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NUCLEAR REGULATORY COMMISSION
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July 29, 1987

Release as bracketed

MEMORANDUM FOR: Harold Walker
Office of Investigations, RIII

FROM: Peter Crane
Office of General Counsel

SUBJECT: UNIVERSITY OF CINCINNATI INCIDENT

As we discussed on the telephone on July 28, I have put down on paper some of my thoughts about the University of Cincinnati incident, in particular my reasons for believing that the licensee deliberately made false statements to the NRC. First, let me review the background.

In August 1986, the Office for the Analysis and Evaluation of Operational Data (AEOD) issued a report (See Tab 2) which discussed the generic problem posed by the use of reusable "seeds" (small metal capsules containing radiopharmaceuticals) that are placed in plastic catheters and inserted directly into tumors to deliver a therapeutic dose of radiation. AEOD's concern had been stimulated by an event in August/September 1984, in which such a seed, inadvertently cut in the process of removing it from a catheter after use, was inserted into the brain tumor of a second patient. Iodine 125 leaked from the seed into the patient's bloodstream and accumulated in her thyroid gland, leading to a dose in excess of 2000 rads to the thyroid. The AEOD report noted that the staff had determined that the event did not constitute a reportable "misadministration," as that term is defined in Part 35 of the Commission's regulations, because the hospital had detected the leak while the four-day treatment was in progress and had chosen to leave the seed in place.

After obtaining backup material on the event from the report's author, on August 27, 1986 I wrote a memo (See Tab 3) to Commissioners' assistants which made two points: (1) as a factual matter, the chronology presented to the NRC by the hospital seemed highly implausible, and (2) even if the facts were as stated by the hospital, the event should still have been classed as a misadministration. To emphasize, my view was that the event was a misadministration, whether or not it was discovered while treatment was in progress. It was the staff's position, however, that it made a difference whether the event was discovered while treatment was in progress or only after treatment was completed.

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The Commission referred the matter to OI, which advised the Commission (1) that it agreed with me that the case record suggested that an attempt had been made to deceive the NRC and (2) that it would investigate the matter.

In response to a staff requirements memo from the Commission, the Executive Director for Operations advised Chairman Zech by memorandum of November 28, 1986 (Tab 5) that the staff had concluded that in fact, a misadministration had occurred. The memorandum also indicated that the chronology was not precisely as the staff and the hospital had earlier indicated. It was now stated for the first time that the hospital had "suspected" leaking iodine sources on August 28 or 29, 1984 (the treatment had begun on August 27) and had "confirmed" the leak on September 1, 1984, when the sources were removed. This chronology was based, the staff said, on the hospital's November 1984 submission and a further conversation with the hospital only four days earlier, on November 24, 1986.

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The staff provided further details in a December 15, 1986 briefing of Commissioners' assistants at which a handout was passed out. (See Tab 6.) That handout indicated that the decision to leave the seeds in place was made by Drs. [ ] of the hospital on August 28 or 29, 1984. The handout included the statement, "October 30, 1984, the attending physician told the NRC during a telephone conference call that even had they known the seeds were leaking during treatment (from the wipe test), therapy would have continued." (Emphasis added.) At the briefing, the staff briefer indicated that this actually meant, "had they known for sure."

On March 18, 1987 the EDO forwarded to the Commission SECY-87-73, the Abnormal Occurrence Report for the third quarter of 1986. It included a description of the Cincinnati incident which represented still another modification of the staff's account:

> On August 27, a total of eight seeds were placed in thin plastic catheter tubes and were temporarily implanted in the brain of a terminally ill patient. The next day, iodine-125 contamination was detected in the brachytherapy source storage room (BSR). Bioassay results showed that the technicians who had worked with the iodine-125 seeds had measurable uptakes of iodine. When the seeds were removed from the patient on September 1, a radiation survey of the patient's neck revealed a radiation level of 1.5 millirem per hour at two inches from the thyroid, which confirmed the seeds were leaking inside the patient. The patient was then discharged from the hospital with instructions to return for further bioassay analyses.

It will be noted that this third account does not claim that the hospital knew of or even suspected the misadministration while it was going on.

