**Section 335.2150 Additional Technical Requirements for Intravascular Brachytherapy Units**

In addition to other provisions required by this Part, the licensee authorized to use an intravascular brachytherapy unit for medical use shall:

a) Have a treatment team consisting of, at a minimum, an interventional cardiologist, an authorized user and an authorized medical physicist and that, at a minimum, an interventional cardiologist and an authorized user will be physically present in the treatment suite during all radioactive procedures.

AGENCY NOTE: The requirements of 32 Ill. Adm. Code 401 regarding radiation therapists must also be met.

b) Independently verify source strength and uniformity. Dwell time at the treatment location must be monitored and recorded. Source uniformity or strength must not differ by more that 10 percent of the expected values.

c) For devices requiring additional shielding, demonstrate compliance with 32 Ill. Adm. Code 340.210 and 340.310 requirements.

d) Inspect sealed sources, source trains or ribbons after each use and ensure sources are removed from service at intervals established by the manufacturer (i.e., confirm that source trains will not be used after the "use by" date, at intervals not to exceed 2 months from the date of shipment, or when evidence of degradation is observed, whichever comes first).

e) Inspect and service devices containing sealed sources at intervals established by the manufacturer, and ensure that maintenance and repair of the device is performed only by the manufacturer or persons specifically authorized by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to perform such service.

f) Prohibit cuts, alterations or splicing of the sealed sources, source trains or ribbons, except in situations involving an emergency where the source wire cannot be returned to its normal safe position. If such cuts, alterations or splicing are necessary, notification in accordance with Section 335.1080 or 32 Ill. Adm. Code 340.1220 shall be made to the Agency.

g) Use only manufacturer provided inducer sheaths, catheters and accessories to ensure their demonstrated equivalents will be used with the devices.

h) Ensure the daily operational checks will be performed prior to patient treatment. At a minimum, they should include position verification, source uniformity, dwell time function, indicator lamps and other status/operational displays, and visual inspection for integrity of all applicators and catheters to be used for the treatment.

i) Perform tests following source or device exchange in accordance with the manufacturer's instruction manual for:

1) Timer accuracy/constancy, if appropriate;

2) Calibration of the source output following the manufacturer's instructions; and

3) Interlock/interrupt checks (i.e., interrupt test, cartridge lock test, emergency retraction test and catheter connection test), if appropriate.

j) The licensee shall retain a record of each item in subsections (b), (d), (e), (h) and (i) for intravascular brachytherapy units for 5 years. The records shall include:

1) The date of the verification, inspection or check.

2) The manufacturer's name, model and serial number of the intravascular brachytherapy unit.

3) Results of the verification, inspection or check.

4) Notations indicating the operability of each component.

5) The identity of the individual who performed the check.

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