UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

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MEMORANDUM FOR: John E. Glenn, Chief
Medical, Academic and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

FROM: Stuart A. Treby
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SUBJECT: REQUEST FOR INTERPRETATION OF 10 C.F.R. §35.33(c) REGARDING DIAGNOSTIC MISADMINISTRATION REPORTING THRESHOLD LEVELS

This responds to the memorandum requesting guidance on which threshold level in 10 C.F.R. §35.33(c) applies for notifying the NRC and the referring physician of a diagnostic misadministration in instances in which "a patient, not scheduled for a nuclear medicine study at all, inadvertently receives a diagnostic dosage of a radiopharmaceutical." (Memorandum, at 1). As discussed below, we believe that both dose thresholds in §35.33(c) apply to any diagnostic misadministration. That is, §35.33(c) requires a licensee to report a diagnostic misadministration if either dose threshold is met, regardless whether the patient was or was not intended to receive any radiopharmaceutical. Thus, as to the specific question raised by the request for guidance, we interpret §35.33(c) to mean that any diagnostic misadministration to a patient not intended to receive any radiopharmaceutical is a dosage "five-fold different" from the intended dosage, thus making applicable the reporting requirements in that section.

DISCUSSION

Although the memorandum did not mention a specific incident or fact pattern, based on discussions with your staff, we determined that there was an incident at Ephrata Community Hospital ("Ephrata") in Region I which gave rise to a request by Region I for guidance. At our request, an April 3, 1991, letter to Ephrata (setting forth the results of a March 4, 1991 NRC inspection at Ephrata and transmitting a "Notice of Violation") were sent to us. According to the request for guidance from Region I, the facts in this incident are as follows: A recent NRC inspection revealed that a diagnostic misadministration of a radiopharmaceutical occurred at Ephrata on November 17, 1987. The

misadministration occurred because the nursing staff submitted an incorrect request for a "billiary study" instead of a "billiary sono study". The Nuclear Medicine staff performed a "hepatobilliary" study using 4 millicuries of Hepatolite Visofenin when the patient should not have received any radiopharmaceutical at all. The licensee's consultant performed an assessment of the dose to the target organ and to the whole body and determined that "a dose of 2.0 and 0.0500 (sic) rem were not exceeded."[1] The record did not include a breakdown of the actual dose received by the target organ or the whole body. The request for guidance from Region I concludes: "The licensee's consultant considers that the above criteria[2] in 10 C.F.R. §35.33 applies in the instance when a patient who is not scheduled to receive any radiopharmaceuticals receives them. Region I requests clarification as to whether the criteria regarding the five-fold difference applies in this case because the patient was not supposed to receive any radioactive material and did." (Request, at 1).

At the outset, we note that as stated in the request for guidance from Region I, this incident was a diagnostic misadministration. The term misadministration is defined (in relevant part) in 10 C.F.R. §35.2 as an administration of:

> (2) a radiopharmaceutical to the wrong patient;
>
> (4) a diagnostic dosage of a radiopharmaceutical differing from the prescribed dosage by more than 50 percent;

The administration of a radiopharmaceutical to a patient who is not supposed to receive any certainly falls within the definition in (2) above. In addition, such an incident is also within the scope of definition (4) above, on the basis that when no dosage of a radiopharmaceutical is prescribed, any dosage is a dosage differing from the prescribed dosage by more than 50 percent.

10 C.F.R. §35.33(c) requires notification of the NRC and the referring physician of a diagnostic misadministration within 15 days:

> "if the misadministration involved the use of byproduct material not intended for medical use, administration of a dosage five-

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[1]We attempted to determine the evidence relied upon to support the conclusion that in this case, the patient was not likely to receive either an organ dose of greater than 2 rem or a whole body dose greater than 500 millirem. Based on the discussion with the inspector, the assessment of the licensee's consultant is not in writing. Rather, the inspector stated that he discussed the assessment with the consultant in a telephone conversation. However, no information was provided as to the basis for the conclusion of the licensee's consultant. In our view, there is no adequate evidence to conclude that the organ dose or whole body dose threshold was not exceeded.

[2]This is a reference to the organ or whole body dose threshold only.

> fold different from the intended dosage, or administration of byproduct material such that the patient is likely to receive an organ dose greater than 2 rem or a whole body dose greater than 500 millirem."[3] (emphasis added)

Region I has asked which of the latter two thresholds applies in this case (i.e., the threshold of a dosage five-fold different from the intended dosage or the threshold of an organ dose of greater than 2 rem or a whole body dose greater than 500 millirem). The licensee applied the organ or whole body dose criterion and therefore did not report the misadministration to the NRC.

