Re Unsel

February 19, 1988

MEMORANDUM FOR: Keith Logan

FROM: Peter Crane Peter Crane

SUBJECT: UNIVERSITY OF CINCINNATI INCIDENT

I. Introduction

The purpose of this memorandum is to put in writing, as clearly as I can, what my concerns are regarding the staff's conduct in the University of Cincinnati matter. We take as a starting point a key fact, of which you informed me on the telephone: that the decision to leave the seed in the patient's head took place on August 31, 1984, when the treatment was almost over, not on August 28 or 29, when the treatment was still in its early stages.

This memorandum works from the hypothesis (for which there is supporting evidence, as discussed below) that the hospital, despite its misleading written submissions, had presented the essential facts of the incident to the NRC staff in oral communications. I should emphasize that I have not seen (as you have) the transcripts of OI's investigative interviews. If those interviews reveal that the hospital deceived the NRC into believing that the decision to leave the seeds in place occurred on August 28 or 29, and that it continued that deception through November 1986, then much of this memorandum may need to be reconsidered.

II. Statement of Concerns

To put it bluntly, I believe that it is reasonably likely that the November 28, 1986 memorandum from the Executive Director for Operations misled the Commission on the facts of the Cincinnati incident, and that it did so in an effort to shut off an investigation which was likely to reveal that the staff's 1984 decision to call the event a non-misadministration was not a reasonable decision, but represented instead a deliberate refusal to enforce a regulation to which the staff was deeply opposed. (I should add that I have no basis for believing that the EDO personally was aware that the memorandum was inaccurate.) In addition, I believe that it was improper of the staff, which knew that the Commission had asked OI in September 1986 to look at the accuracy of the hospital's 1984 chronology, to telephone the hospital on November 24, 1984, to discuss that same chronology. At the very least, that telephone call alerted the hospital to the NRC's continuing

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interest in the chronology, thereby depriving OI investigators of the element of surprise and permitting potential interviewees to coordinate their stories. As such, the telephone call had the potential to subvert the investigation -- an investigation that the staff by its own account wanted not to take place.

1. The November 28, 1986 memo from the Executive Director for Operations to the Commissioners was inaccurate in recounting the facts of the Cincinnati incident, as the decision to leave the seed in the patient's head took place on August 31, 1984, not on August 28 or 29, as claimed in the memo. (The treatment began on August 27 and ended on September 1, 1984.) Although at first glance it may seem unimportant whether the decision was made on August 29 or August 31, and whether the staff knew when the decision was made, in fact those issues are extremely important in assessing the staff's conduct, for two reasons:

(a) The staff's rationale for initially calling the incident a non-misadministration was that the hospital made a conscious decision to let the treatment continue. (Let us leave aside for the moment the fact that as a legal matter, this theory is now conceded by everyone to have no validity.) For that rationale to have any plausibility as applied to the facts of this case, the decision to leave the seed in place had to have been made early in the treatment, not when the treatment was already all but over. Presumably, the staff would not have argued, even in 1984, that if the hospital discovered a misadministration on day 5 of a 6-day treatment, the incident could cease to be a misadministration by virtue of the hospital's decision to leave the seed in place until its scheduled removal on the following day. If it was the hospital which deceived the staff into believing that the decision to leave the seeds in the patient took place on August 28 or 29, then the hospital is at fault and should be held accountable. But if the staff knew in 1984 that the decision to leave the seeds in the patient had actually been made on August 31, when the treatment was almost over, rather than on August 28 or 29, when the treatment was in its early stages, then it is difficult to see how the staff could have been acting in good faith when it initially called the incident a non-misadministration.

(b) If the staff knew at the time of the November 28, 1986 memo that the decision to leave the seeds in the patient was made on August 31, 1984 (rather than on August 28 or 29 as the memo said) then the effect of misrepresenting the date of the decision was to make the initial judgment that no misadministration had occurred seem plausible and legitimate, rather

than a deliberate refusal to enforce an NRC regulation. As such, the misstatement of the facts gave credence to the staff's argument, made explicitly in the November 28, 1986 memo, that there was no need for the Office of Investigations to review the matter. Presumably, the staff had reason to know that the OI investigation, if allowed to take place, would ascertain that the decision to leave the seeds in place occurred on August 31, not August 29, and that this finding would raise questions about the staff's handling of the incident.

