

From: Lloyd Bolling
To: Kathleen Schneider; Monica Orendi; Patricia McGrady-Finneran
Date: 02/05/2007 1:07:46 PM
Subject: Fwd: HDR and Gamma Knife requirements

FYI, this appears to be a legally binding requirements package from NYS DOH. I'm not sure how they are being handled these days. Let me know if you have any questions.

Lloyd

>>> "Robert E. Dansereau" <red07@health.state.ny.us> 02/05/2007 12:39 PM >>>

Lloyd, we issued amendments to 42 HDR and 5 Gamma Knife licensees to address Part 35 requirements which have not yet been incorporated into our regulations. These amendments went out in late January 2007, and are effective 30 days following the effective date of the amendment.

I have attached the applicable documents. Please note that the Part 35 requirements appear in the electronic version as hidden text, highlighted in red. The references did not appear on the printed versions that were sent to licensees. The amendment documents have a single license condition that references the requirements in the applicable addendum. I have included all items, cover letters, license condition and addendums, below.

If you have any questions please contact me or Steve Gavitt.

(See attached file: New -revised license conditions for HDR licenses (ks).doc)

(See attached file: Amendment template for HDR Addendum.doc)

(See attached file: License condition for GAMMA knife license addendum.doc)

(See attached file: New- revised LCs for gamma knife licenses (ks).doc)

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Subject: Fwd: HDR and Gamma Knife requirements
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Recipients

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TWGWPO01.HQGWDO01
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Files	Size	Date & Time
MESSAGE	2915	02/05/2007 1:07:37 PM
New -revised license conditions for HDR licenses (ks).doc	46592	02/05/2007 1:03:58 PM
Amendment template for HDR Addendum.doc	20992	02/05/2007 1:03:58 PM
License condition for GAMMA knife license addendum.doc	19456	02/05/2007 1:03:58 PM
New- revised LCs for gamma knife licenses (ks).doc	53248	02/05/2007 1:03:58 PM

Options

Expiration Date: None
Priority: Standard
ReplyRequested: No
Return Notification: None

Concealed Subject: No

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Standard

Junk Mail Handling Evaluation Results

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(A) Use, Maintenance, and Unit Inspection.

(1) Use of a sealed source in a gamma stereotactic radiosurgery unit. A licensee shall use sealed sources in 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 that for medical use, a licensee may only use sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued under 10 CFR Part 30 and 10 CFR 32.74 or equivalent requirements of an Agreement State.

(2) Installation, maintenance, adjustment, and repair.

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

(b) Only a person specifically licensed by the Nuclear Regulatory Commission or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in gamma stereotactic radiosurgery units.

(c) A licensee shall retain a record of the installation, maintenance, adjustment, and repair of gamma stereotactic radiosurgery units for 3 years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

(3) Five-year inspection for gamma stereotactic radiosurgery units.

(a) A licensee shall have each gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Nuclear Regulatory Commission or an Agreement State.

(c) A licensee shall keep a record of the inspection and servicing for the duration of use of the unit. The record must contain —

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

(2) The date of inspection;

(3) The manufacturer's name and model number and serial number of both the

- treatment unit and source;
- (4) A list of components inspected and serviced, and the type of service; and
- (5) The signature of the inspector.

(B) Safety and Surveys.

- (1) Safety procedures for 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 sources;

- (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 sources 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, for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

(g) A licensee shall retain a copy of the procedures required by (B)(1)(a)(4) and (B)(1)(d)(2) until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

(2) Radiation surveys.

(a) In addition to the survey requirement in 10 NYCRR 16.10, 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 sources 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 maintain a record of radiation surveys required by paragraph (a) of this section for gamma stereotactic radiosurgery units for the duration of use of the unit. The record must include —

(1) The date of the measurements;

(2) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;

(3) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

(4) The signature of the individual who performed the test.

