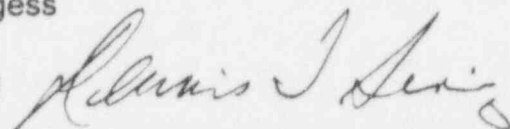


December 9, 1996

NOTE FOR: Michele Burgess
FROM: Dennis Serig 
SUBJECT: REVIEW OF NMED INFORMATION RELATED TO ITEM
NUMBER 941581, A 06/14/94 MISADMINISTRATION AT
BLODGETT MEMORIAL MEDICAL CENTER IN GRAND RAPIDS,
MI INVOLVING A STRONTIUM 90 EYE APPLICATOR

At your request, I reviewed the information in NMED concerning the 06/14/94 misadministration at Blodgett Memorial Medical Center. The review raised several concerns. They are:

- * 1. Information in the abstract is wrong and incomplete. The NMED abstract incorrectly states that "the treatment time of 19.1 seconds in the written directive was misread." Both EN 27398, dated 06/15/94, and the licensee's report dated, 06/16/96, indicate that the treatment time on the written directive was incorrect. The EN indicates that the treatment time on the written directive was 1.9 with no units. The licensee's report indicates that the treatment time on the written directive was 1.91 seconds. The NMED abstract correctly states that the treatment time "in the written directive was misread, and the patient received treatment for 1 minute and 9 seconds." I view this as indicative of a major problem in NMED. Two documents provided information that was misrepresented in NMED.
2. Information in the abstract indicates that "The licensee states that it does not expect any adverse consequences of the misadministration." That statement is accurate, but the NRC Medical Consultant's report dated 07/26/96, indicated "some risk of radiation induced cataract."
- * 3. There is no update in NMED based on the NRC Medical Consultant's report dated 07/26/96. Nor was the Medical Consultant's report cited as a reference document. This appears to be the reason for problem 2, above. Although this may fall outside the scope of your review, I view this as a major problem which can result in misleading analyses.
4. The times for the event and its reporting to the NRC's Operations Center are incorrectly noted to be "CDT." They were EDT. I view this as a minor error.
5. For site of event, "License No." and "Site Name:" are listed as "NA" but "State:" is listed as "MI." While this is correct, it appears to be unnecessary because state is already provided as part of the licensee

information. I view this as a minor error.

- 6. The reference documents are reported with an entry date. I am not sure why this useful, but I will assume it is. A document date would be useful but does not appear to be available. Notification and reporting requirements are triggered by misadministrations and must be completed on a schedule defined in the regulations. Provision of the actual date of a document would allow direct assessment of whether the schedule was satisfied. Since I might want to know more than just whether or not schedules were kept (e.g., the average time it takes to report), a simple yes or no answer is not as good as the document date. The date on the document, along with postmark, and receipt dates for incoming letters might be useful. If I could only have one for incoming letters, I'd reluctantly settle for the date on the letter itself. I view this as a major problem, although I'm not sure it's within the scope of your evaluation.
- * 7. Under "Misadministration Information:" NMED indicates that the patient was informed on 06/15/94. That is useful and correct information. However, we also need to know whether and when the referring physician and NRC Operations Center were notified. On top of that we need to know whether and when the licensee filed a report on the event with the Region and whether and when they sent a written report to the patient. Maybe that information should be under "Reporting Requirements:" but it doesn't appear to be. I tried to look directly into NMED for the information and it crashed my system! In my view this is a major problem that affects our ability to determine whether regulatory requirements have been met.
- 8. A number of dates have entries of 1/1/01. I understand your thoughts on the origin of that entry as a convention for getting past a requirement to enter a date when there is no date available. Still, I view this as at least a minor, and perhaps a major, problem. It can affect sorts of the data. It can also affect the time when an analyst might want to do logical or mathematical operations with dates.

Please let me know if I can be of further assistance.

cc: PHolahan