written instructions at the teletherapy unit console.~~

(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) The instructions required in He-P 4035.50(a) shall inform the operator of: A copy of the procedures required by He-P 4035.50(a)(4) shall be physically located at the unit console.~~

~~(1) The procedure to be followed to ensure that only the patient or human research subject is in the treatment room before turning the primary beam of radiation "on" to begin a treatment or after a door interlock interruption;~~

~~(2) The procedure to be followed if the operator is unable to turn the primary beam of radiation "off" with controls outside the treatment room or any other abnormal operation occurs; and~~

~~(3) The names and telephone numbers of the authorized users and Radiation Safety Officer to be immediately contacted if the teletherapy unit or console operates abnormally.~~

~~(c) A licensee shall provide instruction in the topics identified in He-P 4035.50(a) to all individuals who operate a teletherapy unit and shall provide appropriate refresher training to individuals at intervals not to exceed one year, 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 maintain a record of individuals receiving instruction required by He-P 4035.50(e), a description of the instruction, the date of instruction, and the name of the individual who~~

~~gave the instruction for 3 years.~~ 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 ~~Sealed Source Teletherapy~~Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units.

(a) A licensee shall control access to the ~~teletherapy treatment~~ room by a door at each entrance.

(b) A licensee shall equip each entrance to the ~~teletherapy treatment~~ room with an electrical interlock system that shall:

(1) Prevent the operator from ~~turning the primary beam of radiation "on"~~initiating the treatment cycle unless each treatment room entrance door is closed;

(2) ~~Turn the beam of radiation "off" immediately~~Cause the source(s) to be shielded when an entrance door is opened; and

(3) Prevent the ~~primary beam of radiation from being turned "on"~~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 ~~equip each entrance to the teletherapy room with a beam condition indicator light~~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) ~~A licensee shall have in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status~~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 radiation.

~~(e) Each radiation monitor shall be capable of providing visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source.~~ 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) The visible indicator of high radiation levels shall be observable by an individual entering the teletherapy room.~~ In addition to the requirements specified in He-P 4035.51(a) through (d), 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) Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit.~~ 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.

~~(h) A radiation monitor shall be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients or human research subjects.~~

~~(i) A licensee shall retain for 3 years a record of the check required He P 4035.51(h) including the date of the check, notation that the monitor indicates when the source is exposed, and the initials of the individual who performed the check.(j) If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism.~~

~~(k) The radiation monitoring instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use.~~

~~(l) The licensee shall keep a record of the instrument checks as described in He P 4035.51(i).~~

~~(m) A licensee shall promptly repair or replace the radiation monitor if it is inoperable.~~

~~(n) A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient or human research subject from the teletherapy unit console during irradiation.~~

He-P 4035.52 Possession of Survey Instrument for Use of Sealed Source Teletherapy. 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.

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

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

He-P 4035.53 Dosimetry Equipment ~~for Sealed Source Teletherapy.~~

~~(a) 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 ~~by 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 ~~cobalt-60~~ sealed sources for teletherapy units, the licensee shall use a ~~teletherapy unit with a cobalt-60 source~~ 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) ~~When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.~~ 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 ~~have available a dosimetry system for spot-check measurements,~~ 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.

~~(i) The system required in He-P 4035.53(g) may be compared with a system that has been calibrated in accordance with He-P 4035.53(a) through (g) which shall:~~

~~(1) Have been performed within the previous year and after each servicing that may have affected system calibration; and~~

~~(2) Be the same system used to meet the requirement in He-P 4035.53 (a) through (g).~~

~~(j) The licensee shall maintain a record of each calibration, intercomparison, and comparison for the duration of the license.~~

~~(k) For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by He-P 4035.53(a) through (i), the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine.~~

He-P 4035.54 Full Calibration Measurements for Use of Sealed Source 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 ~~the measurements required for annual calibration by “Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40,” Medical Physics, Vol. 21, No. 4, 1994, pp. 581-618~~ published protocols accepted by nationally recognized ~~bodies~~.

(e) A licensee shall correct mathematically the outputs determined in He-P 4035.54(b)(1) for physical decay for intervals not exceeding one month for cobalt-60, ~~and~~ intervals not exceeding 6 months for cesium-137, or at intervals consistent with 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, teletherapy physicist named on the licensee’s license or authorized by a license issued by the NRC or an Agreement State to perform such services.~~

(g) A licensee 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(a) 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(a) 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.

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

(hv) The record in (gu) 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 for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer accuracy for a typical treatment time, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist.