I believe that investigation will probably show that none of these three versions is accurate, and that in fact the misadministration was discovered on September 4 and almost immediately reported to NRC. My belief is based upon, among other things: (1) Dr. [redacted] contemporaneous (9/12/84) account of the incident, in which he makes no mention of any discovery either during treatment or immediately upon its conclusion (See NRC Report (Tab 1), Attachment 1 (Licensee's Report), Appendix E); (2) the letter from 3M, manufacturer of the seeds, to Dr. [redacted] thanking him for letting 3M know of the incident immediately upon its discovery, which is stated to be September 5, 1984 (See NRC Report (Tab 1), Attachment 6); and (3) the listing of who was tested when at the hospital. (See Tab 1, Attachment 1, Appendix B.)

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At the December 1986 briefing, the staff confirmed that on learning of the event, they asked Tom Dorian (ELD) whether the facts added up to a misadministration. Dorian said that they did. The staff then talked to the hospital again. The result was a different statement of facts, subsequently memorialized in the 11/2/84 submission from the hospital. On the basis of the 11/2/84 submission, the staff concluded, without consulting Dorian again, that there had <u>not</u> been a misadministration. It is not clear how the staff's understanding of the event changed from the time it first presented the facts to Dorian to the time at which it made the decision (1) that no misadministration had occurred and (2) that there was no need to return to Dorian to ask him whether the facts, as now understood by the staff, constituted a misadministration. The December 15 handout does report, however, that the decision that the event did not constitute a misadministration was made in consultation between Region III and NMSS, and that Region III documented its discussion with NMSS in a 12/11/84 memorandum to files. (I have not seen that memorandum.)

The staff's handout of 12/15/86 reports, as noted above, that the hospital had said on October 30, 1984, that "even had they known" during treatment that the seeds were leaking, they would have left them in. Yet the filing submitted three days later claimed that they <u>had</u> known that the seeds were leaking, and that they <u>did</u> leave them in deliberately. Not only was that statement inaccurate, the staff by its own account <u>knew</u> that it was inaccurate.

The undisputed facts of this case are troubling enough. They suggest, at the very least, that the staff tolerated the submission of an account that it knew to be untrue, and accepted that account as the basis of its inspection report. They indicate as well that the staff made a legal conclusion that cleared the

licensee of committing a reportable misadministration after having been advised by counsel that the facts, as presented to counsel, did constitute a misadministration. Even if the staff's understanding of the event had changed substantially, it is reasonable to expect that staff would have consulted counsel a second time before reaching the legal conclusion that there had been no misadministration.

A still more troubling possible hypothesis can be formed from these facts, but it will take investigation to determine whether it has validity. That is the possibility (1) that the hospital intended to be candid both with the NRC and with 3M, reporting the event as soon as they discovered the leaking seed and the contamination of the patient (on or about 9/4/84); (2) that the staff consulted Tom Dorian, who advised that under the facts as presented a misadministration had been committed; (3) that the staff discussed the matter with the hospital again on 10/30/84 and was told that even _if_ the leak had been discovered while treatment was in progress, the seed would have been left in place; (4) that it was the staff which therefore encouraged or permitted the hospital to make the false report that in fact the leak _had_ been discovered while treatment was in progress, and that a conscious decision _had_ been made to leave it in place; (5) that the hospital duly filed a deceptive account, and the staff, knowing the account to be a fiction, proceeded to treat it as factual and on that basis, to clear the licensee of committing a misadministration without asking Dorian whether, under the revised version of the facts, a misadministration had been committed; and (6) that the staff, knowing that the Commission had ordered an investigation of the matter, contacted the hospital on November 24, 1986 to review the facts, thereby putting the hospital on notice that the earlier account was under scrutiny.

I wish to stress that the issue is not simply whether the event was discovered on September 1, as the staff now claims, or on September 4. Even if the staff is proved correct on that point, it does not explain why the staff accepted the hospital's November 2, 1984 account of the facts when it knew from the October 30, 1984 telephone call that the November 2 account was inaccurate.

