

4731.4460 USE OF SEALED SOURCES AND MEDICAL DEVICES FOR DIAGNOSIS.

A. A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the sealed source and device registry for diagnostic medicine. The sealed sources may be used for diagnostic medical 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.

B. A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the sealed source and device registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical 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.

C. Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. 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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