He-P 4035.55 Periodic Spot-Checks for Use of Sealed Source 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:

(b) To satisfy the requirement of He P 4035.55(a), spot checks shall include determination of:

(1) Timer constancy 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(~~ba~~)(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).

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

(~~dc~~) A licensee shall have the ~~teletherapy-authorized medical~~ physicist review the results of each output spot-check within 15 days.

(~~e~~) ~~The teletherapy-~~The authorized medical physicist shall promptly notify the licensee in writing of the results of each output spot-check.

(~~f~~) ~~The licensee shall keep a copy of each written notification for 3 years.~~

(~~gd~~) 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:

(~~h~~) ~~To satisfy the requirement of He P 4035.55(g), safety spot checks shall assure proper operation of:~~

(1) Electrical interlocks at each teletherapy room entrance;

(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation restriction of source housing angulation or elevation, carriage or stand travel, and operation of the beam “on-off” mechanism;

(3) ~~Beam condition~~Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) Viewing and intercom systems;

(5) Treatment room doors from inside and outside the treatment room; and

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned “off”.

(~~ie~~) A licensee shall lock the control console in the “off” position if any ~~door interlocks system~~ malfunctions, until the interlock system is repaired or unless use is specifically authorized by the

~~DHHS/BRH~~ and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

~~(j) A licensee shall not use and shall promptly repair any system identified in He-P 4035.55(h) that is not operating properly.~~

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

(l) The record shall include:

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for both the teletherapy unit and source;

(3) The manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit;

(4) The measured timer ~~accuracy~~ 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 measured timer accuracy for a typical treatment time;~~

~~(8) The calculated "on-off" error, the estimated determined accuracy of each distance measuring or localization device;~~

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

~~(10) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam conditions source exposure indicator light, the viewing and intercom system and doors; and~~

(11) The ~~signature~~ 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(o)(1), spot-checks shall, at a minimum:

(1) ~~Assure~~ 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.

(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 ~~Teletherapy~~ Therapy Facilities.

~~(a) Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by He P 4035.49, the licensee shall perform radiation surveys with an operable radiation measurement survey instrument calibrated in accordance with He P 4035.18 to verify that:~~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 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.~~

~~(1) The maximum and average radiation levels at one meter from the teletherapy source with the source in the "off" position and the collimators set for a normal treatment field do not exceed 100 microsieverts (10 mrems) per hour and 20 microsieverts (2 mrems) per hour, respectively; and~~

~~(2) With the teletherapy source in the "on" position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that:~~

~~a. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in He P 4020.05; and~~

~~b. Radiation levels in unrestricted areas do not exceed the limits specified in He P 4020.13.~~

~~(b) If the results of the surveys required in He P 4035.56(a) indicate any radiation levels in excess of the respective limit specified in that paragraph, the licensee shall lock the control in the "off" position and not use the unit:~~

~~(1) Except as may be necessary to repair, replace, or test the teletherapy unit, the teletherapy unit shielding, or the treatment room shielding; or~~

~~(2) Until the licensee has received a specific exemption from the DHHS/BRH.~~

~~(c) A licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license.~~

~~(d) The record required in He P 4035.56(c) shall include:~~

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

~~(2) The reason the survey is required;~~

~~(3) The manufacturer's name, model number and serial number of the teletherapy unit;~~

~~(4) The source, and the instrument used to measure radiation levels;~~

~~(5) Each dose rate measured around the teletherapy source while in the "off" position and the average of all measurements;~~

~~(6) A plan of the areas surrounding the treatment room that were surveyed;~~

~~(7) The measured dose rate at several points in each area expressed in microsieverts (mrems) per hour;~~

~~(8) The calculated maximum level of radiation over a period of one week for each restricted and unrestricted area; and~~

~~(9) The signature of the Radiation Safety Officer.~~

~~He-P 4035.57 Safety Spot Checks for Teletherapy Facilities 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.~~

~~(a) A licensee shall promptly spot check all systems listed in He P 4035.55(h) for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by He P 4035.49.~~

~~(b) If the results of the spot checks required in He P 4035.57(a) indicate the malfunction of any system specified in He P 4035.55, the 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.~~

~~(c) A licensee shall maintain a record of the facility checks following installation of a source for 3 years.~~

~~(d) The record required in He P 4035.57(e) shall include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, doors, and the signature of the Radiation Safety Officer.~~

~~He-P 4035.58 Modification of Teletherapy Unit or Room Before Beginning a Treatment Program. If the survey required by He P 4035.56 indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by He P 4020.13, before beginning the treatment program the licensee shall:~~Reserved.

