From:	Martin Malsch
To:	Kramer, John
Subject:	[External_Sender] Avera Documents
Date:	Friday, April 22, 2022 1:01:27 PM
Attachments:	2022 04 22 Legal Argument Re Dippers (noid).pdf 2022 04 22 The Facts About Dippers (final noid).pdf

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John – here are the two documents to be referenced in the three confirmatory orders, with identifying headings. Let me know if you need anything further.

April 22, 2022

In the matter of EA-21-027, IA-21-060, and IA-21-061) (NRC Investigation Report 4-2019-007)

Legal Analysis of Regulations Cited by NRC Staff re Dipper Issue

The NRC Staff alleges that, contrary to 10 C.F.R. § 30.10(a) (the so-called deliberate misconduct rule), some licensee employees permitted the use of modified dippers to determine and record activity levels of dosages before medical use during the period of time between: (a) identifying the use of modified dippers and (b) installation of the new dippers, knowing that the practice would cause licensee violations of 10 C.F.R. § 35.63. However, as explained below, this continued use of modified dippers in the circumstances of this case did not cause the licensee to violate 10 C.F.R. § 35.63 and, therefore, there was no violation of 10 C.F.R. § 30.10(a). Also, for the same as well as related reasons, the licensee did not violate either 10 C.F.R. § 35.63 or 10 C.F.R. § 30.9(a).

10 C.F.R. § 35.63 has four related provisions. 10 C.F.R. § 35.63(a) provides that a licensee shall determine and record the activity of each dosage before medical use. 10 C.F.R. § 35.63(b) and (c) then prescribe how those determinations are to be made. In this case, the determinations were made using one of the methods permitted by 10 C.F.R. § 35.63(b) and (c), a direct measurement of radioactivity. 10 C.F.R. § 35.63(d) provides that, unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent. Finally, 10 C.F.R. § 35.63(e) provides that a licensee shall retain a record of the dosage determination required by this section in accordance with 10 C.F.R. § 35.2063.

Understanding the relation between subsection (a) and subsection (d) is key. The relevant interpretation question arises initially from the language in subsection (a), which (as noted above) requires that "[a] licensee shall determine and record the activity of each dosage before medical use." However, the rule does not specify how soon before each medical use the determination is to be made. This would appear, on initial analysis, to be a significant gap in the regulation because the radioactive byproduct material will decay over time. This will change the dosage and cause a recorded dosage to be inaccurate whenever the time period

between the determination and the administration is significant. A commenter on the proposed rule raised this question of decay and the Commission responded as follows in the final rule preamble:

> The NRC does not believe that the rule should specify when, based on half life, a decay correction should be performed. We believe the rule addresses this issue by permitting a licensee to administer a dosage if the dosage activity is within 20 percent of the prescribed dosage or is within the prescribed dosage range. This requirement gives the licensee responsibility for determining when it is appropriate to perform a decay correction. In the case of a long-lived radionuclide, the licensee may make a determination that a decay correction is not needed to verify that the dosage is within 20 percent of the prescribed dosage or is within the prescribed range because of the long half life of the byproduct material. (67 Fed. Reg. 20250, 20296 (April 24, 2002)).

Notably, the Commission did not change the text in the proposed rule, or even explain in the final rule preamble, that the dosage record must note the possibility that the dosage could be inaccurate because no decay correction was made.

While the utility of this interpretation as applied to long-lived radionuclides was cited, the interpretation cannot be limited to long-lived radionuclides. Whether the radionuclide is long- or short-lived can be of no safety consequence in and of itself because the Commission comment response clearly uses the 20 percent range or prescribed dosage range as the applicable safety standard, not half-life. The NRC Staff recognized this in its "Frequently Asked Questions About Licensing Medical Uses of Byproduct Material Under Revised 10 CFR Part 35." (https://www.nrc.gov/materials/miau/med-use-toolkit/faqs-part35.html) In response to the question "[h]ow long before an administration ('medical use') may a dosage determination be performed under § 35.63(a)?" the NRC responded that it "does not have a prescriptive requirement for when dosage measurements must be performed prior to administration, but licensees must ensure that the administered dosage is within the prescribed range or within ±20 percent of the prescribed dosage, as applicable." No qualification based on half-life was mentioned.

