DIFFERING PROFESSIONAL OPINION PANEL

Administrative Judges

Morton B. Margulies, Chairman
Dr. Jerry R. Kline
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REPORT AND RECOMMENDATION OF THE DIFFERING PROFESSIONAL OPINION PANEL TO THE EXECUTIVE DIRECTOR FOR OPERATIONS ON THE CINCINNATI HOSPITAL CONTAMINATION INCIDENT (ASLBP NOS. DPO-1, 90-611-01SP)

JULY 12, 1990

NOTE: THIS REPORT RELATES TO OFFICE OF INVESTIGATIONS AND OFFICE OF THE INSPECTOR GENERAL INVESTIGATIONS AND SHOULD NOT BE DISSEMINATED OR DISCUSSED OUTSIDE THE NRC. TREAT AS "OFFICIAL USE ONLY".

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I. INTRODUCTION

On May 21, 1990 this Differing Professional Opinion Panel (DPOP) was established by the Deputy Executive Director for Nuclear Materials, Safeguards, and Operations Support to make a recommendation regarding a differing professional opinion of Peter G. Crane, Esq. of the Office of the General Counsel and the Office of Investigations. Mr. Crane is an attorney charged with monitoring medical misadministrations and related issues and presents his own views. They do not represent the views of the Office of the General Counsel. The contrary opinion is that of the Office of Investigations (OI) that results from its investigation.

The differing opinion stems from an incident involving the radiopharmaceutical treatment of a patient at the University of Cincinnati Medical Center, Cincinnati, Ohio in August and September, 1984. Succinctly, on Monday, August 27, 1984 a patient with a recurrent malignant brain tumor had an implant containing highly radioactive I-125 placed within her skull next to the tumor. The implant consisted of radioactive seeds contained within catheters and were to remain in place for five days, to be removed on Saturday, September 1, 1984.

Unknown to the physicians, at the time of the insertion of the implant, there was a radioactive leak in a seed. On Tuesday, August 28, 1984 the hospital became aware that the brachytherapy room in the hospital was contaminated. Examination of the patient on Wednesday, August 29, 1984 failed to reveal that the implant was leaking. On Saturday, September 1, 1984, the implant

was removed at the conclusion of the prescribed treatment and it was determined that there was radioactivity near the patient's thyroid. On September 5 quantitative measurements of the patient confirmed that a seed had leaked in the patient. The leak had irradiated the patient's thyroid.

The hospital notified the NRC on September 4, 1984 of the incident and an investigation was conducted in October, 1984 by a radiation specialist from Region III. The circumstances of the incident raised as an issue whether there was a misadministration of a radiopharmaceutical as defined in the 10 CFR 35.41, now incorporated in 10 CFR 35.2. Staff was informed by hospital physicians that the doctors made a medical decision during the treatment to leave the implant in place because of the gravity of the patient's condition irrespective of the consequences of contamination from a leak. The Nuclear Materials Safety and Safeguards Branch then determined that "no misadministration occurred since a medical decision and evaluation was achieved and the patient's implant was continued to achieve treatment."

Crane alleged in August, 1987 that during the investigation of the matter, the licensee misled the NRC into believing (1) that it knew of the patient's inadvertent exposure well before it actually did, and (2) that it made a deliberate medical decision to allow that exposure to continue. He further claimed that the NRC relied on that misleading information in making an erroneous determination that no misadministration of a radiopharmaceutal

occurred and that the matter should be referred to the Department of Justice.

As the result of its investigation, OI had found in October, 1988 that there is "no evidence to substantiate the allegation obviating any need to forward the file." [OI advised DPOP by memorandum dated June 5, 1990 that the conclusion should have been more appropriately "the evidence developed during the investigation did not substantiate the allegation..."]

In this report, we find, on the basis of the information submitted in support of the differing professional opinion, that a misadministration of a radiopharmaceutical had occurred at the hospital but that there was insufficient evidence to support a finding that the licensee significantly misstated facts regarding the incident and misled the NRC. Therefore, DPOP recommends that the professional opinion of OI, that the file be closed and that it not refer the matter to the Department of Justice because of a lack of evidence, be upheld.

II. BACKGROUND

A. The Task

The task assigned tc DPOP, on May 21, 1990, is as follows:

Task: Review the materials available and interview NRC personnel as necessary in order to make a recommendation to the EDO concerning the resolution of the following DPO:

- Contrary to the OI report's conclusion of no evidence to substantiate the allegation, there is substantial evidence to support a

conclusion that the licensee significantly misstated facts regarding the incident. Specifically, there is sufficient evidence to support a finding that the licensee's understanding of the incident while it was in progress and the "medical decision" purportedly made about the patient's case during the incident were not as they were represented to NRC.

The OI report referred to in the task is titled "University of Cincinnati Medical Center Alleged Willful Failure To Report A Therapeutic Misadministration", dated October 27, 1988. The investigation was opened on a request dated December 22, 1986 from Eugene T. Pawlik, Director, OI Field Office, Region III to Ben B. Hayes, Director, OI.

The request recited that an allegation had been made by a staff member from the NRC Office of the General Counsel that in late August/early September, 1984, a misadministration at the University of Cincinnati Medical Center occurred and was knowingly not reported to the NRC. The suspected wrongdoing was reported as an allegation that a physician involved in the radiopharmaceutical treatment of a patient discovered an apparent overexposure/misadministration involving I-125 and changed his original prescription to cover up a possible misadministration.

The OI investigation considered the investigation of the incident conducted in October, 1984 by James R. Mullauer, Radiation Specialist. That investigation report, which found no misadministration, was approved by W. L. Axelson, Chief of Nuclear Materials and Safeguards Branch of Region III. As part of the OI investigation, interviews were conducted in September,

1987 of employees of the 3M Company (the supplier of the radioactive seeds), in December, 1987 of hospital employees and James R. Mullauer.

The October 27, 1988 OI report was closed on the agent's finding, "The investigation revealed no evidence to support the allegation."

