PART 35--MEDICAL USE OF BYPRODUCT MATERIAL

1. The authority citation for Part 35 continues to read as follows:

AUTHORITY: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

2. In § 35.24, paragraph (h) is revised and redesignated as paragraph (i) and a new paragraph (h) is added to read as follows:

§ 35.24 Authority and responsibilities for the radiation protection program.

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(h) A licensee shall provide training on the requirements of § 35.3045, Reporting and notification of a medical event, to all individuals who participate in procedures using byproduct material requiring a written directive prior to the first use, annually, and after each revision of § 35.3045.

(i) A licensee shall retain a record of actions taken under paragraphs (a), (b), (e) and (h) of this section in accordance with § 35.2024.

3~~2~~. In § 35.40, paragraphs (b)(5) and (c) are revised, paragraph (b)(6) is redesignated as paragraph (b)(7), and a new paragraph (b)(6) is added to read as follows:

§ 35.40 Written directives.

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(b) * * *

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

(6) For permanent implant brachytherapy:

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

(ii) After administration (post-implantation) but before the patient leaves the post-treatment recovery area: the total source strength implanted, the date, and the signature of ~~AU~~ an authorized user for § 35.400 uses for manual brachytherapy; or

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(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.

(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.

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~~34~~. In § 35.41, a new paragraph (d) is added to read as follows:

§ 35.41 Procedures for administrations requiring a written directive.

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(d) For permanent implant brachytherapy, a licensee must assess the dose to the treatment site and sites other than the treatment site identified in the pre-implantation written

directive in accordance with then existing current published protocols accepted by nationally recognized professional organizations and no later than 60 days from the date that the patient left the post-treatment recovery area. These assessments must be used to determine if a medical event must be reported as required by § 35.3045.

5. In § 35.2024, paragraph (a) is revised to read as follows:

§ 35.2024 Records of authority and responsibilities for radiation protection programs.

(a) A licensee shall retain a record of actions taken by the licensee's management in accordance with § 35.24(a) and (h) for 5 years. The record for § 35.24(a) must include a summary of the actions taken and a signature of licensee management. The record for § 35.24(h) must include a list of topics covered, the date of training, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the training.

6. In § 35.3045, paragraph (a) and the footnote to paragraph (c) are revised to read as follows:

§ 35.3045 Report and notification of a medical event.

(a) A licensee shall report as a medical event any administration requiring a written directive if a written directive was not prepared and documentation from either an individual's medical records or the licensee's standard written procedures (or both) that existed prior to the administration is insufficient to determine if a medical event has occurred or any event, except for an event that results from patient intervention, in which —

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

(i) A dose to the treatment site that differs from the prescribed dose, or dose that would have resulted from the prescribed dosage, or dose or dosage supported by either an individual's

medical records or the licensee's standard written procedures (or both) that existed prior to the administration when no written directive was prepared, 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) The total dose delivered differs from the prescribed dose, or dose supported by either an individual's medical records or the licensee's standard written procedures (or both) that existed prior to the administration when no written directive was prepared, by 20 percent or more;

(B) The total dosage delivered differs from the prescribed dosage, or dosage supported by either an individual's medical records or the licensee's standard written procedures (or both) that existed prior to the administration when no written directive was prepared, by 20 percent or more or falls outside the prescribed dosage range; or

(C) The fractionated dose delivered differs from the prescribed dose, or dose supported by either an individual's medical records or the licensee's standard written procedures (or both) that existed prior to the administration when no written directive was prepared, for a single fraction, by 50 percent or more.

(ii) 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 a wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure;

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

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

(E) A leaking sealed source.

(iii) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) and by 50 percent or more the dose expected to that site ~~if~~ from the administration ~~had been carried out as specified~~ defined in the pre-administration written directive or dose supported by either an individual's medical records or the licensee's standard written procedures (or both) that existed prior to the administration when no written directive was prepared.

(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)~~ results in —

~~(i) The total source strength administered differing by 20 percent or more from the total source strength documented in the preimplantation written directive.~~

(i) The total absorbed dose delivered to the treatment site differing by 20 percent or more from the intended dose documented in the pre-implantation written directive or supported by an individual's medical records that existed prior to the administration when no written directive was prepared.

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

(ii) The total source strength administered differing by 20 percent or more from the intended total source strength documented in the pre-implantation written directive or supported by an individual's medical records that existed prior to the administration when no written directive was prepared.

~~(iii) Brachytherapy source(s) implanted beyond 3 cm (1.2 in) from the outside boundary of the treatment site, except for brachytherapy source(s) at other sites noted in the preimplantation written directive.~~

(iii) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation written directive.

(iv) The total source strength administered outside the treatment site exceeding 20 percent of the total source strength administered (excluding sources that were implanted in the correct site but migrated outside the treatment site).

(i~~v~~v) 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 the dose expected to that site ~~if~~ from the administration ~~had been carried out as specified~~ defined in the pre-implantation written directive or supported by an individual's medical records that existed prior to the administration when no written directive was prepared (excluding sources that were implanted in the correct site but migrated outside the treatment site).

(~~v~~vi) 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;

(B) An administration by the wrong route of administration;

(C) An administration to the wrong individual or human research subject;

(D) An administration 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 an administered total source strength that delivered a dose differing by more than 20 percent from the intended dose to the treatment site.~~

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(c) * * *

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

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