~~(a) Either equip the unit with stops or add additional radiation shielding to ensure compliance with He P 4020.13;~~

~~(b) Perform the survey required by He P 4035.56 again; and~~

~~(c) Include in the report required by He P 4035.59 the results of the initial survey, a description of the modification made to comply with He P 4035.58(a) and the results of the second survey; or~~

~~(d) Request and receive a license amendment under He P 4020.13(c) and (d) that authorizes radiation levels in unrestricted areas greater than those permitted by He P 4020.13(a).~~

~~He-P 4035.59 Reports of Teletherapy Surveys, Checks, Tests and Measurements 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 Committee 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) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:~~

~~(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 Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by He-P 4035.59(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.

A licensee shall furnish a copy of the records required in He P 4035.56, He P 4035.57, and He P 4035.58, and the output from the teletherapy source expressed as grays (rads) per hour at one meter from

~~the source and determined during the full calibration required in He-P 4035.54, to the DHHS/BRH within 30 days following completion of the action that initiated the record requirement.~~

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 ~~teletherapy~~ source replacement or at intervals not to exceed 5 years, whichever comes first, to ~~assure~~ 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 ~~the~~ DHHS/~~BRH~~RHS, an ~~A~~greement ~~S~~state, or the ~~U.S.~~ Nuclear Regulatory Commission.

(c) A licensee shall maintain a record of the inspection and servicing for the duration of ~~the~~ licenseuse 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 ~~teletherapy~~ 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.~~6271~~, the licensee shall require an individual fulfilling the responsibilities of the ~~R~~adiation ~~S~~safety ~~O~~fficer as provided in He-P 4035.08 ~~shall to be an individual who:~~

~~(a) is certified by a specialty board whose certification process has been recognized by the DHHS/RHS, or an agreement state, or the Nuclear Regulatory Commission, and who 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.

Be certified by the:

(1) American Board of Health Physics in Comprehensive Health Physics;

(2) American Board of Radiology;

(3) American Board of Nuclear Medicine;

(4) American Board of Science in Nuclear Medicine;

~~(5) The American Board of Medical Physicists in Radiation Oncology Physics;~~

~~(6) Board of Pharmaceutical Specialties in Nuclear Pharmacy;~~

~~(7) Royal College of Physicians and Surgeons of Canada in Nuclear Medicine;~~

~~(8) American Osteopathic Board of Radiology; or~~

~~(9) American Osteopathic Board of Nuclear Medicine;~~

~~(b) Meet the following requirements:~~

~~(1) Have had 200 hours of classroom and laboratory training covering:~~

~~a. Radiation physics and instrumentation;~~

~~b. Radiation protection;~~

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

~~d. Radiation biology; and~~

~~e. Radiopharmaceutical chemistry; and~~

~~(2) Have had one year of full time experience in radiation safety at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on an DHHS/BRH, Agreement State, Licensing State, or U.S. Nuclear Regulatory Commission license that authorizes the medical use of radioactive material; or~~

~~(c) Be an authorized user for those radioactive material uses that come within the Radiation Safety Officer's responsibilities.~~

~~He-P 4035.62 Training for Experienced Radiation Safety Officer. An individual identified as a Radiation Safety Officer on an DHHS/BRH, Agreement State, Licensing State, or U.S. Nuclear Regulatory Commission license on October 1, 1986 who oversees only the use of radioactive material for which the licensee was authorized on that date need not comply with the training requirements of He-P 4035.61. Reserved.~~

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

(a) Except as provided in He-P 4035.71 ~~and He-P 4035.72~~, the licensee shall require the authorized user of ~~a radiopharmaceutical~~ unsealed byproduct material listed in He-P 4035.29-27 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 34035.27; 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.

~~in:~~

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

~~a. Nuclear medicine by the American Board of Nuclear Medicine;~~

~~b. Diagnostic radiology by the American Board of Radiology;~~

~~c. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;~~

~~d. Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or~~

~~e. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or~~

(2) Has completed Complete 40-60 hours of instruction training and experience in basic radionuclide handling techniques and radiation safety applicable to the use of prepared radiopharmaceuticals 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).

