July 6, 1987

MEMORANDUM FOR: Sharon R. Connelly
Director, OIA

FROM: Peter Crane

SUBJECT: STAFF HANDLING OF UNIVERSITY OF CINCINNATI INCIDENT

The purpose of this memorandum is to refer to you for evaluation the handling by the NRC staff of an event which occurred at the University of Cincinnati Medical Center in August and September, 1984. In my opinion, the facts are sufficiently suggestive of misconduct by the NRC staff to warrant an investigation by your office. In making this recommendation to you, I am speaking solely for myself, presenting my personal views. The issue is somewhat complicated factually, as you will see from the following outline of my concerns.

In August 1986, the Office for the Analysis and Evaluation of Operational Data (AEOD) issued a report 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 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. 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. That investigation has yet to be completed.

In response to a staff requirements memo from the Commission, the Executive Director for Operations advised Chairman Zech by memorandum of November 28, 1986 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.

The staff provided further details in a December 15, 1986 briefing of Commissioners' assistants at which a handout was passed out. That handout indicated that the decision to leave the seeds in place was made by Drs [redacted] and [redacted] 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 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 an investigation would probably show that none of these three versions is accurate, and that in fact the misadministration was discovered on September 4 and 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; (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; and (3) the listing of who was tested when at the hospital. Ex. 6

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 not 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 had known that the seeds were leaking, and that they did leave them in deliberately. Not only was that statement inaccurate, the staff by its own account knew 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 exculpated 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 an investigation to determine whether it has validity. That is the possibility 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); that the staff consulted Tom Dorian, who advised that under the facts as presented a misadministration had been committed; 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; that the staff therefore encouraged the hospital to 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; that the hospital duly filed a deceptive account, and the staff, knowing the account to be a fiction, proceeded to exculpate the licensee without asking Dorian whether under the revised version of the facts, a misadministration had been committed; and 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 deceptive.

With that as background, the following are questions which in my opinion deserve exploration:

1. If the staff knew on October 30, 1984 that the hospital had not known during the treatment that the seed was leaking, why did it accept the November 2, 1984 claim that a conscious medical decision was made during treatment to leave a leaking seed in place?

2. In view of Tom Dorian's legal advice that the event constituted a misadministration, how was the decision reached by the staff that the event did not constitute a misadministration, and why was Dorian not consulted about the revised version of the facts?

3. Since the staff now acknowledges that the November 2, 1984 account was inaccurate, why is it not troubled by what

appears on its face to be a willful material false statement in that submission, and why does it insist that there was no wrongdoing deserving of an investigation?

4. Why does the staff see no wrongdoing, and no need for regulatory action, in the hospital's failure to notify the NRC within 24 hours of the date on which the hospital (according to the staff) discovered the event, i.e. September 1? (It is at least possible that the staff knows that the licensee would have a valid defense, i.e. that the licensee did notify NRC within 24 hours of discovering on September 4 that a misadministration had occurred.)

5. Why did the staff discuss the chronology by telephone with the hospital on November 24, 1986, when they knew that the Commission had ordered an OI investigation of that very chronology?

6. Was the staff's opposition to an investigation based upon a valid belief that there was nothing worth investigation, or was the staff concerned that an investigation would reveal staff misconduct?

7. Did the staff obtain Commission concurrence in an Abnormal Occurrence report that contained an account of the Cincinnati incident which the staff knew to be inaccurate?

I wish to stress that I believe that these are questions that should be addressed: I do not mean to suggest that I necessarily know all the answers to those questions. OI's investigation will probably throw some light on most if not all these issues.

I would be happy to assist your staff with this matter in any way. I can be reached at 634-1465.

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. Malsch, "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."