It follows, then, that the Commission intended 10 C.F.R. § 35.63(d) as then drafted (and subsequently promulgated) as the complete solution to the problem of inaccurate dosage determinations arising from radioactive decay – the licensee

would have the discretion to avoid a decay correction, even when the result would be a determination and recordation of an inaccurate dosage, provided there was reasonable assurance that the inaccuracy was within the prescribed ranges in subsection (d).

The permissive nature of subsection (d) is also noted in another part of the final rule preamble. The Commission explained that "[p]aragraph (d) *permits* a licensee to use a dosage if the dosage does not differ from the prescribed dosage by more than 20 percent or if the dosage falls within the prescribed dosage range" (*emphasis added*) (67 Fed. Reg. 20250, 20347 (April 24, 2002)).

The critical point, for present purposes, is that neither 10 C.F.R. § 35.63(a) nor (d) mentions decay correction or provides that the plus or minus 20 percent inaccuracy range contemplated and allowed by the Commission applies to some, but not all, of the dosage determinations and records required by subsection (a). Therefore, the authoritative interpretation adopted by the Commission here in the final rule preamble is necessarily a more general one – that it is permissible for dosage determinations (and, necessarily, the related records) to be inaccurate, but only to a defined extent. Patient safety is protected by subsection (d), which limits the inaccuracy to plus or minus 20 percent of the prescribed dosage or to the prescribed range, whichever applies.

In the case at hand, the dose-calibrator study completed on September 13, 2017 showed, with reasonable assurance, that using altered dippers would lead to dosages being underestimated, but not by more than 20 percent of the prescribed dosages. (Dosage ranges were not prescribed in the period in question). Therefore, there was no violation of 10 C.F.R. § 35.63 when the licensee continued to use the altered dippers. In other words, the altered dippers led to inaccurate dosage determinations, but the inaccuracies were within the range expressly contemplated and allowed by the Commission.

True, the precise dosage determinations (and records) were known to be inaccurate in a purely scientific sense because, after completion of the study on September 13, 2017, it was known that using altered dippers led to inaccurate dosage determinations within the 20 percent range. However, this knowing inaccuracy cannot be any more actionable or material than the knowing inaccuracy associated with a decision not to make a decay correction, a practice expressly approved by the Commission. Knowing inaccuracies in dosage determinations were generally contemplated and allowed by the Commission, provided only that the dosage limits in subsection (d) are not exceeded.

If the continued use of the altered dippers did not violate 10 C.F.R. § 35.63, it necessarily follows that there can be no violation 10 C.F.R. § 30.10 (a).

The licensee was alleged to violate not only 10 C.F.R. § 35.63, but also 10 C.F.R. § 30.9 (a), which provides in relevant part that information required to be maintained by a licensee shall be complete and accurate in all material respects. The information-maintenance requirement in question here is 10 C.F.R. § 35.2063. That section simply requires maintenance and preservation of records of dose determinations required by 10 C.F.R. § 35.63. However, under 10 C.F.R. § 35.63, the differences between the dosages as determined and recorded using altered dippers, and the dosages actually administered, were not materially false because differences as large as 20 percent were contemplated and allowed by the NRC. Put another way, using the established NRC standard for proving a material false statement, the dosage records could have no natural tendency to influence the NRC and could not be materially false in this case because the inaccuracies in the dosage records of less than 20 percent were fully contemplated and allowed by the NRC in the regulation alleged to have been violated. A knowledgeable NRC inspector, aware of the Commission's intent in promulgating 10 C.F.R. § 35.63, would know that the licensee's dosage determinations and records for the period in question could be inaccurate by plus or minus 20 percent even if the record failed to mention this fact.

April 22, 2022

In the matter of EA-21-027, IA-21-060, and IA-21-061) (NRC Investigation Report 4-2019-007)

Proposed Statement of Facts Relevant to "Dipper" NRC Enforcement Issues

The factual summaries included with the December 21, 2021 letters from NRC Region IV are essentially correct, insofar as what they address, but certain information that is relevant and material to the allegations made and to the choice of the appropriate NRC response to the events in question is missing. That is provided below.