~~and 20 hours of supervised clinical experience as follows:~~

~~a. To satisfy the basic instruction requirement, 40 hours of classroom and laboratory instruction shall include:~~

- ~~1. Radiation physics and instrumentation;~~
- ~~2. Radiation protection;~~
- ~~3. Mathematics pertaining to the use and measurement of radioactivity;~~
- ~~4. Radiation biology; and~~
- ~~5. Radiopharmaceutical chemistry; and~~

~~b. To satisfy the requirement for 20 hours of supervised clinical experience, training must be under the supervision of an authorized user at a medical institution and shall include:~~

- ~~1. Examining patients or human research subjects and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;~~
- ~~2. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;~~
- ~~3. Administering dosages to patients or human research subjects and using syringe radiation shields;~~
- ~~4. Collaborating with the authorized user in the interpretation of radionuclide test results; and~~

~~5. Patient or human research subject follow-up; or~~

- ~~(3) Has successfully completed a 6-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in He-P 4035.63(a)(2).~~
- ~~(b) Classroom and laboratory training in all the topics identified in He-P 4035.63(a)(2)a., which is not part of a residency program as in He-P 4035.63(a)(3), shall:~~

- ~~(1) Be obtained in a medical teaching institution; or~~
- ~~(2) Be approved by the Accreditation Council for Continuing Medical Education (ACCME) or the Committee on Postdoctoral Training of the American Osteopathic Association (CPTAOA).~~

~~(c) The clinical experience described in He-P 4035.63(a)(2)b. shall be supervised by a physician licensed for the full scope of diagnostic nuclear medicine procedures.~~
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).

~~(a) Except as provided in He P 4035.71 and He P 4035.72, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit specified in He P 4035.32~~

~~to be a physician who:~~

~~(1) Is certified in:~~

- ~~a. Nuclear medicine by the American Board of Nuclear Medicine;~~
- ~~b. Diagnostic radiology by the American Board of Radiology;~~
- ~~c. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;~~
- ~~d. Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or~~
- ~~e. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or~~

~~(2) Has completed 200 hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, 500 hours of supervised work experience, and 500 hours of supervised clinical experience, as follows:~~

~~a. To satisfy the basic instruction requirement, 200 hours of classroom and laboratory training shall include:~~

- ~~1. Radiation physics and instrumentation;~~
- ~~2. Radiation protection;~~
- ~~3. Mathematics pertaining to the use and measurement of radioactivity;~~
- ~~4. Radiopharmaceutical chemistry; and~~
- ~~5. Radiation biology;~~

~~b. To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:~~

- ~~1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;~~
- ~~2. Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;~~
- ~~3. Calculating and safely preparing patient or human research subject dosages;~~
- ~~4. Using administrative controls to prevent the misadministration of radioactive material;~~
- ~~5. Using emergency procedures to contain spilled radioactive material safely and using proper decontamination procedures; and~~
- ~~6. Eluting technetium-99m from generator systems, assaying and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and~~

~~e. To satisfy the requirement for 500 hours of supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:~~

- ~~1. Examining patients or human research subjects and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;~~
- ~~2. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;~~
- ~~3. Administering dosages to patients or human research subjects and using syringe radiation shields;~~
- ~~4. Collaborating with the authorized user in the interpretation of radionuclide test results; and~~
- ~~5. Patient or human research subject follow up; or~~

~~(3) Has successfully completed a 6-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in He-P 4035.64(a)(2).~~

~~(b) Classroom and laboratory training in all the topics identified in He-P 4035.64(a)(2)a., which is not part of a residency program as in He-P 4035.64(a)(3), shall:~~

~~(1) Be obtained in a medical teaching institution; or~~

~~(2) Be approved by the Accreditation Council for Continuing Medical Education (ACCME) or the Committee on Postdoctoral Training of the American Osteopathic Association (CPTAOA).~~

~~(c) The clinical experience described in He-P 4035.64(a)(2)b. shall be supervised by a physician licensed for the full scope of diagnostic nuclear medicine procedures.~~

~~(d) The experience in He-P 4035.64(a)(2)a. and (a)(2)b. may be obtained concurrently.~~

~~He-P 4035.65 Training for Therapeutic Use of Radiopharmaceuticals Use of Unsealed Byproduct Material for Which a Written Directive Is Required. Except as provided in He-P 4035.71, the licensee shall require the authorized user of a radiopharmaceutical listed in He-P 4035.36 for therapy to be a physician who:~~

~~(a) 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 U.S. 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)(4)ba.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 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 ~~a~~ 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).

(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.

