

**4731.4466 REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS; SAFETY PROCEDURES AND INSTRUCTIONS.**

A. This part applies to remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

B. A licensee must:

(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;

(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:

(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 the treatment area to minimize the risk of inadvertent exposure; and

(c) the names and telephone numbers of the authorized user, authorized medical physicist, and radiation safety officer to be contacted if the unit or console operates abnormally.

C. A copy of the procedures required under item B, subitem (4), must be physically located at the unit console.

D. A licensee must post instructions at the unit console to inform the operator of:

(1) the location of the procedures required under item B, subitem (4); and

(2) the names and telephone numbers of the authorized user, authorized medical physicist, and radiation safety officer to be contacted if the unit or console operates abnormally.

E. A licensee must:

(1) prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training; and

(2) provide operational and safety instructions, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties. The instructions must include instruction in:

- (a) the procedures identified under item B, subitem (4); and
- (b) the operating procedures of the unit.

F. A licensee must ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

G. A licensee must retain a record of individuals receiving instruction required under item E according to part 4731.4510.

H. A licensee must retain a copy of the procedures required under item B, subitem (4), and item E, subitem (2), unit (b), according to part 4731.4516.

**Statutory Authority:** *MS s 144.1202; 144.1203*

**History:** *29 SR 755; 46 SR 791*

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