DPOP received a memorandum dated June 5, 1990 from Director Hayes stating that the conclusion was poorly worded and more apprcpriately should have read "the evidence developed during the investigation did not substantiate the allegation that a physician involved in the radiopharmaceutical treatment of a patient discovered an apparent overexposure/misadministration involving Iodine-125 and changed his original prescription to cover up the possible administration."

The memorandum further stated the change in finding was made known last year by OI to Crane and other staff members involved in the review of the report.

The Crane memorandum of August 27, 1986 which caused the opening of the OI investigation, stated the allegation as "it appears that the licensee misled the NRC into believing (1) that it knew of the patient's inadvertent exposure well before it actually did, and (2) that it made a deliberate medical decision to allow that exposure to continue." This has been the gravamen of the Crane case throughout and constitutes the center of the dispute.

Crane on several occasions has said that the OI has misstated his allegation. We agree. OI adds to the Crane allegation the additional element of the physician changing his original prescription to mislead the NRC. However, this misstatement has had no practical effect in impeding the investigation. The scope of the investigation by OI of what occurred was of sufficient breadth so as to overcome any handicap that might have resulted from the misstatement.

In addition to the allegation that the NRC was misled by the hospital and resulted in an erroneous determination that no misadministration of a radiopharmaceutical occurred, Crane further alleged in his memoranda misconduct by NRC staff in conducting the initial investigation and by other NRC personnel connected with further handling of the matter.

Crane raised the matter of personnel misconduct directly with the Office of the Inspector and Auditor which was then charged with investigating those matters. Jurisdiction over that subject was transferred to the Office of the Inspector General (IG). That office has an independent ongoing investigation regarding the actions of NRC staff, both during and after the incident.

On June 8, 1990 the IG made available to DPOP, at its request for information relevant to DPOP's task, transcripts of investigative interviews conducted on May 3 and 4 and June 15, 1989 of five hospital personal who had previously been interviewed by the OI in December, 1987. Other than the

transcripts of the investigative interviews of these individuals supplied to DPOP, we have no information as to what the IG's investigation has disclosed. The IG is not providing information so as not to compromise its ongoing investigation.

We are to determine whether there is substantial evidence to support a conclusion that the licensee significantly misstated facts regarding the incident; more specifically whether there is sufficient evidence to support a finding that the licensee's understanding of the incident while it was in progress and the "medical decision" purportedly made about the patient's case during the incident were not as represented to the NRC.

In regard to the incident, we are to determine what occurred, what the hospital represented and whether it significantly misstated facts.

Although disputant Crane raised the issue of employee misconduct, the OI investigation does not directly deal with it so that it is not an issue in dispute. It is the subject of the independent, ongoing IG investigation.

DPOP is of limited jurisdiction and the assigned task sets the limit of our mandate. The task is quite specific and does not extend to the subject of employee misconduct. We will consider the activities of the NRC staff insofar as it relates to what occurred at the hospital, what the hospital represented and whether it significantly misstated facts. We will not consider or make any recommendation on an issue of alleged employee misconduct or wrongdoing.

As a consequence of the foregoing, we have proceeded on the assumption that the evidence presented is untainted by employee misconduct or wrongdoing. Should it be determined in the IG investigation that this was not the case, we would have to reconsider the findings and conclusions reached in this Report.

There is another area raised in Crane's differing professional opinion which is beyond DPOP's mandate for resolution.

In a memorandum to DPOP dated June 11, 1990 he states that "it is extremely important for the NRC's own integrity and health that this incident be correctly understood and appropriate actions taken. The NRC's business should be to protect the public from being injured through the actions of its licensees, not to protect licensees from having to face the consequences of negligently injuring the public."

Along with the allegation of the hospital coverup of a misadministration, he makes allegations critical of the hospital's medical standards and practices in the treatment of the patient and protection of the patient and the visitors from contamination, that extend beyond the misadministration issue. Emphasis was placed on the alleged negligent exposure of the patient's young daughter and the consequences that might have arisen.

DPOP, as any one, would want to see any and all wrongdoing exposed and rectification made. However, DPOP's role insofar as it concerns the activities of the hospital is limited by its task

which concerns the alleged misadministration and coverup and not other claimed incidents of hospital negligence and its consequences. Those incidents are beyond the scope of the task assigned to DPOP, if not the regulatory concern of the NRC. They will not be considered by DPOP under the mandate of the task.

A question arises on the effect the Hayes memorandum of June 5, 1990 has on the task assigned to DPOP. The memorandum changed the conclusion of the investigation to "the evidence developed during the investigation did not substantiate the allegation..." from "No evidence to substantiate the allegation." It is the latter that is cited in the task.

The changed conclusion has no effect on the assigned task because the task treats the original OI conclusion that "there is no evidence to substantiate the allegation" figuratively rather than literally. The task poses the primary criterion as whether there is "substantial evidence to support a conclusion that the licensee significantly misstated facts regarding the incident." The determination of which professional opinion prevails turns on whether the primary criterion has been satisfied. A major requirement for referring the matter to the Department of Justice would have been met if there were "substantial evidence to support a conclusion that the licensee significantly misstated facts regarding the incident."

B. The Record

By its terms, the task was to be completed by July 6, 1990. DPOP obtained an extension to July 13, 1990.

The information DPOP assembled and reviewed before making its decision in this dispute consists of the materials made available to it by Deputy Executive Director Hugh Thompson when he designated DPOP; the information provided by Crane on June 6 and 11, 1990; the changed conclusion submitted by OI on June 6, 1990; and the transcripts of interviews submitted by the IG on June 8, 1990. Attached Appendix A lists the documents received.

Except for the submission by the IG, all of the other documents have been made available to the principals. The IG transcripts were made available to DPOP with the restriction that they not be made available to the parties. We have reviewed the transcripts of the six interviews to determine if the hospital employees provided any new information on the issue of the alleged misadministration and coverup and whether there were any discrepancies with statements and other information previously provided. Crane was present at the interviews of Dr. Bernard S. Aaron, Dr. Eugene L. Saenger and that of the first day of Kenneth M. Fritz. He was not present on the second day of interview of Kenneth M. Fritz nor at the interview of Dr. John C. Breneman and Vincent J. Sodd. Attached as Appendix B is a list identifying hospital personnel discussed in this Report.