The original misadministration rule required licensees to notify, in writing, the referring physician and the NRC of all diagnostic misadministrations. See (superseded) 10 C.F.R §35.42, "Reports of diagnostic misadministrations." Also see "Misadministration Reporting Requirements," 45 Fed. Reg. 31701 (May 14, 1980). In the revision of Part 35 effective April 1, 1987, the diagnostic misadministration notification requirement was changed so that licensees only have to notify the referring physician and the NRC of those diagnostic misadministrations meeting the threshold levels stated above. 10 C.F.R. §35.33(c). See "Medical Use of Byproduct Material", 51 Fed. Reg. 36932, (October 16, 1986). The statement of consideration for this rule discusses the reasons for the change as follows: "misadministrations that result in a dose to the patient greater than a dose to a member of the public permitted under 10 C.F.R. §20.105(a) should require a report to the NRC and to the referring physician." 51 Fed. Reg. at 36942. However, there is nothing in this discussion of the dose threshold levels to be applied to certain kinds of diagnostic misadministrations.

We believe that if either the "five-fold different" dose level threshold or the organ dose/whole body dose threshold in §35.33(c) is exceeded, then a licensee is required to notify the NRC and the referring physician. It is true, as the memorandum requesting guidance states, that application of the "five-fold different" dose threshold in §35.33(c) would mean that any diagnostic administration to a patient not intended to receive a dosage would have to be reported to the NRC because the intended dosage would be zero. We do not agree with the conclusion in the memorandum that such a result could be considered as inconsistent with the current requirement in §35.33(c), which

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[3]The request for guidance from Region I misstates this threshold as a target organ and whole body dose of 2.0 and 0.500 rem, respectively. The memorandum from NMSS misstates the threshold as the "2 rem whole body and 500 millirem organ dose." The actual threshold is: "organ dose of 2 rem or a whole body dose greater than 500 millirem." 10 C.F.R. §35.33(c) (emphasis added). This threshold is met if there is either an organ dose greater than 2 rem or a whole body dose greater than 500 millirem. It is not necessary for there to be both an organ dose greater than 2 rem and a whole body dose greater than 500 millirem. Because of these misstatements of this dose threshold, it is not clear that this threshold was correctly applied in this case. According to a discussion with the NRC inspector from Region I, the licensee's consultant applied this criterion as it is written in §35.33(c).

makes it clear that not all diagnostic misadministrations have to be reported to NRC.

We believe that the "five-fold different" threshold does apply, on the basis that when no dosage is intended, any dosage is "five-fold different from the intended dosage." In other words, notification is required for any diagnostic misadministration involving a dosage to a patient not intended to receive any radiopharmaceutical, because any dosage is five-fold different from the intended dosage. There is no legal basis, either in the plain language of §35.33(c) or in the statement of consideration, for concluding that the five-fold different dose threshold should not be applied to an incident such as occurred at Ephrata. Not applying this threshold would lead to the strange result illustrated by the following example: If a patient is prescribed 1 millicurie of a radiopharmaceutical and is administered 10 millicuries, a notification is required, but if a patient is not prescribed any radiopharmaceutical and instead is administered 10 millicuries, a notification is not required.[4] In other words, the interpretation suggested by Region I would mean for a patient who is intended to receive a radiopharmaceutical, if the dosage administered is "five-fold" different from the prescribed dosage, notification would be required, even if the dosage administered does not meet the organ or whole body dose threshold. Conversely, under this interpretation, if a patient not intended to receive any dosage is mistakenly administered a radiopharmaceutical, the only applicable dose threshold for reporting would be an organ dose greater than 2 rem or a whole body dose greater than 500 millirem. Interpreting §35.33(c) as Region I suggests would mean that there is, in effect, one less reporting threshold applicable to misadministrations involving patients not intended to receive any radiopharmaceutical. (i.e., that a dosage "five-fold" different from the intended dosage does not apply to a misadministration involving a patient not intended to receive a radiopharmaceutical). The plain language of §35.33(c) states that notification of a diagnostic misadministration is required on the basis of either of two dose thresholds.[5]

CONCLUSION

Based on our interpretation of §35.33(c), both dose thresholds in §35.33(c) apply to any diagnostic misadministration and if either threshold is exceeded, notification is required. Therefore, Ephrata was required to notify both the NRC and the referring physician of the November 12, 1987 diagnostic

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[4]In this hypothetical, we assume that in both cases, the organ or whole body dose threshold is not met.

[5]There is nothing in the documents transmitted to us that suggests the other criteria in §35.33(c) "use of byproduct material not intended for medical use" is at all applicable.

misadministration to the NRC on the basis that the dosage administered was five fold different from the intended dosage.

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