~~(a) Is certified in:~~

- ~~(1) Nuclear medicine by The American Board of Nuclear Medicine;~~
- ~~(2) Radiation oncology, therapeutic radiology, or radiology by The American Board of Radiology;~~
- ~~(3) Nuclear medicine or radiation oncology by the American Osteopathic Board of Radiology after 1984; or~~
- ~~(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada;~~

~~(b) Has completed 80 hours of instruction in basic radionuclide handling techniques applicable to the use of therapeutic radiopharmaceuticals, and has had supervised clinical experience, as follows:~~

- ~~(1) To satisfy the requirement for instruction, 80 hours of classroom and laboratory training shall include:
 - ~~a. Radiation physics and instrumentation;~~
 - ~~b. Radiation protection;~~~~

~~e. Mathematics pertaining to the use and measurement of radioactivity; and~~

~~d. Radiation biology; and~~

~~(2) To satisfy the requirement for supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:~~

~~a. Use of iodine 131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in ten individuals;~~

~~b. Use of soluble phosphorus 32 for the treatment of ascites, polycythemia vera, leukemia, or bone metastases in three individuals;~~

~~e. Use of iodine 131 for treatment of thyroid carcinoma in three individuals;~~

~~d. Use of colloidal chromic phosphorus 32 or of colloidal gold 198 for intracavitary treatment of malignant effusions in three individuals; and~~

~~e. Use of strontium 89 as strontium chloride for the treatment of pain associated with bone metastases in 3 individuals; or~~

~~(c) Has successfully completed a 6 month training program in nuclear medicine as part of a residency program that has been approved by the Accreditation Council for Graduate Medical Education (ACGME) which included classroom and laboratory training, work experience and supervised clinical experience and supervised clinical experience in all the topics identified in He-P 4035.65(b).~~

~~He-P 4035.66 Training for Therapeutic Use of Brachytherapy Source 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 using a brachytherapy source specified in He-P 4035.41 for therapy 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 in 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: Has successfully completed 80 hours of classroom and laboratory training,~~

applicable to the medical use of sodium iodide I-131 for procedures.

(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(c) and (d), 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. and (c)(2)b.2. 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 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.1., 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 user 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(g); 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) An authorized user who does not meet the requirements of He-P 4035.65(c) above, 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. 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

(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)(1), (i)(2) and (i)(3), 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.

a. Radiology or therapeutic radiology by the American Board of Radiology;

b. Radiation oncology by the American Osteopathic Board of Radiology;

e. Radiology, with a specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

d. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(2) Is in the active practice of therapeutic radiology, has completed 200 hours of instruction in basic radionuclide handling techniques applicable to the therapeutic use of brachytherapy sources and 500 hours of supervised work experience, and a minimum of 3 years of

~~supervised clinical experience, as follows:~~

~~a. To satisfy the requirement for instruction, 200 hours of classroom and laboratory training shall include:~~

- ~~1. Radiation physics and instrumentation;~~
- ~~2. Radiation protection;~~
- ~~3. Mathematics pertaining to the use and measurement of radioactivity; and~~
- ~~4. Radiation biology;~~

~~b. To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:~~

- ~~1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;~~
- ~~2. Checking survey meters for proper operation;~~
- ~~3. Preparing, implanting, and removing sealed sources;~~
- ~~4. Using administrative controls to prevent the misadministration of radioactive material; and~~
- ~~5. Using emergency procedures to control radioactive material;~~

~~c. To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution; and~~

~~d. The supervised clinical experience in (2)c. above shall include:~~

- ~~1. Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;~~
- ~~2. Selecting the proper brachytherapy sources, dose, and method of administration;~~
- ~~3. Calculating the dose; and~~
- ~~4. Post administration follow up and review of case histories in collaboration with the authorized user.~~

~~(b) Classroom and laboratory training in all the topics identified in He P 4035.66(a)(2)a., which is not part of a residency program as in He P 4035.66(c), shall:~~

~~(1) Be obtained in a medical teaching institution; or~~

~~(2) Be approved by the Accreditation Council for Continuing Medical Education (ACCME) or the Committee on Postdoctoral Training of the American Osteopathic Association (CPTAOA).~~

~~(c) The clinical experience described in He-P 4035.66(a)(2)b. shall be supervised by a physician licensed for the full scope of therapeutic nuclear medicine procedures.~~

He-P 4035.67 Training for Ophthalmic Use of Strontium-90.

