**Section 335.8010 Use of a Sealed Source in Remote Afterloader Units, Teletherapy Units** **or Gamma Stereotactic Radiosurgery Units**

a) A licensee shall only use sealed sources:

1) Obtained from a person specified in Section 335.35, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

2) 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

3) In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration, provided the requirements of Section 335.35 are met.

b) A licensee shall 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 in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of Section 335.35 are met.

(Source: Amended at 46 Ill. Reg. 966, effective December 21, 2021)