2. If the staff decided to overlook a clear violation of an NRC regulation, the probable reason was that the regulation in question -- the misadministration reporting rule -- was adopted over the bitter opposition of the staff, which has tried repeatedly over the past decade to get the rule repealed or watered down. I believe you have some of the staff papers documenting the staff's opposition to the rule.

III. Discussion

A. Background

The University of Cincinnati incident first came to my attention through the AEOD report sent to the Commission in August, 1986. Its focus was on the generic implications of the leak of a reusable I-125 seed. The report mentioned in passing that the staff had found that the incident was not a misadministration because a conscious decision was made by the hospital to leave the seed in place. After obtaining and studying the backup documents (the staff's inspection report and the hospital's chronology and submissions), I wrote a memo (dated August 27, 1986) to Commissioners' assistants that made two points: (1) the event was a misadministration whether the hospital removed the leaking seed or left it in; and (2) the hospital's chronology, which suggested that the decision to leave the seed in place was made on August 28 or 29, was in any event not credible. (The staff's inspection report included the following statement, at p. 11: "On August 29, 1984, a wipe test was performed on the lead shield covering the patient's head and bandage covering the implant. When the wipe tests revealed no contamination, it was decided to continue the treatment.")

Assuming initially that it was the hospital which had misled the staff, I suggested that OI investigate the hospital's submissions. The Commission subsequently referred the matter to OI and asked the EDO to answer questions related to the staff's handling of the incident.

B. The Staff's November 1986 Account

On November 28, 1986, the EDO replied with a memorandum to the Commissioners which (1) agreed that the event should have been called a misadministration; (2) presented an account of the underlying facts; and (3) urged that there was no basis for any investigations by OI or OIA or for any further enforcement action against the hospital. That memo was inaccurate in its statement of the facts. If the inaccuracy was deliberate, then the memo was deceptive, in that its purpose was to persuade the Commission that no wrongdoing had occurred, that the staff's handling of the matter had been reasonable (if not correct), and that the Commissioners had erred in referring the matter to OI for investigations. Any attempt on the part of the staff to deceive the Commission is in my view an extremely serious issue, and the issue does not disappear simply because the staff now readily acknowledges that the incident should have been called a misadministration from the start.

The November 28, 1986 memo includes the following:

> Based on a November 2, 1984 letter from and a November 24, 1986 telephone conversation with the Director, Division of Radioactive Oncology, the doctors involved suspected leaking iodine-125 sources on August 28 or 29, 1984. In spite of the suspected leaking sources they "... felt that because of the significant medical problem, recurrent malignant brain tumor, that the patient's implant should be continued to achieve full dose."

That statement contains the factual predicate for the staff's initial finding of no misadministration. But now it turns out that the decision to leave the seeds in was not made on August 28 or 29, as the above account indicates, but on August 31, when the scheduled treatment was almost over. Thus the quoted passage is incorrect. The crucial question is whether it was incorrect because the staff was misinformed, or because the staff, which knew the correct date, wished to misinform the Commission.

C. Who Misled Whom?

Did the hospital mislead the staff, or did the staff mislead the Commission? If all we knew were the documents in the hospital's submissions, it would seem to be the hospital which misled the staff. The chronology prepared by the hospital includes the following entry for August 29: "Wipe testing of patient's lead hat and bandage revealed no leakage, and it was therefore decided not to remove the sources." The November 2, 1984 letter from Dr. Aron includes the following, in which no date is specified for the hospital's decision: "When it was noted that there was iodine leakage a conference was held between Drs. Bernard S.

Aron and Peter Ho. It was felt that because of the significant medical problem, recurrent malignant brain tumor, that the patient's implant should be continued to achieve full dose." Putting those two together, it would be reasonable to infer that the hospital intended the NRC to believe that the decision to leave the seeds in place was made on August 29. (That, indeed, is why my memo of August 1986 suggested investigating the accuracy of the hospital's submissions.)

But more recent information indicates that the staff knew more about the incident than just those two writings. In particular, note the entry for October 30, 1986, in the handout prepared for the Commissioners' assistants briefing on December 15, 1986: "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.) If the hospital was intent on deceiving the NRC into believing that a conscious medical decision was made on August 29 to leave the seeds in, that seems like an extraordinary comment to make. That comment seems on its face to have put the staff on oral notice that the hospital did not view itself as "knowing" of the misadministration until the seeds were actually removed. Again, the OI interviews may clarify what it was that hospital personnel believed that they had communicated to the staff orally.