(a) Except as provided in He-P 4035.71, the licensee shall require the authorized user using only strontium-90 for ophthalmic radiotherapy to be a physician who:

(1) ~~Is certified in radiology or therapeutic radiology by the American Board of Radiology an authorized user under He-P 4035.69, or equivalent requirements of an agreement state or the Nuclear Regulatory Commission;~~ or

(2) ~~Is in the active practice of therapeutic radiology or ophthalmology, and h~~as 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, the authorized user who is a physician shall: who: Classroom and laboratory training in all the topics identified in He-P 4035.67(a)(2)a., 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.
- ~~(1) Be obtained in a medical teaching institution; or~~
- ~~(2) Be approved by the Accreditation Council for Continuing Medical Education (ACCME).~~
- (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).

~~The clinical experience described in He-P 4035.67(a)(2)b. shall be supervised by a physician licensed for the use of sealed sources in therapy.~~

He-P 4035.68 Training for Use of Sealed Sources for Diagnosis.

~~(a)~~ Except as provided in He-P 4035.71 the licensee shall require the authorized user using a diagnostic sealed source in a device specified in He-P 4035.39 to be a physician, dentist, or podiatrist who:

~~(1)(a)~~ Is certified in 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

~~a. Radiology, diagnostic radiology with special competence in nuclear radiology, or therapeutic radiology by the American Board of Radiology;~~

~~b. Nuclear medicine by the American Board of Nuclear Medicine;~~

~~c. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or~~

~~d. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or~~

~~(2)(b)~~ Has completed 8 hours of instruction in basic radionuclide handling techniques specifically applicable to the use of the device, including training in:

a. Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;

b. Radiation biology; and

c. ~~Radiation protection and training in the use of the device for the purposes authorized by the license.~~

~~(bc) Classroom and laboratory training in all the topics identified in He-P 4035.68(a)(2), shall: An individual who meets the requirements of (a) or (b) above shall completed training in the use of the device for the uses requested.~~

~~(1) Be obtained in a medical teaching institution; or~~

~~(2) Be approved by the Accreditation Council for Continuing Medical Education (ACCME) or the committee on Postdoctoral training of the American Osteopathic Association (CPTAOA).~~

~~(e) The clinical experience shall be supervised by a physician, dentist, or podiatrist licensed to use the devices.~~

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

(a) Except as provided in He-P 4035.71, the licensee shall require the authorized user of a ~~sealed source specified in He-P 4035.47 in a teletherapy unit manual brachytherapy source for the uses authorized under He-P 4035.41~~ to be a physician who:

(1) ~~Is certified in: 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 Committee on Post-Graduate Training of the American Osteopathic Association; and~~

~~b. Pass an examination, administered 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; or~~

~~c. Meets the requirement of He-P 4035.68(c).~~

~~(2) Meets the requirements in He-P 4035.69(b)(3); 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

(c) All physicians who meet the requirements of (a) and (b) above shall ~~Has~~ 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 Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by He-P 4035.69(b)(1)b; and

(d) All physicians who meet the requirements of (a) and (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, the Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in He-P 4035.69(a)(1), or He-P 4035.69(b)(1) and (b)(2), 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.

a. Radiology or therapeutic radiology by the American Board of Radiology;

b. Radiation oncology by the American Osteopathic Board of Radiology;

c. Radiology, with specialization in radiotherapy, as a British “Fellow of the Faculty of Radiology” or “Fellow of the Royal College of Radiology”; or

d. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(2) Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radionuclide techniques applicable to the use of a sealed source in a teletherapy unit, 500 hours of supervised work experience, and a minimum of 3 years of supervised clinical experience, as follows:

~~a. To satisfy the requirement for instruction, the classroom and laboratory training shall include:~~

- ~~1. Radiation physics and instrumentation;~~
- ~~2. Radiation protection;~~
- ~~3. Mathematics pertaining to the use and measurement of radioactivity; and~~
- ~~4. Radiation biology;~~

~~b. To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at an institution and shall include:~~

- ~~1. Review of the full calibration measurements and periodic spot checks;~~
- ~~2. Preparing treatment plans and calculating treatment times;~~
- ~~3. Using administrative controls to prevent misadministrations;~~
- ~~4. Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and~~
- ~~5. Checking and using survey meters;~~

~~c. To satisfy the requirement for a period of supervised clinical experience, training shall include 1 year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution; and~~

~~d. The supervised clinical experience in (2)c. above shall include:~~

- ~~1. Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;~~
- ~~2. Selecting the proper dose and how it is to be administered;~~
- ~~3. Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses as warranted by patients' or human research subjects' reaction to radiation; and~~
- ~~4. Post-administration follow-up and review of case histories.~~