(3) Safety precautions 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 sources to be shielded when an entrance door is opened; and
- (3) Prevent the sources from being exposed following an interlock interruption until all treatment room entrance doors are closed and the sources 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) 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) In addition to the requirements specified in paragraphs (a) through (e) of this section, a licensee shall —

- (1) 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;
- (2) 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.

(f) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source remaining in the unshielded position.

(C) Calibration, Dosimetry Equipment and Spot-checks Gamma Stereotactic Radiosurgery Units.

(1) Full calibration measurements on gamma stereotactic radiosurgery units.

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit —

- (1) Before the first medical use of the unit;
- (2) Before medical use under the following conditions —
 - (i) 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;

(ii) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(iii) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

(3) At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

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

(1) The output within ± 3 percent;

(2) Relative helmet factors;

(3) Isocenter coincidence;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error;

(6) Trunnion centricity;

(7) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(8) Helmet microswitches;

(9) Emergency timing circuits; and

(10) Stereotactic frames and localizing devices (trunnions).

(c) A licensee shall use the dosimetry system described in (C)(2) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.

(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) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section at intervals not exceeding 1 month for cobalt-60.

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

(g) A licensee shall maintain a record of gamma stereotactic radiosurgery unit full calibrations for 3 years. The record must include:

- (1) The date of the calibration;
- (2) The manufacturer's name, model number, and serial number of the gamma stereotactic radiosurgery unit, the sources, and the instruments used to calibrate the unit(s);
- (3) The results and an assessment of the full calibrations;
- (4) The signature of the authorized medical physicist who performed the full calibration.

(2) Dosimetry equipment.

(a) 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) A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment for the duration of the license. For each calibration, intercomparison, or comparison, the record must include —

- (1) The date;

(2) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (a) and (b);

(3) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

(4) The names of the individuals who performed the calibration, intercomparison, or comparison.

(3) Periodic spot-checks for gamma stereotactic radiosurgery units.

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit —

(1) Monthly;

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

(3) After each source installation.

(b) A licensee shall —

(1) 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.

(2) 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.

(c) To satisfy the requirements of paragraph (a)(1) of this section, spot-checks must, at a minimum —

(1) Assure proper operation of —

(i) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(ii) Helmet microswitches;

(iii) Emergency timing circuits; and

(iv) Stereotactic frames and localizing devices (trunnions).

(2) Determine —

(i) The output for one typical set of operating conditions measured with the dosimetry system described in (C)(2)(b);

(ii) The difference between the measurement made in paragraph (c)(2)(i) of this section 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);

(iii) Source output against computer calculation;

(iv) Timer accuracy and linearity over the range of use;

(v) On-off error; and

(vi) Trunnion centricity.

(d) To satisfy the requirements of paragraphs (a)(2) and (a)(3) of this section, spot-checks must assure proper operation of —

(1) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(2) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Timer termination;

(5) Radiation monitors used to indicate room exposures; and

(6) Emergency off buttons.

(e) A licensee shall arrange for the repair of any system identified in paragraph (c) of this section that is not operating properly as soon as possible.

(f) 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.

(g) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units for 3 years. The record must include —

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit, and the instrument used to measure the output of the unit;

- (3) An assessment of timer linearity and accuracy;
- (4) The calculated on-off error;
- (5) A determination of trunnion centricity;
- (6) The difference between the anticipated output and the measured output;
- (7) An assessment of source output against computer calculations;
- (8) Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and 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.

(h) A licensee shall retain a copy of the procedures required by (C)(3)(b) until the licensee no longer possesses the gamma stereotactic radiosurgery unit. A licensee shall retain a record of each check required by paragraphs (c) and (d) for a period of three years.

(D) 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 must include, as applicable, verification of:

- (1) The source-specific input parameters required by the dose calculation algorithm;
- (2) The accuracy of dose, dwell time, and treatment time calculations at representative points;
- (3) The accuracy of isodose plots and graphic displays;
- (4) The accuracy of the software used to determine sealed source positions from radiographic images; and
- (5) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

Attention:

Radiation Safety Officer

RE: NYS Dept. of Health Radioactive
Materials License No.
DH No.