The nature of the dispute between Crane and OI is such that it did not require DPOP to make any independent investigation or conduct interviews of NRC personnel. We did offer the parties the opportunity to supplement the file with other documentation and to make an additional presentation in writing. Crane

accepted the offer and responded with a statement and materials on June 11, 1990.

The dispute has been a long standing one. The parties had assembled extensive materials in support of their positions. Their positions have been expressed to one another a great many times in arguments that have evolved over several years. The record they presented was very clear on their positions.

C. General Overview Of The Dispute

1. The Crane Position

Crane alleges in numerous memoranda to various individuals within NRC that during the original investigation by Region III it appears that the hospital misled the NRC into believing (1) that it knew of the patient's inadvertent exposure well before it actually did, and (2) that it made a deliberate decision to allow the exposure to continue. Crane's hypothesis is that the hospital by this alleged deception attempted to prevent an NRC finding of medical misadministration as defined in the 10 CFR 35.2. In Crane's view, the hospital believed that the alleged deception would accomplish that goal because it felt that a medical decision to continue therapy would put the inadvertent irradiation of the patient's thyroid beyond the reach of the definition of misadministration contained in Part 35. A plausible claim of a medical decision to continue the therapy may logically depend on the hospital staff having factual knowledge of thyroid uptake of I-125 during the course of therapy and not after it was completed. In Crane's view there is no evidence

that the hospital staff had this knowledge during the therapy and thus there is a basis to conclude that the hospital staff fabricated it's "medical decision" explanation after the incident was over, as well as its claimed early diagnosis of the problem and provided false factual information to NRC to avoid a citation for misadministration.

Crane believes that the event should be found to be a misadministration without regard to whether any medical decision was made to continue the treatment. Thus, he believes that the hospital promulgated its alleged deception under an incorrect interpretation of NRC's definition of misadministration.

2. The OI Position

After investigating the allegation of Crane, OI closed its report of October 27, 1988 based on the conclusion that the investigation revealed no evidence to substantiate the allegation. Sometime last year the OI changed its conclusion to "the evidence developed during the investigation did not substantiate the allegation..." The softening of the conclusion did nothing to change the OI decision to close the file nor did it alter its evaluation of the evidence.

OI concluded that despite no actual knowledge that the source was leaking, there was ample evidence for the doctors to consider it a possibility and make a "medical decision" as to further treatment with that as a supposition.

OI contended that the statements of the two physicians that they held a discussion and made a "medical decision" on future

treatment, taking into account the possibility that the source might be leaking, cannot be disproven. No other doctor was involved. It asserts mere suspicion cannot be used as evidence to suggest otherwise.

As to other evidence that indicates the hospital had knowledge of the leaking source prior to when it actually did, OI said the evidence had been explained away. It stated that the "Report of I-125 Contamination Detected on 8-28-84 at the University of Cincinnati Medical Center" when read as a chronology of factual statements contains inaccuracies. However, the person responsible for the report when interviewed said it was not a verbatim chronology of events. Various occurrences were claimed to have been placed under the same date because they were of the same subject. Evidence to suggest otherwise is lacking.

OI concluded that it had proceeded as far as it reasonable could be expected to go and that there was nothing more to be done. The Crane theory of the case was said to have insufficient evidence to support it, let alone to make a referral to the Department of Justice.

Where the parties raised positions or arguments that are not discussed in this Report, it is because we found them wanting either in consequence or merit.

III. FINDINGS OF FACT

1. On Monday, August 27, 1984 a female patient with recurrent brain tumor received an implant of sealed I-125 sources in her skull for therapeutic irradiation of the tumor. The source was planned for removal on Saturday, September 1, 1984 after a dose of 8000 rads had been delivered to the tumor. At the time of implant the patient was supplied with a lead "hat" to go over the skull at the site of the implant to act as a radiation shield.

2. The radioactive sources used for brain cancer therapy in this case consisted of eight small "seeds" made of cylindrical titanium capsules each of which contained about 40 mCi of I-125. The seeds were loaded into two plastic tubes known as catheters; five seeds in one and three in the other. The loading operation was done in the brachytherapy room by radiation health technicians. The two catheters were implanted at the patient's brain tumor through a small hole drilled in her skull.

3. The high activity I-125 seeds were intended for repeated use and they had been inserted and removed from catheters twice previously. Unknown to the brachytherapy technicians or physicians in attendance at the time of the implant procedure one of the seeds had been cut during a previous manipulation and I-125 was released to the environment of the brachytherapy room.

4. The brachytherapy room and instruments used for preparation and implantation of the source were routinely surveyed for contamination at the time of source preparation and implant but none was detected.

5. The release of I-125 was discovered on August 28, the day after the source was implanted. Routine wipe testing of Ir-192 containers in the brachytherapy room revealed the presence of external removable radioactive contamination. The contamination was ascertained to be I-125 rather than Ir-192.

6. On August 28 the only high activity I-125 the hospital had on hand was contained in 10 I-125 seeds then in its possession, eight of which were in the patient's skull. The radiation health technician stated on December 1, 1987 that the two remaining high activity seeds were leak tested and ruled out as a source of the contamination. However the hospital had also used low activity I-125 seeds previously for other cancer therapy and at that stage of the investigation the source of the contamination was uncertain to the technician.

7. The radiation health technicians notified their supervisor and commenced a search for the source and extent of contamination in and around the brachytherapy storage room on August 28. They found other I-125 contamination on surfaces in the brachytherapy room but did not find the source. The room was sealed off and decontamination was started.

8. The radiation health technicians suspected but did not know that one or more of the eight seeds in the patient's skull

was the source of contamination because these were the only other sources of I-125 that had been used in the brachytherapy room at that time.

