OTHER OPTIONS CONSIDERED

PETITION FOR RULEMAKING AND RULEMAKING PLAN FOR REPORTING NUCLEAR MEDICINE INJECTION EXTRAVASATIONS AS MEDICAL EVENTS

The U.S. Nuclear Regulatory Commission staff considered the status quo and several rulemaking options in its evaluation of potential reporting requirements for radiopharmaceutical extravasations. The staff also assessed whether extravasations could be reported under any of the existing criteria in Title 10 of the *Code of Federal Regulations* (10 CFR) 35.3045, "Report and notification of a medical event." The staff provided three options to the Commission for consideration; the other four options in this enclosure are presented for completeness, but the staff does not recommend them for Commission consideration.

Option 4, "Reporting extravasations under existing medical event regulations," would involve an interpretive rule to classify extravasations as medical events under 10 CFR 35.3045(a)(1)(iii).[1] This regulation applies only to administrations requiring a written directive, so it would apply only to extravasations of therapeutic radiopharmaceuticals that result in 50 rem (0.5 Sieverts (Sv)) and 50 percent or more than the expected dose to the administration site. Assuming the tissue around the administration site should get no dose, reporting under 10 CFR 35.3045(a)(1)(iii) would mean that even minor leakage at the administration site of a therapeutic radiopharmaceutical would trigger the reporting criteria, resulting in almost all therapeutic extravasations being reportable medical events. The staff rejected this option because (1) it would exclude diagnostic extravasations and would require monitoring and dosimetry for all therapeutic administrations, and (2) as discussed in Option 2, the staff believes the 50-rem dose threshold is too low for reporting extravasations.

The staff also considered whether reporting extravasations under 10 CFR 35.3045(a)(1)(i)[2] criteria would be appropriate: a dose that differs from the prescribed dose 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. The staff does not consider an extravasation to be an underdosage because the extravasated radiopharmaceutical will eventually clear from tissue and enter the bloodstream via the lymphatic system; reporting extravasations based on their tissue effects would be a more effective and efficient reporting requirement.

Option 5, "Administration site dose for procedures requiring a written directive," would be a rulemaking that would look like the criteria in 10 CFR 35.3045(a)(1)(iii) except that it would

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[1] According to 10 CFR 35.3045(a)(1)(iii)—

> A dose to the skin or an organ or tissue other than the treatment site that exceeds by: (A) 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and (B) 50 percent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

[2] According to 10 CFR 35.3045(a)(1)(i)—

> 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) The total dose delivered differs from the prescribed dose by 20 percent or more; (B) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or (C) The fractionated dose delivered differs from the prescribed dose for a single fraction, by 50 percent or more.

be written specifically for extravasations, and authorized user physicians could potentially account for a reasonable dose at the administration site in the written directive. The staff contemplated that this "reasonable dose" could screen out expected effects from radiopharmaceutical therapy associated with normal intravenous leakage or a minor extravasation. The staff rejected this option because (1) it would require monitoring and dosimetry for all therapeutic administrations, (2) it would exclude diagnostic extravasations, and (3) it would be complicated for physician authorized users to determine a reasonable "side effect" dose at the administration site.

Option 6, "Extravasation events that cause a significant dose," would require medical event reporting for extravasations that meet the 10 gray (Gy) (1,000 rad) dose threshold requirement for abnormal occurrences. This option would be similar to the staff's recommended rulemaking, Option 3, except reporting would be required only if dosimetry confirmed that the extravasation resulted in a 10 Gy dose to tissue. The staff estimates that fewer than 10 extravasation events would be reported annually under this option. Some pros of this option include (1) the 10-Gy dose threshold is a dose of public health and safety significance that would screen out diagnostic injections and less significant therapeutic extravasations, (2) relying on a dose threshold for reporting could be clearer to licensees than relying on a subjective assessment of radiation injury, and (3) this option would not require monitoring of radiopharmaceutical administrations. The staff rejected this option because the 10-Gy dose threshold associated with abnormal occurrences may be too high—it would screen out lower dose extravasations that could still cause patient harm, which the staff believes should be reported.

Option 7, "Extravasation events that cause permanent functional damage," would require extravasations that result in permanent functional damage to be reported as medical events. This would be like the current reporting requirements for events caused by patient intervention that result in unintended permanent functional damage as determined by a physician. The staff would expect infrequent reporting of extravasation events, if any, under this option. Some pros of this option include that it does not rely on a dose threshold for reporting, nor does it require dosimetry or administration monitoring. The staff rejected this option because permanent functional damage is a very high threshold.