Parenthetically, I do not see what the hospital personnel would have had to gain by representing themselves as knowing of the event earlier (unless they knew of the staff's theory that a misadministration allowed to continue is not a misadministration). On the contrary, they would probably have seen it as in their interest to show that they were timely in reporting the problem once they were aware of it.

The October 30, 1984 entry quoted above is also significant because it may illuminate what was really going on in the minds of hospital personnel while the incident was taking place. There seems to be no dispute that the wipe test on August 29, 1984 failed to show any contamination, because no radiation was leaking from the patient's lead hat. The hospital's written chronology seems to imply that the conscious medical decision to leave the leaking seeds in place was made on August 29 on the basis of that wipe test. In fact, to the extent that there was a decision on August 29 to leave the seeds in, it was not because her brain tumor took precedence over possible damage to her thyroid, but because the clean wipe test convinced the doctors that the source of the contamination had to be elsewhere, and it therefore did not occur to them to discontinue the treatment. (They also did not give the patient potassium iodide to block the accumulation of radioiodine in her

thyroid, as might have been expected if they seriously suspected on August 29 that radioiodine was loose in her bloodstream.) Not until August 31, when they took the first urine sample from the patient did they again focus on her. By then, the scheduled treatment period was almost over.

In addressing the question of whether the hospital misled the staff or the staff misled the Commission, it is worth noting that the November 2, 1984 letter claiming that a deliberate decision was made to leave the seeds in place was not volunteered by the hospital. We know from the staff briefing of December 15, 1986, that it was the staff which requested the letter from the hospital. The hospital obliged with a letter that contained no date for the decision to leave the seeds in and no suggestion that the hospital merely suspected the seeds were leaking. The first suggestion from the staff that the hospital had only suspected that the seeds were leaking came only after my memo of August 1986 had made the point that the original account in the hospital's chronology (on which the staff's inspection report had relied) was implausible. Until my memo, the staff did not take issue with the hospital's written account of the facts, although the hospital's account made it appear that the hospital knew that seeds were leaking on August 29, whereas the staff knew, from its October 30, 1984, conference call with the hospital, that hospital personnel at best suspected a leak during the treatment.

The foregoing raises another question, for which I have no answer: whether there was collusion between the hospital and the staff, by which the hospital furnished the November 2, 1984 letter (with no date specified for the decision to leave the seeds in) with actual knowledge that the staff planned to use it to claim, inaccurately, that the decision to leave the seeds in took place on August 29, 1984, in order to be able to find that no misadministration had taken place.

D. Legal Advice Rejected

We know from the staff's December 15, 1986 briefing that Bill Axelson of Region III contacted Tom Dorian, an attorney in the Office of the Executive Legal Director, presented the facts to Dorian as he knew them, and was told that it <u>was</u> a misadministration. Subsequently, after further discussions with the hospital and consultation between Region III and headquarters, the decision was made that it was <u>not</u> a misadministration, without any further consultation with Dorian. I think it is important to know what the thought processes were of the staff people involved. If their understanding of the facts had changed, it is worth knowing in what way it changed, for if the staff's view of the facts did not change, it is hard not to

surmise that the staff decided to disregard a legal opinion that it did not like.

E. Staff Antagonism to the Misadministration Reporting Rule

As noted above, the staff's conduct with regard to this particular misadministration may be related to its overall antagonism to the misadministration reporting rule. The rule was a Commission initiative, adopted over strong opposition in NMSS. I do not now have all the staff papers on the subject, but I seem to recall that the staff submitted a "reclama" to the Commission after it voted to institute the rule. That paper urged the Commission to reverse itself immediately. I cannot remember any other issue on which the staff has filed such a reclama with the Commission on a major issue of regulatory policy.

The misadministration rule went into effect on November 10, 1980, almost six months after publication in the Federal Register. At the affirmation session approving the rule, the Commission requested the staff to reexamine the rule after it had been in place for three years. When the rule had been in place less than seven months, the staff came back to the Commission with an NMSS-authored proposal (SECY-81-333, "Reexamination of the Medical Misadministration Rule") to issue a Federal Register notice announcing that the rule was being reexamined. The proposed notice would have said that the rule was being reexamined because there was already a sufficient data base for evaluating it, the rule was perceived in the medical community as both costly and an "unwarranted intrusion of the federal government into the physician-patient relationship," and implementing the rule "could cause a significant drain on NRC staff resources." The Commission did not accept the staff proposal.