~~(b) The classroom and laboratory training in all the topics identified in He P 4035.69(a)(2)a. shall:~~

- ~~(1) Be approved by the Accreditation Council for Continuing Medical Education (ACCME); or~~

~~(2) Be approved by the Committee on Postdoctoral Training of the American Osteopathic Association (CPTAOA).~~

~~(c) The supervised work and clinical experience described in He-P 4035.69(a)(2)b. and (a)(2)c. and d., respectively, shall be supervised by a physician licensed for teletherapy procedures.~~

~~(d) The experience in He-P 4035.69(a)(2)b.—c. may be obtained concurrently.~~

He-P 4035.70 Training for Teletherapy 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) The licensee shall require the teletherapy physicist to: 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 meets the requirements in He-P 4035.70(c).

(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) Holds 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) ~~h~~Hasve 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 afterloading units as applicable; and

(5) Have obtained written attestation that the individual has satisfactorily completed the requirements in He-P 4035.70(b)(1) and (b)(2) or (b)(3) and (b)(4), 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 the requirements of 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) 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.

~~(1) Be certified by the American Board of Radiology in:~~

~~a. Therapeutic radiological physics;~~

~~b. Roentgen-ray and gamma-ray physics;~~

~~c. X-ray and radium physics; or~~

~~d. Radiological physics;~~

~~(2) Be certified by the American Board of Medical Physics in radiation oncology physics; or~~

~~(3) Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full-time training in therapeutic radiological physics and also one year of full-time work experience under the supervision of a teletherapy physicist at a medical institution.~~

~~(b) To meet the requirement in He P 4035.70(a)(3), the individual shall have performed the tasks listed in He P 4035.21, He P 4035.54, and He P 4035.56 under the supervision of a teletherapy physicist during the year of work experience.~~

He-P 4035.71 ~~Training for Experienced Authorized Users~~ 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 a Nuclear 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.

~~Practitioners of the healing arts identified as authorized users for the human use of radioactive material on an DHHS/BRH, NRC, Agreement State, or Licensing State license on April 1, 1997 who perform only those methods of use for which they were authorized on that date need not comply with the training requirements of He P 4035.61 through He P 4035.73.~~

~~He-P 4035.72 Physician Training in a Three Month Program. A physician who, before July 1, 1984, began a 3 month nuclear medicine training program approved by the Accreditation Council for~~

~~Graduate Medical Education and has successfully completed the program, shall be exempt from the requirements of He-P 4035.63 or He-P 4035.64.~~Reserved.

He-P 4035.73 Recentness of Training. The training and experience specified in He-P 4035.59, and He-P 4035.61 through He-P 4035.70 shall have been obtained within the 7 years preceding the date of application, or the individual shall have had continuing-on-going education and applicable experience since the required training and experience was completed.

He-P 4035.74 Training for an Authorized Nuclear Pharmacist. ~~The-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) ~~Has current board certification as nuclear pharmacist by the Board of Pharmaceutical Specialties; or 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~~Has met the following requirements:

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

a. Didactic training in the following areas:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive-byproduct material for medical use; and
5. Radiation biology; and

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

1. Shipping, receiving, and performing related radiation surveys;
2. Using and performing checks for proper operation of ~~dose-calibrators 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 ~~mistakes—medical events~~ in the administration of ~~radioactive-byproduct~~ material;
5. Using procedures to prevent or minimize ~~radioactive~~ contamination and using proper decontamination procedures; and

(2d) In addition to the requirements in (b) and (c) above, all nuclear pharmacists shall Has obtained a written ~~certification~~attestation, signed by a preceptor authorized nuclear pharmacist, that the ~~training in (b)(1) individual~~ has ~~been~~ satisfactorily completed the requirements in He-P 4035.74(ab), or (c) (a)(2), and (a)(3) or (b)(1) and that the individual has achieved a level of competency sufficient to independently operate as an authorized nuclear pharmacy.

He-P 4035.75 ~~Training for Experienced Nuclear Pharmacist.~~Reserved.

