December 19, 1986

MEMORANDUM FOR: The Files

FROM: Peter Crane

SUBJECT: CINCINNATI INCIDENT

The NRC staff came to H Street on Monday, December 15, 1986, to brief the Commissioners' assistants on the Cincinnati incident that was the subject on my memo to the Commissioners' assistants in August of this year. The briefing was conducted by Glenn(Schulblum), an IE branch chief, Vandy Miller (NMSS), and Bill Axelson of Region III NMSS. The briefers provided a more detailed chronology than had previously been furnished, and they offered an account that differed in some significant ways from that which had previously been put forward.

For the most part, the information which the briefers supplied is contained in the attached handout. In addition, the briefers advised us that the staff solicited from the hospital the November 2, 1984 submission which had been the focus of my concerns in August.

According to the staff, the licensee suspected as early as August 28 or 29, 1984, that the seed was leaking into the patient's head; they confirmed this on removing the seed on September 1, 1984. (This contrasts with the account provided by the licensee in its November 2, 1984, letter, where there is no suggestion of initial uncertainty followed by later certainty.) According to the handout, the licensee advised the staff, in a telephone call on October 30, 1984, that "even if they had known" during the treatment that the patient was being exposed to iodine from a leaking seed, they would have allowed the treatment to continue. (See handout.) The staff clarified this in the briefing, explaining that it meant, "even if they had known for sure, as opposed to merely suspecting etc."

The staff briefers informed us that the decision to call the event a non-misadministration was a mistake, although they considered it a "grey area." They also informed us that the patient died on November 22, 1985.

The staff briefers were asked why, if the urine sample was taken from the patient on August 31, 1984, it took until September 5, 1984, to get a count of the thyroid burden. The staff said they didn't know, and suggested that it might have been a delay caused by the Labor Day weekend.

The staff briefers were asked, by Janet Kotra, how the decision was made that it was not a misadministration: specifically, whether there had been any legal input. The reply was that Tom Dorian (who was present at the briefing) had been asked initially and had responded preliminarily that it was a misadministration. Axelson said that in retrospect he should have gone back to Dorian after talking to the licensee on October 30 and after getting the licensee's submission on November 2 to ask whether, under the facts as stated in the November 2 submission, the event was a misadministration. To the question, "who made the decision that it was not a decision," the response was equivocal. The briefers said that both headquarters and regional people were involved, and Vardy Miller said that he was "in on it." There was no clear answer as to the level at which the determination was made.

Janet Kotra also asked why, if they knew that the pateint was getting a dose of iodine to the thyroid, no thyroid blocking agent, such as potassium iodide, was administered. This was a good question, the briefers said, adding that in a recent case (the hospital in Toledo, I believe), where a patient was mistakenly given radioiodine, the NRC suggested that it would be appropriate to give KI for thyroid protection and that recommendation was rejected by the attending physician.

Early in the briefing, Janet Kotra commented that the staff seemed to think that the licensee had failed to follow proper procedures. But didn't it seem more than a mere failure to follow procedures when the technicians were unaware that the seeds were to be reused, she asked. In responding to this, it was clear that Schulblum was not fully familiar with the IE report on the incident. First, he didn't know, until it was pointed out to him, that the technicians had been interviewed by IE and were unaware of the intention to reuse the seeds. Second, he commented that the technicians clearly hadn't been trained in the procedure with dummy seeds. Had he been more familiar with the IE report, he would have known that the technicians told the NRC that they had been trained with dummy seeds -- they just hadn't been told that the seeds would be reused.

Two days after the briefing, in reviewing the background papers, I focused for the first time on the letter from 3M, the manufacturer of the seeds, to Dr. [redacted] of the hospital's radiation oncology department. That letter, a copy of which was sent to James Mullauer of Region III, was dated October 15, 1984, and includes the following: "You notifed one of us (J.B. Gergen) immediately upon learning of the contamination (9/5/84)..." The point is reiterated in the letter: "Dr. [redacted] thank you for your prompt attention to this matter and for immediately getting 3M involved."

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EX 6

This letter, which points to a discovery of the leaking seed several days after the seed was removed from the patient, is consistent with the contemporary account dictated by Dr. [redacted] on September 12, 1984. (It is also consistent with the timetable I hypothesized in my memo to the Commissioners' assistants of August 27, 1986.) It is wholly at odds, however, both with the licensee's November 2 account (i.e., we knew that the leak was taking place even while the seeds were in the patient) and with the staff's later revision of that account (i.e., the licensee suspected that the leak was taking place while the seeds were in the patient, and knew for a fact of the leak on September 1, when the seed was removed and the patient and the patient's friend were briefed). This would also help explain why no one began to test the nurses who had attended the patient until after September 5.

At least one possible explanation suggested by all this is that the licensee was prepared to be straightforward with the NRC and with 3M, informing both as soon as the leaking seed and the exposure of the patient were known -- that is, on September 4 and 5. Yet the November 2, 1984 account told a different story. We now know from the staff that the staff itself solicited the November 2 submission. We do not know, at this point, whether the staff suggested to the hospital what it should say in that submission.