My memory is hazy as to the next several years of the implementation of the misadministration reporting rule, but in 1986, the staff sent the Commission a paper (SECY-86-168, "Final Revision of 10 CFR Part 35 'Medical Use of Byproduct Material'") that would have cut back the requirements for reporting diagnostic misadministrations to the NRC, and would have eliminated altogether the requirement that diagnostic misadministrations be reported to the patient's referring physician. In support of its position, the staff explained:

> Diagnostic radiopharmaceuticals are, by design, non-physiologically active and thus do not present a hazard to patients. The patient's dose from a single dosage of a diagnostic radiopharmaceutical is about 0.1 rad to the whole body, and 2 rads to the target organ.

This statement was patently inaccurate. (The staff contact on the paper later explained orally that the statement was intended to be a generalization about most diagnostic misadministrations.) As OGC and OPE advised in a joint memo, dated June 25, 1986, the National Institutes of Health advised that NIH administers some diagnostic scans using radioiodine that result in doses of 1500 rads to the thyroid. In addition, radioiodine is of course "physiologically active," whether in diagnostic or therapeutic doses: that is why it is useful. These statements were made, moreover, at a time at which the staff was getting repeated reports (later documented in an AEOD report) of diagnostic misadministrations involving high radiation doses from radioiodine. It is thus hard to see how the staff could have believed these statements to be accurate.

To sum up, it may be relevant, in determining whether the staff misled the Commission in November 1986 on a particular case of misadministration, that in July 1986, the staff had furnished inaccurate information to the Commission in an effort to have the misadministration reporting rule partially rescinded. I should add that the current senior management of NMSS (which recently got a new Office Director) is to the best of my knowledge fully committed to enforcing NRC regulations governing medical licensees.

F. Recontacting the Hospital in November 1986

I believe that it was improper of the staff, knowing of the Commission's referral of the matter to OI, to contact the hospital about the very chronology which OI would be investigating. Whoever made that call had to have known that even if no mention were made of the pending OI investigation, the hospital would be placed on notice of the NRC's doubts about the accuracy of the chronology. The call deprived OI investigators of the advantage of surprise, and gave hospital personnel an opportunity to synchronize their recollections. Of course, I have no idea whether that opportunity is used. The point, rather, is that the telephone call had the potential to sabotage an investigation before the investigation could begin.

In addition, it is noteworthy that the memo of November 28, 1986, with its inaccurate statement of when the decision to leave the seeds in place occurred, was written only four days after the telephone call to the hospital. That telephone conversation was the last chance that the hospital had either to mislead the staff or to correct the staff's mistaken understanding of the incident. Thus it is very much worth knowing who made the call, who received it, and what was said on both sides.

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The Cincinnati incident has produced an interesting legal question on what constitutes a material false statement. Assume arguendo that the following facts are true: The hospital is describing the incident to the NRC staff. They mention that they realized even before the treatment was over that the seeds were leaking in the patient's head but decided to leave them in place. The NRC staff replies, "If you made a conscious medical decision to leave the seeds in, then you did not commit a misadministration, so please send us a letter to that effect." The hospital is aware -- though the NRC staff is not -- that this decision was made on the evening of 8/31/84, when the treatment, five days long, had only a few hours left, so the damage had already been done. The hospital reasons that the NRC would be forced to find that a misadministration occurred if it discovered that the decision to leave the seed in was made at a time at which the treatment was already all but over. It therefore submits a letter which states that the decision was made during treatment without specifying when it took place, accompanied by a chronology which deceptively indicates that the decision to leave the seed in place occurred on 8/29/84.

In fact, the NRC staff did not care when the misadministration took place. Under the original staff theory, even a last-minute decision to leave the seeds in place would have sufficed to turn the misadministration into a non-misadministration. Under a correct view of the rule, it also did not matter when the misadministration took place, since it was irrevocably a misadministration whenever in the treatment period it occurred. But the hospital did not know that. From the hospital's standpoint, it was reasonable to assume that it did matter that the decision to leave the seed in took place earlier than 8-31-84. Thus the question is: does a licensee commit a material false statement when it falsifies a fact in the mistaken belief that that fact is material to the question of whether it has violated NRC regulations?

Peter

4-21-88 Release

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