

August 5, 2009

Materials Licensing Branch  
U.S. NRC Region III  
2443 Warrenville Rd.  
Suite 210  
Lisle, IL 60532-4352

IN REFERENCE TO: MAIL CONTROL NUMBER 318337

NRC Representative:

This letter is to confirm that, pursuant to the amendment request for NRC radioactive materials license 24-32517-01 dated July 13, 2009, Kansas City Cancer Center will comply with all requirements as listed in 10 CFR sections 35.604, 35.605, 35.610, 35.615, 35.630, 35.633, 35.643, and 35.652.

Please direct any questions about this request to myself (see phone number and e-mail address below).

Sincerely,



Brian Wichman, MS  
Chief Medical Physicist, RSO  
Kansas City Cancer Centers  
913-234-0502  
[brian.wichman@usoncology.com](mailto:brian.wichman@usoncology.com)

**Department of Environmental  
Health and Safety**  
University of Louisville  
1800 Arthur Street  
Louisville, Kentucky 40208-2729

**Biological Safety**  
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**Radiation Safety**  
(502) 852-5231  
Fax: (502) 852-8911

August 5, 2009

Brian Wichman  
U. S. Oncology  
Kansas City Cancer Center

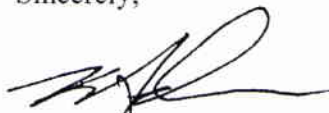
Subject: Preceptor of Dr. Kenon Qamar

Mr. Wichman:

Per your request, I verify that the Preceptor for Dr. Kenon Qamar, M.D. on HDR was Dr. Kristi Paris, M.D. Dr. Paris was an Authorized User at the University of Louisville, James Graham Brown Cancer Center for, among other things the use of Ir-192 remote afterloading brachytherapy devices. She was authorized for this use from 1995 through her departure in 2007. The University of Louisville maintains a Broadscope, Type "A" License from the State of Kentucky, #202-029-22.

Should you have any questions, please feel free to contact me at (502) 852-5231.

Sincerely,



Ken Helm  
Radiation Safety Officer

**Mullauer, James**

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To: brian.wichman@usoncology.com  
Subject: Confirmations to Part 35

Hi Brian, please provide a response signed and dated that your program will comply with all the requirements in;

10 CFR Part 35.604, 605, 610, 615, 630, 633, 643, and 652.

This can be sent along with the information concerning Dr. Qamar.

Thanks, Jim



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## Subpart H--Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

### § 35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic 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 § 35.49(a) are met.

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*brian.wichman@usoreology.com*  
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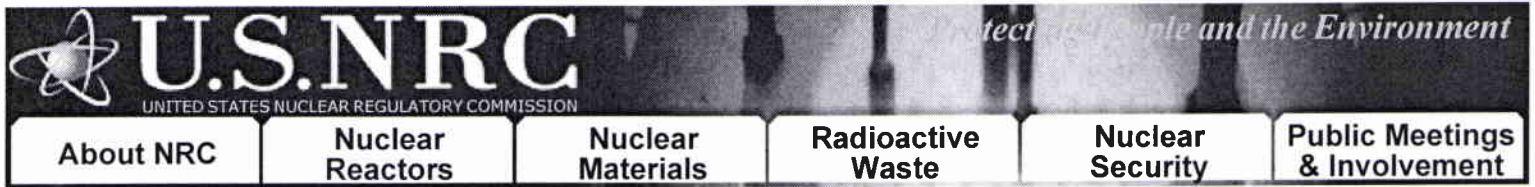
[Home](#) > [Electronic Reading Room](#) > [Document Collections](#) > [NRC Regulations \(10 CFR\)](#) > [Part Index](#) > § 35.604 Surveys of patients and human research subjects treated with a remote afterloader unit.

## § 35.604 Surveys of patients and human research subjects treated with a remote afterloader unit.

(a) Before releasing a patient or a human research subject from licensee control, a licensee shall 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.

(b) A licensee shall retain a record of these surveys in accordance with § 35.2404.

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## § 35.605 Installation, maintenance, adjustment, and repair. <sup>OK</sup>

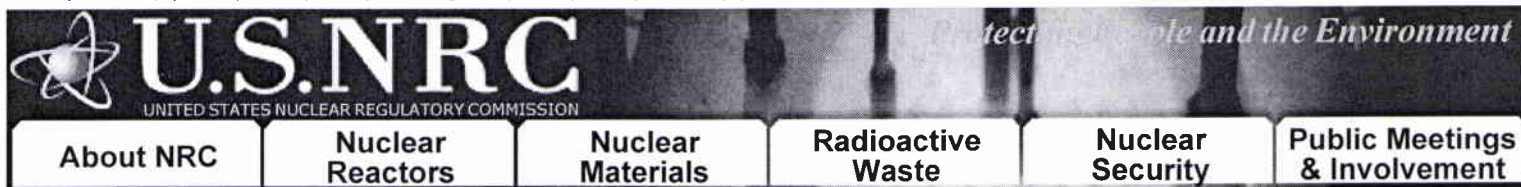
(a) Only a person specifically licensed by the Commission or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s). ✓