9. On August 29 the patient's lead hat, skin and room were wipe tested for I-125. No contamination was found.

10. Dr. Peter Y. C. Ho, the attending oncologist, wrote on the patient's chart for August 29: "sources intact and the patient is tolerating implant well. Plan 5 days 6 hours to be removed Saturday 9/1/84 at 5 pm to deliver 8000 rads to tumor!" Dr. Ho's note did not mention the wipe testing or indicate that he was aware of such testing. Dr. Ho stated in 1987 that he was aware that there was contamination around the brachytherapy room and that the lead hat had been wipe tested but that he did not know that the implanted source was leaking.

11. Dr. Vincent J. Sodd, Ph.D., a nuclear chemist, prepared a report that was submitted to NRC by Dr. Saenger entitled: "Report of I-125 Contamination Detected on 8-28-84 at the University of Cincinnati Medical Center." The document lists the events related to the I-125 contamination incident by date. The entry for August 28 stated: "Wipe testing of patient's lead hat and bandage revealed no leakage, and it was therefore decided not to remove the sources." Region III Inspector Mullauer wrote in his report of the same incident "When the wipe tests revealed no contamination it was decided to continue with the treatment."

12. There is no independent evidence showing that Dr. Ho linked the negative result of the wipe test to a decision to continue therapy at the time he made his chart notes on August 29. His chart notes reflect his direct observation at the time that the patient was tolerating the implant and that the therapy would continue as planned. The apparent linkage stated in the chronology for August 29 was Dr. Sodd's inference arrived at sometime after September 5 as he attempted to reconstruct the event by compiling information from others. He explained to an OI investigator in 1987 that he was providing information to the reader and not a chronology of events *per se*. He stated that his intent was to illuminate the situation not to mislead.

13. Investigation of the contamination in the brachytherapy room proceeded on August 28-31 without conclusive results as to the source of the contamination.

14. On August 30 thyroid counting showed that one of the technicians who had prepared the I-125 seeds for implant had 209 nCi of I-125 in his thyroid. Thyroid counts were ordered for all personnel who could have been exposed. Some 60 persons were measured for I-125 activity in their thyroids during the period August 30 through September 10. Dr. Ho was tested for thyroid uptake on August 30 and he was therefore aware of the general contamination problem.

15. Urine and blood samples were taken from some nurses and the patient on August 31. The result of measurement of I-125 in the patient's urine sample was obtained on September 4 and

showed that the patient had I-125 in her body fluids. The I-125 content of the urine sample was not used to calculate the patient's thyroid burden of I-125 or for any diagnostic purpose.

16. Dr. Ho stated under oath in 1987 that he was unaware of the release of I-125 in the patient on August 31. He did not prescribe potassium iodide to prevent thyroid uptake of radioiodine during the week of therapy.

17. Dr. Ho stated that he and Dr. Aron his department head were aware of the contamination of the brachytherapy room and hospital personnel and that they had a conversation on the afternoon of August 31 in which they discussed whether they should remove the implant that night or wait until the next morning "if it was her." Dr. Aron agreed that such a conversation had taken place but could not remember whether it occurred on August 31 or August 30. Both doctors considered the possibility that an implanted seed was leaking in the patient. They decided that the benefit of irradiating the tumor outweighed the possible effects from irradiation of the thyroid "because it was the last hope. If we don't do it she has absolutely no chance of even living."

18. Dr. Aron was asked in 1987 what the words "iodine leakage" meant in Aron's letter of November 2, 1984.

Aron answered: "The words iodine leakage as outlined in the letter of 2 November refers to contamination in the brachytherapy storage room. We had no knowledge 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...."

"A discussion was held between Dr. Ho and myself and the department related to the medical problems of the patient as to whether if there was a leakage in the patient what should we do as far as treating the patient. But the information that we had at that point only yielded some contamination in the brachy therapy room and negative information about the patient."

When asked if the wordage could indicate iodine contamination as opposed to leakage, Aron replied: "Correct. That is what was meant actually by the words."

18. Dr. Ho dictated a report dated September 12, 1984 in which he documented his view that the need to continue treatment outweighed the possible effects of irradiation of the thyroid. The report did not mention that there had been a medical decision to continue irradiation in spite of the possibility that a seed was leaking in the patient.

19. No testimony or document submitted to NRC confirms or suggests that either doctor had direct actual knowledge of I-125 uptake in the patient's thyroid at the time the decision to continue irradiation of the brain tumor was made on August 31. Neither doctor claimed a strong suspicion of leaking seeds in their statements during the OI investigation. Both stated when interviewed in 1987 that they considered the possibility of a seed leaking in the patient and decided that possibility would

not change the plan to deliver the prescribed dose to the tumor because the condition of the patient was grave.

20. Drs. Ho and Aron neither knew nor focused on the possibility that the patient might have a dose commitment of over 2000 rad to the thyroid when they made their decision. Dr. Ho stated to the investigator: "...treatment was going to outweigh the slight contamination she was going to get..." Aron said: "any contamination from the iodine was minuscule for the patient's health..." (Emphasis added) When they made their decision, Drs. Ho and Aron expected any possible contamination in the patient to be small.

21. The catheters containing the eight I-125 seeds were removed by Dr. John C. Breneman, Resident in Radiation Oncology, on Saturday, September 1, after completion of the full prescribed dose to the brain tumor. He surveyed the patient after the sources were explanted and found a radiation level of 1.5 millirem per hour at two inches near her thyroid. This survey was the first indication by direct measurement that there had been leakage from an I-125 seed into the patients body fluids during the course of therapy. There is no record that Dr. Breneman had prior notification of a possible leaking seed. The patient was discharged on September 2 with instructions to return to the hospital for more counting later.

22. The next business day at the hospital was Tuesday, September 4, because Monday, September 3, was Labor Day, a holiday. Investigation of the contamination incident resumed in

the brachytherapy room and among the hospital personnel on September 4. NRC Region III was notified of the contamination of the brachytherapy room, the thyroid contamination in hospital personnel, and that a patient had thyroid uptake after brachytherapy treatment of a brain tumor.

