PART 35 PRELIMINARY DRAFT LANGUAGE
(February 21, 2008)
Revision 1
Changes from the February 7, 2008 document are in italic and double strikethrough.

The following is preliminary draft rule language for proposed changes to 10 CFR 35.40 and 35.3045 related to medical events in brachytherapy. The goal of this rulemaking is to better define medical events arising from permanent implant brachytherapy procedures. The proposed amendments will also change the criteria for defining a medical event for permanent implant brachytherapy from dose based to activity based, will add a requirement to report as a medical event any administration requiring a written directive if a written directive was not prepared, and make certain administrative and clarification changes to the existing rule text. This rulemaking is based on recommendations from the NRC's Advisory Committee on Use of Radioactive Isotopes (ACMUI). The availability of the preliminary draft rule language is intended to inform stakeholders of the current status of the NRC's activities and solicit public comments on the information at this time. Redline strikeout is used to delineate between original rule language and the proposed changes.

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§ 35.40 Written directives.

(a) A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (μCi)), any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.

(1) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The

information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

(b) The written directive must contain the patient or human research subject's name and the following information--

(1) For any administration of quantities greater than 1.11 MBq (30 μCi) of sodium iodide I-131: the dosage;

(2) For an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

(4) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

(5) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; ~~or~~

(6) For permanent implant brachytherapy:

(i) Before administration: the treatment site, the radionuclide, the intended dose to the treatment site and other sites as applicable, and the corresponding calculated total source strength required; and

(ii) After administration but before the patient leaves the post-~~*operative*~~ *treatment* recovery area: the number of sources and *nominal* activity per source implanted, the date, and signature of AU; or

(~~7~~6) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

(i) Before implantation: treatment site, the radionuclide, and dose; and

(ii) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

(c)*(1)* A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(~~1~~ *2*) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

(d) The licensee shall retain a copy of the written directive in accordance with § 35.2040.

§ 35.3045 Report and notification of a medical event.

(a) A licensee shall report ~~any~~ as ~~an~~ *a medical* event any administration requiring a written directive if a written directive was not prepared or any event, except for an event that results from patient intervention, in which ~~the administration of byproduct material or radiation from byproduct material results in~~--

(1) The administration of byproduct material or radiation from byproduct material, except permanent implant brachytherapy, results in--

(i ~~1~~) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

(A ~~i~~) The total dose delivered differs from the prescribed dose by 20 percent or more;

(B ~~ii~~) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(C ~~iii~~) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

(ii ~~2~~) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following--

(A ~~i~~) An administration of a wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure;

(B ~~ii~~) An administration of a radioactive drug containing byproduct material by the wrong route of administration or by use of the wrong applicator in a brachytherapy procedure;

(C ~~iii~~) An administration of a dose or dosage to the wrong individual or human research subject;

(D ~~iv~~) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(E ~~v~~) A leaking sealed source.

(iii ~~3~~) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) ~~to an organ or tissue~~ and by 50 percent or more ~~of~~ the dose expected to that site ~~from the administration~~ if *the administration had been* carried out as specified ~~defined~~ in the written directive ~~(excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site)~~.

(2) The administration of byproduct material or radiation from byproduct material for permanent implant brachytherapy (excluding sources that were implanted in the correct site but migrated outside the treatment site) ~~that~~ results in--

(i) The total source strength implanted in the treatment site differing from the *preimplantation* written directive by 20 percent or more.

(ii) The total source strength implanted outside the treatment site and within 3 cm (1.2 in) of the boundary of the treatment site ~~being more than~~ *exceeding* 20 percent of the total source strength documented in the preimplantation written directive.

(iii) Brachytherapy source(s) implanted beyond 3 cm (1.2 in) from the *outside* boundary of the treatment site.

(iv) A dose to the skin or an organ or tissue other than the treatment site exceeding by 0.5 Sv (50 rem) and by 50 percent or more ~~of~~ the dose expected to that site ~~from the administration~~ if *the administration had been* carried out as specified in the *preimplantation* written directive.

(v) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following--

(A) An administration of the wrong radionuclide ~~for a brachytherapy procedure~~;

(B) An administration ~~of a brachytherapy source~~ by the wrong route of administration;

(C) An administration ~~of a brachytherapy source~~ to the wrong individual or human research subject;

(D) An administration ~~of a brachytherapy source~~ delivered by the wrong mode of treatment; or

(E) A leaking sealed source.

(3) An error in calculating the total source strength for permanent implant brachytherapy documented in the preimplantation written directive that resulted in a total source strength that delivered a dose that differed by more than 20 percent from the intended dose to the treatment site.

(b) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(c) The licensee shall notify by telephone the NRC Operations Center[3] no later than the next calendar day after discovery of the medical event.

(d) By an appropriate method listed in § 30.6(a) of this chapter, the licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 15 days after discovery of the medical event.

(1) The written report must include--

(i) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the individual(s) who received the administration;

(vi) What actions, if any, have been taken or are planned to prevent recurrence; and

(vii) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(2) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(e) The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

(g) A licensee shall:

(1) Annotate a copy of the report provided to the NRC with the:

(i) Name of the individual who is the subject of the event; and

(ii) Social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

[3] The commercial telephone number of the NRC Operations Center is (301) 816-5100 ~~951-0550.~~