With that as background, the following are questions which may deserve exploration:

1. Why did Dr. [redacted] 9/12/84 account (Appendix E to Attachment 1 to Tab 1) include no mention of any discovery of the leaking seed during the treatment? Why, if the hospital and the staff claim that the decision to leave the leaking seed in place was made on 8/28 or 8/29, does Dr. [redacted] 9/12 memo speak of the iodine leak being discovered "several days after" insertion on 8/27?

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2. If the hospital was telling the staff on 10/30/84 that "even if they had known" during treatment of the leaking seed, they would have left it in, why did it tell the staff on 11/2/84 that they had known? Did the hospital get queried about that discrepancy by anyone at NRC?

3. Did anybody from the NRC know in advance that the hospital would make the assertion contained in the November 2 letter from Dr. Aron to Bill Axelson in Region III (Attachment 9 to Tab 1)? If so, did the staff approve that account of the facts in advance? Did anyone in the NRC suggest that the hospital should provide that account of the facts to NRC so that the incident could be classified as a non-misadministration? (We know, from the staff's 12/15/86 briefing of Commissioners' assistants, that the NRC staff solicited the November 2 letter from the hospital. See Tab 8, my memo to files of 12/19/86. What we don't know is whether the staff advised the hospital on the content of the letter.)

4. If the hospital knew of the leak on September 1, as the staff now claims, why did it wait until September 5 to call NRC? (Attachment 6 to Tab 1.)

5. If the hospital knew of the leak on September 1, why did it wait until September 5 to call 3M, and why did 3M praise Dr. [redacted] for bringing 3M into the picture "immediately" on learning of the leak? Ex 6

6. If the hospital knew of the leak while the treatment was going on, or suspected it, why didn't they give the patient potassium iodide as a thyroid blocker? (We know that other people at the hospital got potassium iodide a few days later, so the hospital was aware of its function for thyroid protection.)

7. What was the patient's friend told at the time that the patient was released from the hospital on 9/1/84, and at any other time? If the hospital knew that the patient had a significant burden of radioactive iodine in her thyroid, why did the friend not get potassium iodide as a thyroid blocker? Was the friend cautioned about getting too close to the patient? (The staff handout of 12/15/86 says that Dr. [redacted] counseled the patient and the patient's friend on 9/1/84.) Ex 6

8. If they had traced the contamination to the patient by 8/29/84 or even on 9/1/84, why did they wait until 9/7/84 to start testing the nurses who had taken care of the patient? (Appendix F to Attachment 1 to Tab 1.)

9. What is the significance of the correction on Appendix D of the hospital's report (Attachment 1 to Tab 1), where the

patient's urine sample is stated (in typed text) as having been taken on 9/2/84, and this date is then crossed out and replaced with a handwritten "8/31/84"?

10. Did the hospital obstruct the staff's investigation by failing to make Dr. [illegible] available for an interview? (This question is based on what you told me on the telephone yesterday.)

11. What was said in the November 24, 1986 telephone call from the NRC staff to the hospital?

Attachments: List attached

LIST OF ATTACHMENTS

1. 2/6/85 NRC Inspection Report, with 9 attachments, including the hospital's statement that "the decision to continue the implant was a medical decision" made "when it was noted that there was iodine leakage." (Attachment 9.)

2. AEOD Case Study Report on the Rupture of an Iodine-125 Brachytherapy Source at the University of Cincinnati Medical Center, AEOD/C601, August 1986. (S. Pettijohn, author.)

3. 8/27/86 Memorandum, P. Crane to M. Clausen, M. Lopez-Otin, S. Droggitis, J. Kotra, J. Milhoan, "University of Cincinnati Incident."

4. 11/26/86 Memorandum, P. Crane to M. Malsh, "Draft Stello Memo on Cincinnati Iodine-125 Incident." (With attachments.)

5. 11/28/86 Memorandum, V. Stello to Chairman Zech, "Staff Requirements - AEOD Case Study Report on the Rupture of an Iodine-125 Brachytherapy Source at the University of Cincinnati Medical Center."

6. 12/15/86 Briefing Handout, "Ruptured Iodine-125 Seed Incident."