(b) ~~Except for low dose-rate remote afterloader units,~~ only a person specifically licensed by the Commission or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units. ✓

(c) ~~For a low dose-rate remote afterloader unit,~~ only a person specifically licensed by the Commission or an Agreement State 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 in accordance with § 35.2605. ✓

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## § 35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(a) A licensee shall--

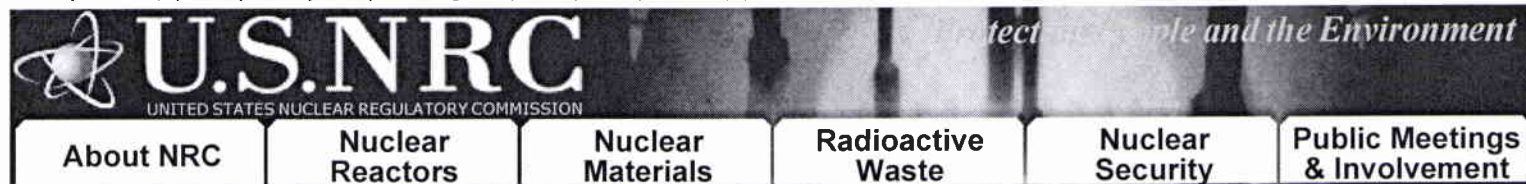
- ✓ (1) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;
- ✓ (2) Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);
- ✓ (3) Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and
- ✓ (4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include--
  - (i) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;
  - (ii) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and
  - (iii) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.
- ✓ (b) A copy of the procedures required by paragraph (a)(4) of this section must be physically located at the unit console.
- (c) A licensee shall post instructions at the unit console to inform the operator of--
  - (1) The location of the procedures required by paragraph (a)(4) of this section; and
  - (2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.
- (d) A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in--
  - (1) The procedures identified in paragraph (a)(4) of this section; and
  - (2) The operating procedures for the unit.
- (e) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.
- (f) A licensee shall retain a record of individuals receiving instruction required by paragraph (d) of this section, in accordance with § 35.2310.
- (g) A licensee shall retain a copy of the procedures required by §§ 35.610(a)(4) and (d)(2) in accordance with § 35.2610.

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## § 35.615 Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

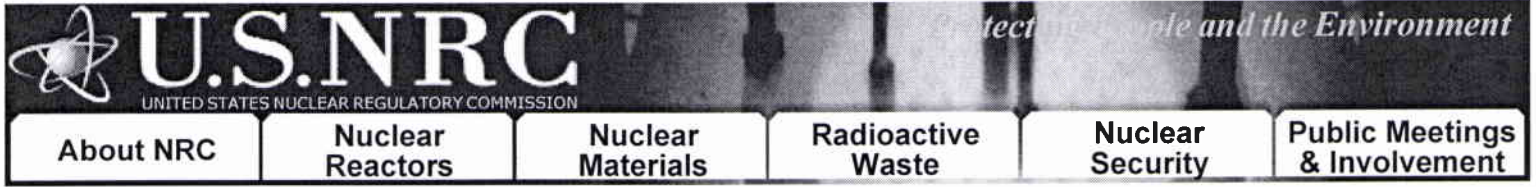
- ✓ (a) A licensee shall control access to the treatment room by a door at each entrance.
- ✓ (b) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will--
  - (1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;
  - ✓ (2) Cause the source(s) to be shielded when an entrance door is opened; and
  - ✓ (3) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.
- (c) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.
- (d) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.
- (e) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.
- (f) In addition to the requirements specified in paragraphs (a) through (e) of this section, a licensee shall--
  - (1) For medium dose-rate and pulsed dose-rate remote afterloader units, require--
    - (i) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and
    - (ii) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.
  - (2) For high dose-rate remote afterloader units, require--
    - (i) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and
    - (ii) 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.
  - (4) Notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

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✓

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

- (1) Remaining in the unshielded position; or
- (2) Lodged within the patient following completion of the treatment.

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## § 35.630 Dosimetry equipment.

(a) Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.

(1) The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous 4 years. Eighteen to thirty months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must indicate that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

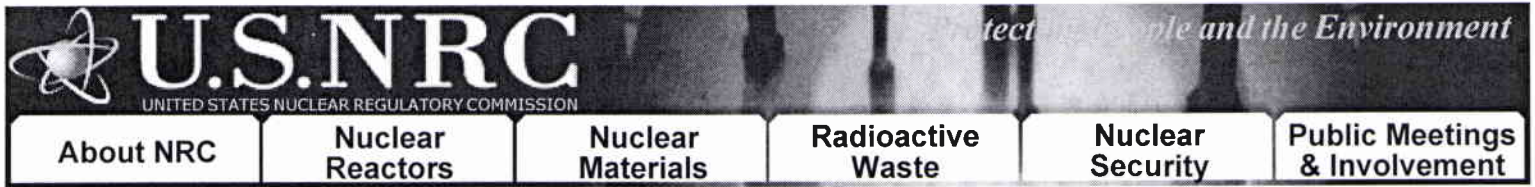
(b) The licensee shall have a dosimetry system available for use for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph (a) of this section. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in paragraph (a) of this section.

