

4731.4450 USE OF BRACHYTHERAPY SOURCES.

A licensee must use only brachytherapy sources:

A. as approved in the sealed source and device registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the sealed source and device registry, but must be used in accordance with the radiation safety conditions and limitations described in the sealed source and device registry; or

B. in research to deliver therapeutic doses for medical use, 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; 46 SR 791*

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