7. 5/12/87 Federal Register Notice, 52 F.R. 17855, "Abnormal Occurrences for Third Quarter CY 1986."

8. 12/19/86 Memorandum, P. Crane for files, "Cincinnati Incident."

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NOTES ON OI INVESTIGATION

Exhibit 3. Interview with Dr. [redacted]

p. 8 Explains that if contamination is found, "we could elect to block the thyroid," i.e. with potassium iodide. The fact that they didn't suggests that there was no great suspicion that she was contaminated -- early in the treatment, at least.

p. 10. Note that because the hospital also used I-125 to treat prostate cancer, with permanent implants, the fact of I-125 contamination did not necessarily point to the seeds in our patient. This same point is made by Hamilton at p. 22 (Exhibit 4).

p. 11. Walker: "At that time on the 30th of August when they did the counts, there still wasn't an apparent knowledge of these seeds that were leaking?"
He: "No."

Note that Dr [redacted] mentions, with regard to the fact that they were all required to have physical exams, "Dr [redacted] who is thyroid specialist." So the hospital's thyroid specialist was brought into the picture on August 30 or 31. It might be worth interviewing him, because he is not on the line in the way that the nuclear medicine people are.

p. 12. On August 31, "I don't recollect that anybody has definitely told me at that time that the actual contamination was inside that patient still."

Walker asks, "Was there anything else that occurred on the 1st of September that would lead you to believe that beyond a doubt it was the leak, the seeds in that lady's treatment that was leaking?" [redacted] answers, "they did a thin window counting on the patient's thyroid glands that indicated some activity so that kind of --" Walker: "That would give you a hint?" [redacted] "Yes." But note that [redacted] is not saying that the hospital knew; he is pointing to evidence that if properly interpreted would have indicated what is going on. We don't have a statement here that they knew on August 31.

p. 13. Walker asks, regarding September 4, "At this point up to this point in time it is still kind of a mystery as to exactly what is going on and there are still tests being conduct; is that accurate?" [redacted] replies, "Yes."
p. 14. "I think by that point (September 4) we had pretty much pinpointed the most likely cause would be those seeds that went into the patient."

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p. 15 "We have the only whole body counter in the whole Midwest or whatever." This means that they are an extremely well equipped hospital. As such, there is no reason why it should take days and days to get counts on the urine samples. As I understand it, it should take about 20 minutes to get a count.

p. 20-21. Dr [redacted] talks of having talked to the patient before the treatment, and is vague on the existence of the patient's boyfriend, who "might have got counted, too." But the NRC staff handout of 12/15/86 said that Dr [redacted] talked to the patient and the patient's friend prior to her dismissal from the hospital and told her to return for followup counting. Dr [redacted] doesn't refer to this, and I wonder where the NRC staff got this information.

p. 25 Dr. [redacted] indicates he really isn't in the line of knowing about contamination, that this is the province of radiation safety.

p. 26-27. On leaving the seed in:

"I think we discussed it with [redacted] who was head of the department and in case at that time we weren't sure it was her. If it was her, then still I think the treatment was going to outweigh the possible slight contamination that she was going to get." Does Dr. [redacted] remember this himself, or was he reminded of it by someone else? Who is "we"? Is his memory vague, or is this just he way he expresses himself?

Q "As I recall, and I got the impression from your phone conversation that this was a discussion that may have taken place as late as the last day of her treatment?"

A "Yes. There was some suggestion that it might be her. That is why they took the urine test, but the actual results were not done until the following Monday. So we could not pinpoint it. ... If it was her, should we take it out that night or wait until tomorrow morning and take it out." Who is "they"? Why did it take so long to get a reading? Was [redacted] there when the sample was taken, or did he hear about this from others?

p. 28. [redacted] agrees with the Region III memo to files (which I have never seen) dated December 11, 1984 which includes a statement "indicating the physician stated that even if they had known that the seeds were leaking at the time of the treatment, therapy would have continued." What does [redacted] mean by "known"? The staff insists that this really means, "known for sure."

