Interim Enforcement Policy on Permanent Implant Brachytherapy

9.3 Enforcement Discretion for Permanent Implant Brachytherapy Medical Event Reporting (10 CFR 35.3045)

This section sets forth the interim policy that the U.S. Nuclear Regulatory Commission (NRC) will use for medical event reporting violations under the current 10 CFR Part 35. Enforcement discretion will typically be exercised for reporting violations in the following scenarios when the authorized treatment mode is permanent implant brachytherapy: (1) the licensee uses total source strength and exposure time for evaluating the existence of a treatment site medical event; or (2) the total absorbed dose to the treatment site equals or exceeds 120 percent of the prescribed dose. This policy does not provide regulatory relief from complying with any other aspect of §§ 35.41 or 35.3045, including the requirements related to the evaluation of dose to normal tissue.

The interim policy applies to violations that result from an otherwise appropriate use of total source strength and exposure time when determining the existence of a medical event and when the use of these values does not result in the misapplication of byproduct material by the licensee.

Specifically, under this interim Enforcement Policy, the NRC will normally not take enforcement action for using total source strength and exposure time to compare the dose delivered to the treatment site with the prescribed dose when evaluating whether a medical administration is a medical event under § 35.3045(a)(1) if the authorized treatment mode is permanent implant brachytherapy and all of the following criteria are met:

a. The licensee's documented procedures required under § 35.41 specify total source strength and exposure time as the regulatory evaluation values for treatment site dose comparisons;

b. The licensee entered both the prescribed dose and the delivered dose into the written directive as total source strength and exposure time; and

c. Per § 35.3045, the licensee timely reported the event based on that treatment site dose comparison, if applicable.

In addition, the NRC will normally not take enforcement action against a licensee for not submitting a medical event report if the permanent implant brachytherapy treatment site total dose equals or exceeds 120 percent of the prescribed dose. This enforcement discretion would only apply if: (1) licensees are using absorbed dose to compare the dose delivered to the treatment site with the prescribed dose; (2) doses to normal tissues and structures do not exceed the regulatory dose limits for reporting medical events specified in current § 35.3045(a)(3); and (3) the total dose for the treatment site was expressed in the written directive as absorbed dose.

This discretion will not be exercised for licensees using source strength and exposure time to compare the dose delivered to the treatment site with the prescribed dose, since it is expected that the licensee has more control over delivery of the prescribed dose when using source strength and exposure time. However, this is not intended to limit the physician's current ability to make intraoperative adjustments in the quantity of source strength to be implanted based on the conditions encountered during the surgical procedure.

Licensees shall comply with all other requirements, as applicable, unless explicitly replaced or amended in this interim policy.

This interim policy will remain in place until the implementation date of a final rule associated with the medical event reporting requirements.