Dear Dr. :

Enclosed is Amendment No. XX to New York State Department of Health Radioactive Materials License No. XXXX, which contains revised requirements for the possession and use of a gamma stereotactic radiosurgery unit. These requirements are to be implemented within 30 calendar days of the effective date of the amendment.

These requirements were essentially copied verbatim from U.S. Nuclear Regulatory Commission (NRC) regulations in 10 CFR 35 which govern the medical uses of radioactive materials. We are in the process of amending Part 16 (10 NYCRR 16) to incorporate these requirements, as well as requirements in other program areas, to ensure compatibility with the federal regulations. In the interim, during the regulatory process, we are amending applicable licensees, including gamma knife licensees, to implement various requirements.

Please carefully review the amendment. I believe that you will find these revised requirements are consistent with your existing policies and procedures and standards of practice.

You are requested to indicate, in writing, to this office, within 25 days of receipt of this correspondence, that you have implemented the requirements. If you determine that you are unable to implement the requirements, submit an explanation of the circumstances that will impede you from doing so.

If you have any questions or if we may be of assistance, please contact Janaki Krishnamoorthy, Ph.D., or me at (518) 402-7590 or:

New York State Department of Health
Bureau of Environmental Radiation Protection
Radioactive Materials Section
547 River Street, Flanigan Square - Room 530
Troy, New York 12180-2216

Sincerely,

Robert E. Dansereau, Chief
Radioactive Materials Section

Bureau of Environmental Radiation Protection

Enclosure: Amendment No. XX

(A) Use, Maintenance, and Unit Inspection.

(1) Installation, maintenance, adjustment, and repair.

(a) Only a person specifically licensed by the Nuclear Regulatory Commission or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, that involves work on the source shielding, the source 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.

(b) Only a person specifically licensed by the Nuclear Regulatory Commission or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in remote afterloader units.

(c) A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units for 3 years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

(B) Safety and Surveys:

(1) 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 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 for 3 years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

(2) Safety procedures and instructions.

(a) A licensee shall —

(1) Secure the unit, any additional source, 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;

(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 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.

(3) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(e) A licensee shall retain a record of individuals receiving instruction required by paragraph (d) of this section for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

(f) A licensee shall retain a copy of the procedures required by paragraphs (a)(4) and (d)(2) until the licensee no longer possesses the remote afterloader.

(3) Radiation surveys.

(a) In addition to the survey requirement in 16.10 of this chapter, the 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 paragraph (a) of this section at installation of a new source and following repairs to the source shielding, the source driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the unit or the source.

(c) The licensee shall retain a record of the radiation surveys required by paragraph (a) for the duration of use of the unit. The record must include —

- (1) The date of the measurements;
- (2) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;
- (3) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and
- (4) The signature of the individual who performed the test.

(4) Safety precautions for remote afterloader.

(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 to be shielded when an entrance door is opened; and
- (3) Prevent the source from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source

(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) A licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of and communication with the patient or the human research subject from the treatment console during irradiation.

(e) For licensed activities where source is 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 ensure that —

- (1) An authorized user and a medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

(2) A 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) 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.

(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.

(C) Calibration, Dosimetry Equipment and Spot-checks.

(1) Full calibration measurements.

(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 calendar quarter for high dose-rate units with sources whose half-life exceeds 75 days.

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

(1) The output within ± 5 percent;

(2) Source positioning accuracy to within ± 1 millimeter;

(3) Source retraction with backup battery upon power failure;

(4) Length of the source transfer tubes;

(5) Timer accuracy and linearity over the typical range of use;

(6) Length of the applicators; and

(7) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(c) A licensee shall use the dosimetry system described in section (D)(2) 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) 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.

(f) 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.

(g) A licensee shall retain a record of each calibration required by (d)(2). The record must include —

(1) The date of the calibration;

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

(3) The results and an assessment of the full calibrations;

(4) The signature of the authorized medical physicist who performed the full calibration.