~~(a) A licensee may apply for and shall receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist.~~

~~(b) A pharmacist who has completed a structured educational program as specified in He-P 4035.74(b) before December 2, 1994, and who is working in a nuclear pharmacy shall qualify as an experienced nuclear pharmacist.~~

~~(c) An experienced nuclear pharmacist shall not need to comply with the requirements on preceptor statement of He-P 4035.74(b)(2) and recentness of training in He-P 4035.73.~~

APPENDIX

<u>RULE</u>	<u>STATUTE OR FEDERAL REGULATION IMPLEMENTED</u>
He-P 4035	Section 274 of the AEA of 1954, as amended, and Title 10, Code of Federal Regulations (CFR), Part 35
He-P 4035.01	10 CFR 35.1
He-P 4035.02	10 CFR 35.1
He-P 4035.03	10 CFR 35.2
He-P 4035.04	10 CFR 35.11, 35.6
He-P 4035.05	10 CFR 35.12, 35.13
He-P 4035.06	10 CFR 35.14
He-P 4035.07	10 CFR 35.24, 35.26, 35.2026
He-P 4035.08	10 CFR 35.24
He-P 4035.09	10 CFR 35.24

He-P 4035.10	10 CFR 35.24, 35.2024
He-P 4035.11	10 CFR 35.27
He-P 4035.12	10 CFR 35.80, 35.2080
He-P 4035.13	10 CFR 35.40, 35.41, 35.100, 35.2040, 35.2041
He-P 4035.14	10 CFR 35.3045
He-P 4035.15	10 CFR 35.49
He-P 4035.16	10 CFR 35.60, 35.2060
He-P 4035.17	10 CFR 35.60, 35.2060
He-P 4035.18	10 CFR 35.61, 35.2061
He-P 4035.19	10 CFR 35.63, 35.2063
He-P 4035.20	10 CFR 35.65
He-P 4035.21	10 CFR 35.67, 35.2067, 35.3067
He-P 4035.22 Reserved	
He-P 4035.23	10 CFR 35.69
He-P 4035.24	10 CFR 35.70, 35.2070
He-P 4035.25	10 CFR 35.75, 35.2075
He-P 4035.26	10 CFR 35.80, 2080
He-P 4035.27	10 CFR 35.100
He-P 4035.28	10 CFR 35.92, 35.2092
He-P 4035.29	10 CFR 35.1000
He-P 4035.30 Reserved	
He-P 4035.31	10 CFR 35.200
He-P 4035.32	10 CFR 35.204, 35.2204
He-P 4035.33	RSA 125-F:5, V
He-P 4035.34 Reserved	
He-P 4035.35	10 CFR 35.300
He-P 4035.36	10 CFR 35.310, 35.2310
He-P 4035.37	10 CFR 35.315
He-P 4035.38	10 CFR 35.3047
He-P 4035.39	10 CFR 35.500
He-P 4035.40	10 CFR 35.457
He-P 4035.41	10 CFR 35.400
He-P 4035.42	10 CFR 35.410, 35.2310
He-P 4035.43	10 CFR 35.415
He-P 4035.44	10 CFR 35.406, 35.2406
He-P 4035.45	10 CFR 35.404, 35.604, 35.2404
He-P 4035.46	10 CFR 35.432, 35.2432
He-P 4035.47	10 CFR 35.600
He-P 4035.48	10 CFR 35.605, 35.2605
He-P 4035.49	10 CFR 35.12, 35.13
He-P 4035.50	10 CFR 35.610, 35.2310, 35.2610
He-P 4035.51	10 CFR 35.615
He-P 4035.52	10 CFR 35.647
He-P 4035.53	10 CFR 35.630, 35.2630
He-P 4035.54	10 CFR 35.632, 35.632, 35.633, 35.635
He-P 4035.55	10 CFR 35.642, 35.643, 35.645, 35.2642, 35.2643, 35.2645
He-P 4035.56	10 CFR 35.652, 35.2652
He-P 4035.57	10 CFR 35.657

He-P 4035.58 Reserved	
He-P 4035.59	10 CFR 35.690
He-P 4035.60	10 CFR 35.655, 35.2655
He-P 4035.61	10 CFR 35.50
He-P 4035.62 Reserved	
He-P 4035.63	10 CFR 35.190
He-P 4035.64	10 CFR 35.290
He-P 4035.65	10 CFR 35.390
He-P 4035.66	10 CFR 35.392, 35.394, 35.396
He-P 4035.67	10 CFR 35.433, 35.491
He-P 4035.68	10 CFR 35.590
He-P 4035.69	10 CFR 35.490
He-P 4035.70	10 CFR 35.51
He-P 4035.71	10 CFR 35.57
He-P 4035.72 Reserved	
He-P 4035.73	10 CFR 35.59
He-P 4035.74	10 CFR 35.44
He-P 4035.75 Reserved	