November 7, 1988

NOTE FOR: Dennis Rathbun

FROM: Peter Crane

SUBJECT: U. OF CINCINNATI INCIDENT

I am taking the liberty of writing to you to draw your attention to a situation that illustrates forcefully that the fact that the Commission directs that something be done doesn't always mean that it gets done quickly.

Just about two years ago, on November 10, 1986, Chairman Zech was gracious enough to send a memorandum to the General Counsel commending me for bringing an investigatory matter to the Commission's attention. The matter in question was a misadministration which occurred at the University of Cincinnati Medical Center in August/September 1984, and which was described in an AEOD report issued in the summer of 1986. In that incident, radioiodine was implanted into a patient's brain tumor in small metal "seeds." Because one of the seeds had inadvertently been torn prior to its implantation, and because no one had noticed the damage, a significant amount of radioiodine accumulated in the patient's thyroid during the five-day treatment period.

I first learned of the incident when the AEOD report was circulated, and I sent a memo to you and other Commissioners' assistants in August 1986 which made two points: (1) that the NRC staff had erroneously called the event a non-misadministration, and (2) that the hospital's account of the facts, which the staff had accepted as true, was highly implausible and probably represented an effort to deceive the NRC. I don't want to get into a detailed repetition of the factual background here, but the heart of the matter was my contention that if the hospital had, as they claimed, discovered on August 28 or 29, 1984 (early in the treatment period) that an iodine seed was leaking into the patient's bloodstream, they would at once have taken a urine sample and analyzed it. The fact that they did not do so until days later suggested to me that they were misrepresenting to the NRC the extent to which they were on top of the situation while the treatment was going on. The distortion was highly relevant, because the NRC's finding of a non-misadministration was grounded on a theory that because there had been (supposedly) a deliberate decision to allow the treatment to continue, notwithstanding the presence of a leaking seed, a "represcription" had taken place. (The NRC staff later conceded that this theory was invalid and that the incident should have been considered a misadministration. I was not aware at the time of my original memo that the staff's legal advisor on this issue,

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Tom Dorian of ELD, had advised from the beginning that the event was a misadministration but that his advice had been disregarded.)

The Commission therefore referred the matter to OI for evaluation, and OI responded on October 30, 1986 with a memorandum that said (1) there did indeed appear to be an effort to deceive the NRC, and (2) because of other priority cases in the Region III office of OI, it might not be possible to conduct the investigation before the end of 1986.

Several weeks later, on November 28, 1986, the EDO sent a memorandum to the Commission which purported to give the real facts of the Cincinnati incident. It stated, based both on the hospital's submissions and on a November 24, 1986 telephone conversation with the hospital, that the decision to leave the leaking seed in place had occurred on August 28 or 29, 1984, as the hospital had claimed originally. The EDO was thus vouching for the accuracy of the hospital's account, and his memorandum urged that there be no investigation of the incident. */

As of the summer of 1987, the OI investigation had not yet begun. In July of 1987, I approached the Director of OI to ask about the cause of the delay. The investigation began soon thereafter. Also in July 1987, I referred the staff's conduct of the matter to OIA for investigation. (I had originally thought that the OI investigation would provide the factual predicate for any OIA investigation that might be necessary, but the delay in starting the OI investigation

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*/ I did not know until recently that at the same time that the staff was vouching for the hospital's veracity, and trying to prevent an investigation, it was in receipt of a letter from 3M, the manufacturer of the iodine seeds, which cast further doubt on the hospital's truthfulness. According to the hospital's January 1985 submittal to the NRC, 3M had agreed that the product, not the hospital, was to blame. 3M did not learn of this assertion until a draft of the AEOD report was circulated for review. 3M then wrote to the NRC (on February 11, 1986) to deny in emphatic terms that any such admission was ever made. On the contrary, said 3M, the company had taken the position with the hospital that while reusable seeds were safe in proper hands, they should not be used by "any institution that doesn't have adequate facilities or health physics support for handling" -- in which category they placed the U. of Cincinnati Medical Center.

It is also worth noting that the staff, by contacting the hospital on November 24, 1986 to discuss the facts of the incident again, was at the very least alerting the hospital to the NRC's continuing interest in the events of August/September 1984 at the hospital. Thus the element of surprise was lost irrevocably for the investigation which the Commission had just authorized.

convinced me that I should not wait to refer the matter to OIA.)

The Commission has yet to receive the report either of OI or OIA. It is my firm understanding that the OI report will substantiate my basic claim: that the decision to leave the leaking seed in place did not take place on August 28 or 29, as the hospital claimed, but later (apparently on August 31, almost at the end of the treatment period, when the first urine sample was taken). Thus the EDO's memo of November 28, 1986 gave the Commission incorrect information when it too told the Commission that the decision took place on August 28 or 29. In saying that, let me emphasize that I am not suggesting that the EDO himself knowingly gave incorrect information to the Commission.

To me, it seems more than a little strange that with regard to the facts of an incident inquired into not once but twice by the NRC staff, the Commission should have got more accurate information from an OGC lawyer -- who knew no more about the incident than what he could figure out from reading the documentary record and having been a patient in nuclear medicine departments -- than from its own staff.

But the Commission is not going to know any of this unless and until it gets the reports of OI and OIA. I very much hope that the Commission gets the opportunity to review those reports and take any appropriate action on them before Chairman Zech's term expires. I wish to add that I have no reason to doubt the diligence or the competence of the individuals who have been conducting the investigations.