23. The patient returned for more extensive assessment of her I-125 uptake on September 5. Measurements made by Dr. Sodd showed that the patient had a burden of 557 uCi of I-125 in her thyroid which would result in a dose of 2087 rads to the thyroid.

24. The chronology of the entire incident compiled by Dr. Sodd stated for August 30: "The results of thyroid counting on more than sixty (60) hospital personnel and the patient's friend ranged from 0.04 to 209 nCi; there was 557 uCi found in the patient. (See Appendix B)." Appendix B showed that the determination of a thyroid burden of 557 uCi was made on September 5. The narrative chronology and Appendix B therefore contained conflicting information as to when the patient was found to have 557 uCi in her thyroid.

25. Dr. Sodd stated in his interview in 1987 that he had reconstructed the narrative chronology at the request of Dr. Saenger by compiling information from participants in the event after it was over. He asserted that his intent in writing the entry was to summarize what was ultimately learned about thyroid contamination in hospital personnel and the patient and not to provide an exact chronology.

26. Inspector Mullauer wrote in his inspection report for August 30 only that the technician had a thyroid uptake of 209 nanocuries. His account for September 5 stated: "The patient returned for a bioassay of the thyroid and the results indicated a thyroid burden and exposure of 557 microcuries and 2087 rad respectively. (See Attachment 4 for dose calculations)."

27. Dr. Sodd's chronological entry for August 30 was inconsistent with Appendix B as to when the hospital learned that the patient's thyroid contained 557 uCi of I-125. However, the chronological statement and the appendix were both prepared by him and both were in the possession of Inspector Mullauer when he wrote his inspection report. The Inspector correctly resolved the inconsistency and was not mislead by it.

28. Dr. Ho contacted the 3M Company by telephone on September 5 to report that seeds of their manufacture had leaked. He was instructed by 3M to return the seeds for inspection. Their inspection found that one of the seeds had been mechanically cut during a previous manipulation.

29. The NRC conducted a special announced inspection to review the facts surrounding the damaged seed that was used for patient treatment on October 10-12 and October 30, 1984. The inspection was conducted by Region III Inspector Mullauer. His inspection report was completed December 17, 1984.

30. At the end of the inspection on October 12, an exit interview was held with the licensee. Persons who attended the exit interview included hospital management personnel who had no

disputed role in this investigation and Dr. Eugene L. Saenger who was Chairman of the hospital Radiation Safety Committee.

31. Dr. Saenger has expressed strong views opposing NRC enforcement of medical misadministration rules because in his opinion it constitutes intrusion on the practice of medicine by the NRC.

32. Inspector Mullauer stated in a letter dated October 9, 1987 that he had discussed the question of misadministration at length with hospital personnel at the exit interview. It was the licensee's opinion that no misadministration occurred since a medical decision was made to continue the treatment as planned. The licensee asserted at the exit interview that the source of contamination was unknown during the time of treatment.

33. The inspection finding in dispute in this review states:

> Based on information in letter (attachment 5) dated November 8, 1984 from the licensee, the NRC has determined that no misadministration occurred since a medical decision and evaluation was achieved and the patient's implant was continued to achieve treatment.

The Executive Director for Operations reversed the conclusion of the Inspection Report on November 28, 1986 and reported to the Commission that a misadministration had occurred in this case.

34. Inspector Mullauer's finding was based upon a letter to Mr. Axelson of Region III from Dr. Bernard S. Aron dated November 2, 1984. The letter stated as follows:

> 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. This was felt to be of primary importance, far overshadowing the effects of iodine 125 irradiation of the thyroid gland.
>
> In summary, the decision to continue the implant was a medical decision based on the patient's undergoing a treatment for a recurrent malignant brain tumor.

35. Crane interpreted the words "...there was iodine leakage..." in the foregoing passage to be a claim by Dr. Aron that he had knowledge during therapy that a seed was leaking in the patient. Dr. Aron stated to the OI investigator in 1987 that his reference to iodine leaking referred to the leak in the brachytherapy room and not in the patient.

36. Dr. Aron stated to OI investigators in 1987 that his letter of November 2, 1984 was submitted at the request of NRC. When questioned by an OI investigator in 1987 about his preparation for the letter Dr. Aron was asked: "Was it brought to your attention or did you discuss the fact that if there had been a medical decision, then that this would not constitute a misadministration?" Dr. Aron answered: "No, the question that was posed to me was strictly one of medical decision making, nothing to do with misadministration or direction or something...the NRC as far as I understood, wanted to know who made the decision to go ahead with the implant. That was my decision." Later in the same transcript Aron asserted: "...my request related to this letter was to comment on the medical decision. Not on anything other than the medical decision. I am sure there were discussions as to what represents a

misadministration and the Radiation Safety Committee would be the place to have those discussions, but I don't recall anything specifically three years ago."

37. Dr. Aron was a party to a telephone conference call between NRC and hospital personnel on October 30, 1984, at which time medical decision making and misadministration were discussed. He was requested by NRC during this call to file his letter documenting the medical decision that was made.

38. Dr. Aron was not ignorant of the possible linkage between the medical decision and a decision by NRC about misadministration when he drafted his letter of November 2.

39. Dr. Saenger filed the licensee's report of the subject incident on October 3, 1984. The report consisted of the cover letter, the licensee's chronology of the event (prepared by Dr. Sodd) and Appendix B to the chronology which consisted of the actual thyroid contamination data for the patient and hospital staff. Dr. Saenger's cover letter states that "It was found that the seed was inadvertently crushed during manipulation in the brachytherapy room." No other information supplied to NRC during the Region III investigation suggests that the hospital attempted to show that the seed was faulty on arrival from the 3M Company.

40. The Region III Investigator's report shows that he did not cite or rely on the statements for August 29 and 30 for his finding that there had been no medical misadministration.

41. Crane obtained the patient's medical charts during the IG inquiry in 1989 for the period August 27 to September 1, 1984.

