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

A licensee must 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, 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.

Statutory Authority: *MS s* 144.1202; 144.1203

History: 29 SR 755

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