Manager A first became aware of the alteration of the dippers during a routine visit to North Central Heart Nuclear Medicine Department (a division of Avera Heart Hospital) on September 12, 2017. Manager A attempted to measure a dosage during this visit and immediately noticed the alteration of the dipper. (The dosages were being used for imaging purposes, not for therapy). The dosage determinations were being made by one of the methods permitted by the NRC (direct measurement of radioactivity) but altered dippers were being used in the dose calibrators. Manager A's observation and discovery that day unveiled that the practice of altering dippers had been going on for many years, based on assurances by several longstanding and seemingly knowledgeable nuclear medicine imaging employees to their colleagues that the practice was perfectly acceptable because quality assurance had been applied to the calibration and the dosages administered would be within acceptable ranges. Manager A notified the Assistant VP Imaging Services of the discovery.

The same day Manager A consulted Manager B and they both agreed that a study must be done immediately to determine the extent to which the use of altered dippers could lead to dosage measurements that were not precisely correct. This study, completed the next day (September 13, 2017), established with reasonable certainty that: (1) the use of altered dippers would lead to dosages to patients being recorded at amounts that were, in fact, somewhat less than the dosage amounts actually administered; (2) the dosages as administered would differ from (be somewhat greater than) the dosages that were prescribed, but not by more than 20

percent; (3) no patient would be harmed by the increased radiation dose and the diagnostic images would still be accurate; and (4) the administration of dosages greater than those prescribed did not need to be reported to NRC. This is because the administrations were purely diagnostic in nature and would not result in excess doses to patients that met or exceeded the criteria for a reportable medical event in 10 C.F.R. §35.3045. It is notable in this regard that the NRC does not claim in its December 21, 2021 letters that any reportable medical event occurred.

During the conversation on September 12, 2017, following Manager A's notification to Manager B about the altered dippers, both Manager A and Manager B agreed that new dippers must be ordered immediately and used as soon as possible. The new dippers were ordered on September 13, 2017. On September 18, 2017 Manager A and Manager B met with a human resources manager about the dipper alteration. On September 20, 2017 Manager A and Manager B met with hospital executives to present the dose calibrator findings.

The new dippers arrived on September 22, 2017, and employees were ordered to use them thereafter. Also, on October 4, 2017, Manager A and Manager B presented findings on the dipper practice and on the results of the September 13, 2017 dosage study to the Licensee's Radiation Safety Committee. The Radiation Safety Committee agreed unanimously that the problem needed to be fixed, agreed with the decision to order and use new dippers, and agreed that no reportable medical events had occurred.

The key question arises whether Manager A and Manager B should have halted the administrations with altered dippers when the practice was first discovered September 12 2017, or on September 13, 2017, when the study established that the administered imaging dosages differed somewhat from those prescribed and recorded for the affected patients. Manager A and Manager B both thought that the altered dippers should continue to be used pending receipt and use of the new dippers for the following reasons.

First, no patients would be harmed. The dosages to be administered would be within the variation range permitted by the NRC and no reportable medical event would occur. Second, both were concerned that patients could be harmed by the delay in medical care. In fact, during the ten-day period when altered dippers continued to be used, over 116 patients arrived at Avera Heart Hospital for medically necessary cardiac scanning (232 dosages administered). In that ten-day period, it was believed these patients could not have been absorbed by the other facility in the area (Sanford Health) in addition to its own patients. Some of these

patients were emergency cases and scheduled for pre-op imaging during the period in question.

Neither Manager A nor Manager B had any financial incentive to allow the altered dipper practice to continue; their judgments were made in good faith to promote patient health and safety.

Finally, it is relevant that the licensee's Nuclear Medicine Department has substantially improved in recent years, to a great extent because of the initiatives of Manager A and Manager B. No violations similar to the ones alleged have occurred since the events of 2017 and the most recent NRC inspection uncovered no violations.