The charts, though relevant to the controversy had not been reviewed previously in the OI investigation.

42. It was found from the charts that:

Chart records of suspected iodine leakage were not made; urine sampling was not ordered until late in the therapy period; no thyroid blocker was ordered; the thyroid specialist did not examine the patient; nurses were not warned of possible exposure to visitors; Dr. Breneman who removed the seeds was not warned by any entry that they might be leaking.

43. Transcripts of the IG interviews of Drs. Aron, Sodd, Saenger, Breneman and Mr. Fritz in 1989 were supplied to DPOP, however, they provided nothing materially different from prior interviews of the same persons. Memories were further clouded by the passage of time.

IV. ISSUES IN DISPUTE

A. Was There A Misadministration As Defined In 10 CFR 35.41, Now Incorporated In 10 CFR 35.3?

As pertinent the regulation provided as follows:

35.41 Definition of a misadministration.

For this part, misadministration means the administration of:

* * *

(c) A radiopharmaceutical or radiation by a route of administration other than that intended by the prescribing physician;

* * *

(e) A therapeutic dose of a radiopharmaceutical differing from the prescribed dose by more than 10 percent;

* * *

Section 35.42, now incorporated in 35.33, requires telephone and written reports to the NRC within prescribed periods after the licensee discovers the misadministration.

As the result of the radiological leakage of the brachytherapy source implanted to administer a therapeutic dose of I-125 directly to a tumor in the patient's brain, I-125 was carried by her blood stream and taken up by her thyroid gland. Radiation measurements showed the patient to have a burden of 557 uCi of I-125 in her thyroid which resulted in an unintended dose of 2087 rads to her thyroid.

Crane asserts that occurrence met the misadministration definition in two ways. The definition of 10 CFR 35.41(c) was satisfied because the administration of the radiopharmaceutical was by a route of movement other than that intended by the prescribing physician and 35.41(e) because the administration of a therapeutic dose of a radiopharmaceutical differed from the prescribed dose by more than ten percent. He further asserted that there is nothing in the Commission's misadministration reporting rule which lends any support to the notion that a conscious decision to continue a misadministration exempts the misadministration from the rule.

The staff investigator, in his report of December 12, 1984 found that "no misadministration occurred since medical decision and evaluation was achieved and the patient's implant was continued to achieve treatment." The decision was based on the November 2, 1984 letter from Dr. Aron in which he stated "the decision to continue the implant was a medical decision based on the patient's undergoing a treatment for a recurrent malignant brain tumor."

OI, in its report of October 27, 1988, never made a determination one way or the other as to whether a misadministration occurred. It reported the opinion of Dr. Saenger that the regulatory area of misadministration was an unacceptable intrusion in the practice of medicine. His position was that regulating unintentional misadministrations was wrong.

In a memorandum dated November 28, 1986 from Victor Stello, Executive Director for Operations, to then Chairman of the Commission Lando Zech, he stated that after further staff and OGC review, the event should be more appropriately classified as a misadministration under 10 CFR 35.41(c).

1. DPOP Findings

We agree with the changed staff conclusion. The prescribing physician intended to irradiate the patient's brain tumor but not her thyroid. The leaking source irradiated both. In so doing, a radiopharmaceutical was administered by a route of administration other than that intended by the prescribing physician. The definition of a misadministration was met.

Whether or not the misadministration was intentional is irrelevant to the definition of a misadministration. The fact that the hospital disagrees with the concept of the NRC regulating in the area of misadministration is also irrelevant to the issue of whether a misadministration occurred.

We disagree with Crane's conclusion that the event also constituted a misadministration under 35.41(e). The letter from the Executive Director for Operations to the Chairman did not relate to this section.

The purpose of 35.41(e) is to identify as a misadministration the administration of a therapeutic dose of a radiopharmaceutical if it differs by more than 10 percent from that prescribed. The crux of the regulation is whether the therapeutic dose administered is more or less, by a fixed percentage, than that prescribed. The therapeutic dose the patient received was the amount prescribed so that the definition of 35.41(e) is not met. The fact that no dosage of I-125 was prescribed for the thyroid and that it showed 557 uCi of I-125 does not alter the conclusion that the definition in 35.41(e) is not satisfied. She received the therapeutic dose that was prescribed but unfortunately it did not remain where it was directed and affected an unintended gland. That satisfies the definition of a misadministration under 35.41(c), as previously discussed.

Crane is correct when he charges that the misadministration reporting rule does not support the contention that a conscious

medical decision made subsequent to the misadministration but that takes the misadministration into account in further prescribing treatment, exempts the misadministration from the reporting rule.

There is nothing in the regulation which reasonably supports an argument that a subsequent medical decision can nullify a prior misadministration, render it nonexistent and that it not be subject to the reporting requirements. For example, if we looked to 10 CFR 20.107, "Medical diagnosis and therapy," it would not support the medical decisions nullification theory. The section provides:

> Nothing in the regulations in this part shall be interpreted as limiting the intentional exposure of patients to radiation for the purpose of medical diagnosis or medical therapy.

The obvious meaning of this regulation is that under Part 20 -- Standards For Protection Against Radiation -- nothing shall be construed as limiting physicians in their medical practice from intentionally prescribing radiation for their patients. It does not extend to nullifying misadministrations as defined in 10 CFR 35.41, whether unintentional or intentional.

Although the medical decision nullification theory is not meritorious under the existing regulations, the hospital had the perfect right to argue its interpretation of the regulations to the staff, to OI and the IG so long as it was not part of a misrepresentation of material fact. The issue of whether there

were misrepresentations of material fact will be discussed below. It was the responsibility of the NRC personnel to apply the correct regulatory standard whether or not this was a misrepresentation of fact, as alleged by Crane. For whatever reason, the staff applied an incorrect standard in accepting the medical decision nullification theory in finding no misadministration occurred.