(2) Dosimetry equipment.

(a) 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) A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment for the duration of the license. For each calibration, intercomparison, or comparison, the record must include —

(1) The date;

(2) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (a) and (b);

(3) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

(4) The names of the individuals who performed the calibration, intercomparison, or comparison.

(3) Periodic spot-checks:

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader unit —

(1) Before the first use of a high dose-rate remote afterloader unit on a given day; and

(2) After each source installation.

(a) 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. A licensee shall retain a copy of the procedures until the licensee no longer possesses the remote afterloader unit.

(b) 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.

(c) 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-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.

(d) If the results of the checks required in paragraph (c) 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.

(e) A licensee shall retain a record of each check required by paragraph (c) for 3 years. The record must include, as applicable —

- (1) The date of the spot-check;
- (2) The manufacturer's name, model number, and serial number for the remote afterloader unit and source;
- (3) An assessment of timer accuracy;
- (4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and
- (5) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(D) 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. A licensee shall retain a copy of the acceptance testing until the licensee no longer possesses the remote afterloader unit. At a minimum, the acceptance testing must include, as applicable, verification of:

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

- (2) The accuracy of dose, dwell time, and treatment time calculations at representative points;
- (3) The accuracy of isodose plots and graphic displays;
- (4) The accuracy of the software used to determine sealed source positions from radiographic images; and
- (5) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

Attention:

Radiation Safety Officer

RE: NYS Dept. of Health Radioactive
Materials License No.
DH No.

Dear Dr. :

Enclosed is Amendment No. XX to New York State Department of Health Radioactive Materials License No. XXXX, which contains revised requirements for the possession and use of a high dose rate remote afterloader brachytherapy unit. These requirements are to be implemented within 30 calendar days of the effective date of the amendment.

These requirements were essentially copied verbatim from U.S. Nuclear Regulatory Commission (NRC) regulations in 10 CFR 35 which govern the medical uses of radioactive materials. We are in the process of amending Part 16 (10 NYCRR 16) to incorporate these requirements, as well as requirements in other program areas, to ensure compatibility with the federal regulations. In the interim, during the regulatory process, we are amending applicable licensees, including HDR licensees, to implement various requirements.

Please carefully review the amendment. I believe that you will find these revised requirements are consistent with your existing policies and procedures and standards of practice.

You are requested to indicate, in writing, to this office, within 25 days of receipt of this correspondence, that you have implemented the requirements. If you determine that you are unable to implement the requirements, submit an explanation of the circumstances that will impede you from doing so.

If you have any questions or if we may be of assistance, please contact Janaki Krishnamoorthy, Ph.D., or me at (518) 402-7590 or:

New York State Department of Health
Bureau of Environmental Radiation Protection
Radioactive Materials Section
547 River Street, Flanigan Square - Room 530
Troy, New York 12180-2216

Sincerely,

Robert E. Dansereau, Chief
Radioactive Materials Section
Bureau of Environmental Radiation Protection

Enclosure: Amendment No. XX

NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE

License Number

Amendment Number

DH Number

Attention:

Radiation Safety Officer

Dear Licensee:

New York State Department of Health Radioactive Materials License No. XXXX has been amended as follows:

Add Condition No. XX:

- XX. The licensee shall, within 30 days of the effective date of the amendment, implement the procedures and record keeping requirements in the LICENSE ADDENDUM - High Dose Rate Remote Afterloader Units, dated 12/20/06.

FOR THE NEW YORK STATE DEPARTMENT OF HEALTH

Date:
RD/JK/AD

By _____
Robert E. Dansereau, Chief
Radioactive Materials Section
Bureau of Environmental Radiation Protection

cc:

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- xx. The licensee shall, within 30 days of the effective date of the amendment, implement the procedures and record keeping requirements in the LICENSE ADDENDUM - Gamma Stereotactic Radiosurgery, dated 12/20/06.