(c) The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with § 35.2630.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19326, Apr. 21, 2003]

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## § 35.633 Full calibration measurements on remote afterloader units.

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit--

- (1) Before the first medical use of the unit;
- (2) Before medical use under the following conditions:
  - (i) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and
  - (ii) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
- (3) At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and
- (4) At intervals not exceeding 1 year for low dose-rate remote afterloader units.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include, as applicable, determination of:

- (1) The output within  $\pm 5$  percent;
- (2) Source positioning accuracy to within  $\pm 1$  millimeter;
- (3) Source retraction with backup battery upon power failure;
- (4) Length of the source transfer tubes;
- (5) Timer accuracy and linearity over the typical range of use;
- (6) Length of the applicators; and
- (7) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(e) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in paragraph (b) of this section, a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding 1 quarter.

(f) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with paragraphs (a) through (e) of this section.

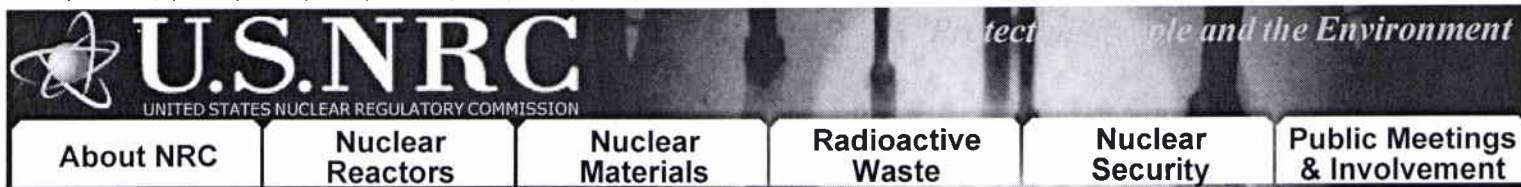
(g) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section for physical decay at intervals consistent with 1 percent physical decay.

(h) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (g) of this section must be performed by the authorized medical physicist.

(i) A licensee shall retain a record of each calibration in accordance with § 35.2632.

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## § 35.643 Periodic spot-checks for remote afterloader units.

(a) 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 remote 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.

(b) A licensee shall perform the measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

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

(d) To satisfy the requirements of paragraph (a) of this section, spot-checks must, at a minimum, assure proper operation of--

- ✓ (1) Electrical interlocks at each remote afterloader unit room entrance;
- ✓ (2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
- ✓ (3) Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;
- (4) Emergency response equipment;
- (5) Radiation monitors used to indicate the source position;
- (6) Timer accuracy;
- (7) Clock (date and time) in the unit's computer; and
- (8) Decayed source(s) activity in the unit's computer.

(e) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each check required by paragraph (d) of this section and a copy of the procedures required by paragraph (b) of this section in accordance with § 35.2643.

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## § 35.652 Radiation surveys.

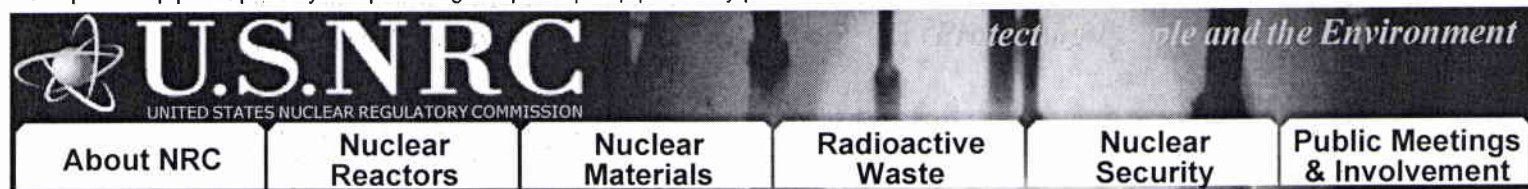
- (a) In addition to the survey requirement in § 20.1501 of this chapter, a person licensed under this subpart shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.
- (b) The licensee shall make the survey required by paragraph (a) of this section at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).
- (c) A licensee shall retain a record of the radiation surveys required by paragraph (a) of this section in accordance with § 35.2652.

*OK Confirmation*

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Kezoz Damar, M.D.



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

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

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (b)(3) and (c) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) 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 diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

(b)(1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes—

(i) 200 hours of classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements at a medical institution, involving--

(A) Reviewing full calibration measurements and periodic spot-checks;

(B) Preparing treatment plans and calculating treatment doses and times;

(C) Using administrative controls to prevent a medical event involving the use of byproduct material;

(D) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(E) Checking and using survey meters; and

(F) Selecting the proper dose and how it is to be administered; and

(2) Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic

Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b) (1)(ii) of this section; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (a)(1) or (b)(1) and (b)(2), and (c) of this section, 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 must be signed by a preceptor authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

(c) Has 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.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19326, Apr. 21, 2003; 69 FR 55739, Sep. 16, 2004; 70 FR 16366, Mar. 30, 2005; 71 FR 15011, Mar. 27, 2006]

## **Subpart I--[Reserved]**

## **Subpart J--[Reserved]**

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