

4731.4463 USE OF A SEALED SOURCE; REMOTE AFTERLOADER UNIT, TELETHERAPY UNIT, OR GAMMA STEREOTACTIC RADIOSURGERY UNIT.

A. A licensee must only use sealed sources:

(1) approved and as provided for in the sealed source and device registry in photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses; or

(2) in research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units according to an active investigational device exemption application accepted by the Food and Drug Administration, provided the requirements of part 4731.4410, item A, are met.

B. A licensee must use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

(1) approved in the sealed source and device registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the sealed source and device registry, but must be used in accordance with radiation safety conditions and limitations described in the sealed source and device registry; or

(2) in research according to an active investigational device exemption application accepted by the FDA provided the requirements of part 4731.4410, item A, are met.

Statutory Authority: *MS s 144.1202; 144.1203*

History: *29 SR 755; 46 SR 791*

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