(For the OIA side of this, it is hard to reconcile this memo with the staff's memo of 11/28/86 to the Commission.)

p. 32. Dr. [redacted] asked if he was in on the discussions between NRC and Saenger, says: "No. I think we were all kept out of those."

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Exhibit 4. [redacted]

p. 22 Note that it was not clear that iodine leakage necessarily pointed to the seeds in the patient's head, because they also performed prostate implants with I-125. [redacted] makes the same point at page 10 of his interview.

p. 24. "The multi-channel analyzer is very capable of counting." Again, they have sophisticated equipment.

p. 25. "I think the consensus was, or at least certainly my understanding was tht this test would be sufficient to detect any ongoing leakage." (He is describing the wipe test of the patient's lead hat.)

p. 27. THYROID COUNTS WERE TO BE MADE ON THE WHOLE BODY COUNTER. If that is right, why wait to test the patient? I don't see any record that the patient was ever put under the whole body counter. I thought they counted her just on the basis of the urinalysis.

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p. 28. [redacted] is the whole body counter. Let's see his records.

(NOTE that [redacted] is relying heavily on the hospital chronology, not on memory. See e.g. p. 28, 30.)

p. 35. "At the time, we didn't know whether those seeds were in fact leaking..."

p. 38 "It was clear that the patient had been contaminated with Iodine and that it was sequestered in the thyroid." (This is on explant. Why then was it a mystery to [redacted] until September 4? Was Radiation Safety passing on the information to [redacted] or were they keeping information from him?)

p. 44. Note that [redacted] does not squarely answer the question, "were you involved in any meetings with any of hte management personnel -- and I mean, when I say management, you'll have to tell me who that may be -- Dr. Saenger, [redacted] [redacted] regarding the chronology which was submitted to the NRC?"

Exhibit 5. Interview with [redacted]

p. 17 Aware on August 31 that they were collecting patient's urine, [redacted] When did they get the

reading on [redacted] urine must check the listing.

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Exhibit 6. Interview with [redacted] RSO.

p. 19 Doesn't answer the question, "why was there such a long time frame from the 31st of August to the 5th of September when the count was conducted?" (But see p. 22, where he answers "probably" when asked if the Labor Day weekend is the reason.)

p. 27 Believes he called Srenowski at NRC on September 4, told him of iodine contamination hot urine, hot thyroid.

p. 33-34. Very vague as to whether she was brought back in for a whole body count or the 557 count came from getting the urine counted. ("One of the few whole body counters in the country," says [redacted])

p. 35 Doesn't answer the question about discussions of whether there was a misadministration, except to say it was discussed with NRC personnel "just to confirm that this was not under the definition of a misadministration." BUT DOESN'T THE HOSPITAL CLAIM SOMEWHERE THAT THEY NEVER DISCUSSED WITH NRC WHETHER OR NOT THIS WAS A MISADMINISTRATION?

Exhibit 7. Interview with [redacted] (Radiation physicist, Radiation Oncology Division)

p. 7 [redacted] says he was informed later that [redacted] had made the decision to leave the seeds in for the patient's benefit. Not clear when or by whom.

p. 11 [redacted] was the resident who actually removed the sources. Again, there is uncertainty as to what kind of a count she got: whole body or something else.

Exhibit 8. Interview with [redacted] Division of Radiation Oncology.

p. 5 NRC chronology is more accurate than hospital's.

p. 7 Believes that [redacted] notified him of the contamination.

p. 8 Doesn't disagree with [redacted] recollection that the conversation abovut leaving in seeds was Friday; his own recall seems hazy. See also p. 20, where he says he thought it was earlier in the week.

p. 9 "We did not know [on Friday, August 31] that the patient was contaminated. The evidence we had at that point was there was something going on in the storage area. We did not know which seed or seeds, even, had been the source of contamination. Or, in fact, we had positive evidence that the patient wasn't contaminated. THE ONLY BIT OF THINGS THAT WE DID ARGUED AGAINST CONTAMINATION."

p. 12 The thin window count on the patient was routine, done in every case.

p. 13 Asked if he was privy to the instructions given to the patient, he replies, "I would not necessarily have been involved in that." Not a direct answer.

