



Ohio Administrative Code

Rule 3701:1-58-55 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

Effective: August 15, 2021

(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 in accordance with an active investigational device exemption (IDE) application accepted by the United States food and drug administration provided the requirements of paragraph (A) of rule 3701:1-58-17 of the Administrative Code 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 in accordance with an active investigational device exemption (IDE) application accepted by the United States food and drug administration provided the requirements of paragraph (A) of rule 3701:1-58-17 of the Administrative Code are met.
