



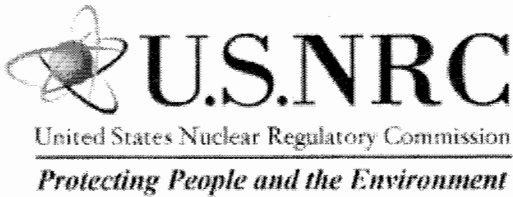
CONVERSATION RECORD

NAME OF PERSON(S)/TITLE CONTACTED OR IN CONTACT WITH YOU Ann H. Maitz, M.S.		DATE OF CONTACT 01/11/2019	TYPE OF CONVERSATION	
E-MAIL ADDRESS Ann.Maitz@beaumont.org		TELEPHONE NUMBER 248-551-1194	<input type="checkbox"/> E-MAIL	<input type="checkbox"/> INCOMING
			<input checked="" type="checkbox"/> TELEPHONE	<input checked="" type="checkbox"/> OUTGOING
ORGANIZATION Beaumont Health System		DOCKET NUMBER(S) 030-37359		
LICENSE NAME AND NUMBER(S) Beaumont Health System, 21-01333-02		MAIL CONTROL NUMBER(S) 610456		

SUBJECT
Additional information required regarding the requested use of Icon

SUMMARY AND ACTION REQUIRED (IF ANY)
See the attached regulations.

NAME OF PERSON DOCUMENTING CONVERSATION MAGDALENA R. GRYGLEK	
SIGNATURE Magdalena R. Gryglek	DATE OF SIGNATURE 1/11/19



Additional information needed discussed with A. Katz on 1/11/19. Also, the information was provided in an email.

Home > NRC Library > Document Collections > NRC Regulations (10 CFR) > Part Index > § 35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

§ 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.

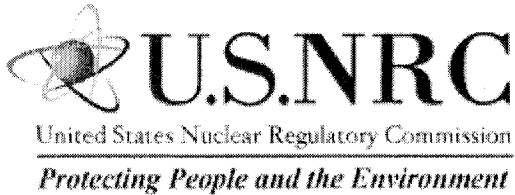
missing Address drills

(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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Home > NRC Library > Document Collections > NRC Regulations (10 CFR) > Part Index > § 35.645 Periodic spot-checks for gamma stereotactic radiosurgery units.

§ 35.645 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; *OK*
- (ii) Helmet microswitches; *N/A*
- (iii) Emergency timing circuits; and *N/A*
- (iv) Stereotactic frames and localizing devices (gonnions). *OK* *N/A*

(2) Determine--

- (i) The output for one typical set of operating conditions measured with the dosimetry system described in § 35.630(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) ^{Address} Viewing and intercom systems; (explain how the check is done)

(4) ^{Address} Timer termination; (explain how the check is done)

(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 check required by paragraphs (c) and (d) and a copy of the procedures required by paragraph (b) of this section in accordance with § 35.2645.

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Additional checks to be addressed based on guidance

• Leksell Gamma Knife Perfexion and Leksell Gamma Knife Icon Licensing Guidance, May 25, 2016, Rev 0.1

Please address / describe how you will perform the following spot checks:

✓ frame adapter

✓ mask adapter

✓ docking device

✓ location of the radiation focal point with respect to the table position

✓ collision table location