Clarifying the New NRC Misadministration Reporting Rules

Many questions have arisen concerning changes in the misadministration reporting requirement published by the US Nuclear Regulatory Commission (NRC) in its final revision of "Medical Uses of Byproduct Material," 10 CFR Part 35 (*Federal Register,* Oct. 16, 1986, pp. 36932-36968).

Diagnostic misadministrations must be reported if: the dosage is five-fold different than prescribed; material not intended for medical use is administered; or the patient will receive an organ dose of 2 rem or a whole-body dose of 500 mrem.

Will diagnostic misadministrations continue to be reported as they are now? Reports will have to be submitted within 15 days in writing to the NRC and the referring physician on an NRC form designed specifically for this purpose. When notifying referring physicians, licensees may include a cover note explaining the reporting requirements.

Must dose calculations be patient-specific? Dose calculations may be made by using the dosimetry tables in the package insert, corrected only for dosage administered. There is no requirement to correct for the patient's size, organ mass, or compartment transfer rates. Although these corrections would make the calculation more accurate, the NRC believes that to require them would be unduly burdensome.

How much effort should be spent on making calculations? For most cases, in which the calculations simply require multiplying whole-body and target-organ doses in the package insert by the dosage administered, the calculations should each take less than a minute. The NRC expects a licensee to expend the appropriate effort in calculating the dose to the patient and does not believe, in most cases, that this effort will be inordinate.

How does one calculate dose in cases of wrong-route misadministrations, where dosimetry models are not readily available? In those few cases where the package insert does not provide sufficient information, the licensee may use the Medical Internal Radiation Dose (MIRD) tables or a dosimetry algorithm that has been published in the literature or a textbook and assume a fairly simple compartment model (examples, *1,2*). This question, however, may be a theoretical one. The NRC's analysis of diagnostic misadministrations reported to date shows that virtually 100% of these events involve administration of the wrong radiopharmaceutical (74%), the wrong dosage (4%), or administration of a radiopharmaceutical to the wrong patient (22%). Based on the reports submitted, the NRC believes that almost all diagnostic misadministrations involve conventional administrations and radiopharmaceuticals, for which dosimetry is provided in the package insert (*3*).

How does one calculate dose in cases of pediatric misadministrations? The NRC does not have any information about the number of diagnostic misadministrations involving children, but believes the number is small based on reports that provide the patients' ages. In unclear cases the licensee may consult the licensing staff.

If a misadministration were unreported because the licensee, based on an incorrect dose calculation, believed no report was required, would a citation be issued? A diagnostic misadministration, with its attendant calculation, is no different than other reporting requirements based on a combination of physical measurements and calculations—the NRC expects its licensees to make these calculations correctly. If these calculations are made improperly and a licensee, as a result of this error, fails to report an event, a severity-level-IV violation has occurred. The NRC will issue a notice of violation that requires a formal response from the licensee describing corrective actions.

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References

1. Marcus CS, Stabin MG, Watson EE: Pediatric radiation dose from ^{111}In leukocytes. *J Nucl Med* 1986, 27:1220-1221
2. Shapiro J: Part III—Radiation dose calculations. In *Radiation Protection: A Guide for Scientists and Physicians.* Cambridge, Harvard University Press, 1972
3. McElroy NL: NRC reports on misadministrations and unannounced safety inspections. *J Nucl Med* 1986, 27:1102-1106

of supervision is needed, said Mr. McElroy. All tasks, from package receipt through quality control, prescription, administration, interpretation or follow-up for individual clinical procedures, and radioactive waste disposal may be delegated.

Prior instruction and periodic review of work habits and records is required, noted Mr. McElroy. The licensee retains responsibility for the acts and omissions of the supervised individual, he added.

[For more information on how the revision of 10 CFR 35 will affect the agreement states, contact: Lloyd Bolling, Office of State Programs, NRC, Washington, DC 20555 (301) 492-9889.]

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