If the NRC were considering enforcement action regarding a medical therapeutic misadministration, which is classified under 10 CFR Part 2, App. C, Supplement VI C.6. as a Severity III violation, the staff could consider medical decisions made subsequent to the misadministration in determining whether to issue a civil penalty or notice of violation. Part 2, App. C, V. G.5. It cannot be considered to determine whether a misadministration occurred.

Crane was correct in alleging that the staff used an erroneous interpretation of the regulations to base its closing of the file on the subject incident. There was a misadministration as defined in 10 CFR 35.41(c).

B. Is There Sufficient Evidence To Support A Finding That The Licensee's Understanding Of The Incident While It Was In Progress (Setting Aside The "Medical Decision" Issue) Was Not As It Was Represented To The NRC?

1. Crane's Position

In addressing this issue, Crane alleged in his first memorandum on this matter dated August 17, 1986 that the hospital submitted information to Region III which the NRC staff relied on

and which misled the NRC into believing that it knew of the patient's inadvertent exposure well before it actually did. The specific information alleged to be misleading by Mr. Crane is as follows:

The chronology statement for August 29 stated that a wipe test of the patient was performed, found to be negative and that a decision was made not to remove the sources irradiating her brain tumor. This statement implies in Crane's view that the hospital claimed to know of the patient's thyroid contamination on August 29. These are assertions shown by other evidence to be false according to Crane.

The chronology statement of August 30 stated that the hospital learned that there were 557 uCi I-125 in the patient on August 30 while Appendix B shows that this was not learned by the hospital until September 5. The conflicting information in the chronology statement was interpreted by Crane to reflect a claim by the hospital that it knew of the patients thyroid contamination on August 30, when other evidence establishes that such a claim is false.

The hospital filed a letter with NRC written by Dr. Aron on November 2, 1984 which referred to "iodine leakage" in the context of a discussion involving a medical decision and irradiation of the patient's thyroid. Crane states that Aron's letter was consistent with the August 29 and 30 chronology entries which he says were false and this was therefore a further effort to mislead NRC.

Crane outlined a hypothesis showing in his view that because the hospital did not know of the leaking seed until September 1 and did not obtain confirmed evidence of the patient's thyroid contamination until September 5 it could not have rendered the medical decision later claimed by Dr. Aron in the letter to NRC. Crane claims that Dr. Aron's letter shows that he and Dr. Ho purported to know of the leaking seed on the disputed dates of August 29 and 30.

Crane asserts that the Aron letter was misleading to the NRC staff, citing the Executive Director for Operations' memorandum to the Commission Chairman of November 28, 1986 in which the staff said:

> Based on a November 2, 1984, letter and a November 24, 1986, telephone conversation with the Director, Division of Radiation Oncology, the doctors suspected leaking iodine-125 sources on August 28 or 29, 1984.

In numerous subsequent memoranda, Crane refined his argument by compiling a list of circumstances all incompatible with the hospital having knowledge that a seed was leaking during the treatment period. Crane asserts that these circumstances reinforce the correctness of his conclusion that the hospital in reality did not know of the leaking seed until after the treatment was over.

2. The OI Position

The OI inquiry into the possibly misleading chronology statement of August 29 revealed that Dr. Sodd had compiled the statement from information supplied by others, that he had no

first hand information about the medical decision made on August 29 to continue the treatment as planned and that it was his inference that the decision to continue therapy was based on the negative wipe test that was performed on that date. That inference appeared to be reasonable to Dr. Sodd but there is no evidence that Dr. Ho made the same connection when he recorded the results of his examination on the patient's medical chart.

The OI investigation revealed that neither Dr. Aron nor Dr. Ho made any specific independent claim to NRC that they had knowledge of a leaking seed on August 29. To the contrary, their claims were consistently they did not have actual knowledge of a leaking seed during the treatment period.

The OI report concluded that the chronology statement of August 29 was inaccurate. OI concluded that the medical decision claimed by Dr. Aron was made later in the treatment period most probably on Friday, August 31.

The OI report attached no importance to the chronology statement of August 30 which can be read to mean that the hospital staff knew the patient had 557 uCi in her thyroid on August 30. OI noted from other evidence that the patient's thyroid contamination was first discovered on September 1 when the seeds were removed from the patient and confirmed on September 5.

The OI report reviewed the asserted medical decision in the Aron letter but does not mention or credit any inferred linkage between the timing of the medical decision and the chronology

statements for August 29 and 30. OI found no evidence to contradict the asserted medical decision described in the Aron letter.

3. DPOP Findings

DPOP finds that the chronology statement of August 29 that links the negative wipe test to the medical decision to proceed was an innocent error. The error was caused by an interpretation of Dr. Sodd in his role as a compiler of the information that went into the chronology. As a nuclear chemist Sodd for the most part had no first hand knowledge of the events he described. Dr. Sodd reported correctly that a decision was made to continue the tumor irradiation on August 29. Dr. Ho made and recorded the decision based on his examination of the patient. Sodd's error was in inferring that the decision to continue treatment was based on the negative wipe test that was performed the same day. However, Sodd did not state or create a misleading inference that the decision to continue treatment was rendered after taking account of irradiation of the patient's thyroid.

We find that the decision to continue the tumor irradiation as planned which is shown on the patient's chart for August 29 was not the "medical decision" referred to in Dr. Aron's letter. The first medical decision referred to on the patient's chart does not relate to irradiation of the patient's thyroid whereas it is a concern of that described in the Aron letter.

The wipe test of August 29 produced negative findings. The doctors learned nothing about the patient's thyroid from this

test. There is no merit to any suggestion that these results could be used by the hospital to mislead NRC into believing that it knew of I-125 in the patient's thyroid on August 29 or that the disputed medical decision was made on that date with knowledge that the patient's thyroid was contaminated.

Neither Dr. Aron nor Dr. Ho claimed that the first medical decision to continue treatment was the disputed medical decision referred to in the Aron letter. Their claim has always been that the disputed medical decision was made at a different time [August 31] under different circumstances.

Nothing in the Aron letter speaks to the time when the medical decision he described was reached. The first link between the Aron letter and the chronology statements for August 29 and 30 was that of Crane. It has no support in the record.

