WAC 246-240-351 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit. (1) A licensee shall use sealed sources:

(a) 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

(b) In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active IDE application accepted by the FDA provided the requirements of WAC 246-240-066(1) are met.

(2) A licensee shall use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

(a) 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

(b) In research in accordance with an active IDE application accepted by the FDA provided the requirements of WAC 246-240-066(1) are met.

[Statutory Authority: RCW 70A.388.040 and 70A.388.110. WSR 22-19-084, \$ 246-240-351, filed 9/20/22, effective 10/21/22. Statutory Authority: RCW 70.98.050. WSR 06-05-019, \$ 246-240-351, filed 2/6/06, effective 3/9/06.]