p. 20 Letter of Nov. 2 came in response to the NRC's request.

p. 21 Says that the letter to NRC had nothing to do with the question of whether there was a misadministration. This seems inconsistent with [redacted] recollection at 35.

then what was the "problem"?

p. 22 Says he sat in on a discussion of the chronology with NRC and [redacted]

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Second [redacted] interview

p. 3 "The words 'iodine leakage' as outlined in the letter of 2 November refers to contamination in the brachy therapy storage room. WE HAD NO KNOLWEDGE AT THAT TIME OF ANY LEAKAGE IN THE PATIENT. AND IN FACT, THE ONLY KNOWLEDGE THAT WE HAD IN THE PATIENT AT THAT TIME WAS NEGATIVE. . ."

p. 4 Q Then the wordage could just indicate iodine contamination as opposed to leakage?

A Correct. That is what was meant actually by the words.

p. 5 Reiterates that there was no discussion related to whether it was a misadministration.

Exhibit 9. Interview with [redacted]

NOTE: THIS INTERVIEW IS FASCINATING. [redacted] IS DEEPLY INVOLVED IN THIS -- HE WAS THERE FOR IMPLANT AND EXPLANT -- AND HE IS DODGING EVERY QUESTION PUT TO HIM.

P. 5 Doesn't recall whether he learned of the contamination during treatment period or after.

p. 6 Doesn't recall whether discussions linking contamination to patient's seeds occurred before or after

explant. HOW IS THIS POSSIBLE? SURELY IF THE LEAK HAD BEEN SUSPECTED, IT WOULD HAVE BEEN ON EVERYONE'S MIND AT THE TIME OF EXPLANT.

p. 7 Doesn't recall what instructions were given to patient after explant. When asked whether she was in a position at the time of her release to be told about this, [redacted] answers by asking whether the interviewer has the medical record. When told no, he replies that he does not recall.

p. 8 Doesn't recall instructions given; it might have been by him, might have been Dr. [redacted]

p. 10 Doesn't squarely answer the question whether the thin window counting was enough evidence to say that there was leaking in her head.

Exhibit 12. Interview with Dr. Eugene Saenger.

p. 7 Saenger, Chairman of the Radiation Safety Committee at the time of the incident, can't recall if he learned of the contamination during the event or afterwards. Seems hard to credit.

p. 8 Can't recall if he was in the exit interview.

p. 10 Asked whether it would have been feasible to give her a thyroid blocker, he answers that it would not have made a difference for her -- a different question.

p. 12 14 Attacks the misadministration rule as constituting the practice of medicine by NRC; says he has written an editorial to this effect.

p. 15 Implies that the request for the [redacted] letter came in one of his (Saenger's) many conversations with Axelson.

Exhibit 13. Memo, Mullauer to Walker.

Says that there was lengthy discussion at the 10/12/84 exit interview of whether a misadministration occurred; that they felt there was no misadministration because a medical decision was made to continue the treatment as planned; that although the source of the contamination was unknown (!) during treatment, they did not rule out the possibility of a seed leaking in the patient, and even if they had evidence at the time of treatment that the contamination came from a seed implanted in the patient, this would not have changed the course of treatment. Mullauer says he presented this information to RIII staff on return to the office.

Hard to square this with [redacted] claim that the letter on the medical decision had nothing to do with the claim that there was no misadministration, unless [redacted] was told to write the letter without knowing what its purpose was. Conceivably, the solution was reached by Saenger (and/or [redacted]) and NRC officials, and Saenger then informed [redacted] simply that the NRC wanted a letter confirming that he was the one (with [redacted]) who made the medical decision to leave the seeds in. Note that [redacted] was not present at the October 12 exit interview, but was present at the October 30 telephone conference call. Perhaps the solution was developed between October 12 and October 30. Note that Mullauer (in the OIA interview) seems puzzled when asked about the October 30 phone conversation; it's as though he wasn't there.

Exhibit 14. Interview with [redacted]

Says that the urine sample was not considered; the 557 uCi figure came from the whole body count of September 5. Then what did the urine show?