Contrary to Crane's assertion, the NRC Region III Inspector did not rely on the entry for August 29 for any regulatory finding, and his report does not reflect that he was misled into believing that the doctors had knowledge of the leaking seed earlier than they actually did. He appears to have uncritically accepted Sodd's inference for August 29, but that was a harmless error.

The Inspector found that there had been no misadministration based on the medical decision described in the Aron letter. The timing of any occurrence of August 29 and 30 was not a factor cited by the investigator in closing the file. Although the

Inspector rendered an incorrect regulatory conclusion when he found that there had been no misadministration, he cited only Dr. Aron's letter as his basis for the finding. Nothing in the Inspection Report suggests that the Inspector's incorrect legal conclusion was founded on the August 29 chronology statement.

What caused the Executive Director for Operations to make the linkage in his memorandum to the Chairman on November 28, 1986 is not known. That is a matter that deals with staff conduct that occurred more than two years after the incident and long after the staff report of investigation. It is a matter that may be considered independently of this proceeding.

The chronology statement for August 30 appeared on its face to be a claim by the hospital that it knew the patient's thyroid was contaminated on that date. However, the statement referenced Appendix B which was submitted at the same time and which showed that the definitive thyroid measurement was made on September 5. The conflicting statements were both submitted to the NRC as part of the hospital's report of the incident and both were products of the same hand. Standing alone, the chronology statement might plausibly be interpreted as an effort to mislead the NRC. However, in context with Appendix B, it is clear that conflicting data were inadvertently submitted and that one or the other of the statements is in error. The OI interviews clarified the matter. Further, the hospital report made no effort to persuade the NRC to afford more weight to the chronology statement than to Appendix B and, in fact, the statement referenced the Appendix.

The conflicting information submitted by the hospital in connection with the events of August 30 were shown by the OI investigation to be adequately accounted for by error in describing or interpreting the events. The information was not submitted as part of an effort by hospital officials to mislead the NRC into believing that they knew of the patient's thyroid contamination earlier than they actually did.

The Inspection Report shows that contrary to Crane's assertion, the Inspector did not rely on the incorrect chronology statement for a regulatory decision and that he was not otherwise misled by it. He correctly concluded that the hospital's knowledge that the patient had 557 uCi in her thyroid was obtained on September 5.

DPOP concludes that the two incorrect statements in the chronology submitted by the hospital were inadvertent and innocent. We agree with OI that the two statements did not constitute an effort by the hospital to willfully mislead the NRC. DPOP finds that the Aron letter made no claim as to when the disputed medical decision was made. DPOP therefore concludes that OI correctly treated the Aron letter as standing alone and not linked to the chronology statements as part of an effort by the hospital to mislead the NRC as to when the critical decision was made.

There is insufficient evidence to support a finding that the licensee's understanding of the incident while it was in progress

(setting aside the "medical decision" issue) was not as it was represented to the NRC.

C. Is There Sufficient Evidence To Support A Finding That The "Medical Decision" Claimed To Have Been Made By Hospital Officials During The Incident Was Not As It Was Represented To The NRC?

1. Crane's Position

Crane outlined a hypothesis in his August, 1986 memorandum which convinced him that the hospital had no knowledge of a leaking seed during the treatment period. In Crane's view, the hospital learned only after treatment was over that a seed had leaked in the patient. At that point it needed an explanation for the fact that it had permitted irradiation of the patient's thyroid to proceed undetected for several days without taking any remedial action. According to Crane's reconstruction, the hospital fashioned a claim that it had made the "medical decision" described in Dr. Aron's letter, of November 2, 1984 to the NRC, as an explanation for the inadvertent thyroid irradiation and as a means of preventing the NRC from deciding that a misadministration had occurred.

Essential to Crane's version of events is that any "medical decision" that was rendered, required prior knowledge by the hospital that a seed was leaking. Crane found numerous facts that were inconsistent with the hospital having prior knowledge of a leaking seed and this caused him to question whether the medical decision claimed in Aron's letter had taken place.

Crane, in various memoranda, stated that the following support his view that the hospital had no early knowledge and therefore did not make the medical decision as it claimed: There is no record in the charts of suspected iodine leakage during the treatment period; the charts show no record of the medical decision claimed by Dr. Aron in his letter; urine sampling was not ordered on the dates when the hospital claimed knowledge; a thyroid specialist was consulted when it became known that hospital staff had I-125 uptake in their thyroids but he did not examine the patient; thyroid blocking therapy with potassium iodide was not ordered at any time prior to explant of the seeds; the nurses were not warned of possible exposure to visitors; and Dr. Breneman was not warned of the leaking seeds prior to the time he removed them. He discovered radioactivity near the patient's thyroid after he removed the seeds by routine survey, not because of any prior alert from the hospital.

Important to Crane's theory that the hospital misled the Commission in claiming a "medical decision" was made to continue treatment was his interpretation of the Aron letter. He read it as saying the physicians "knew that the seed was leaking in the patient's head and decided to leave it there anyway because they felt she needed the treatment and that this need outweighed the harmful effect on her thyroid." He believed any ordinary reader would interpret the letter as he had. He concluded that the letter was misleading because he claimed that Aron had made a claim of knowledge which other facts showed he did not have.

As support for his claim that the Aron letter was misleading, he cites the 1986 Executive Director for Operations's memorandum to the Commission which stated the doctors involved suspected leaking I-125 sources on August 28 or 29, 1984. The memorandum was previously mentioned by us under IV. Issues In Dispute B.

When Dr. Aron was interviewed in 1987, he stated under oath that the "iodine leakage" he referred to in the letter was not leakage in the patient, but rather to generalized contamination in the hospital's brachytherapy storage room. Crane called this a reinterpretation of the November 2, 1984 letter which he said is just not believable. He argues that if Dr. Aron had really been talking about contamination in the brachytherapy storage room, rather than leaking in the patient, there would be no reason for him to mention the effect on the patient's thyroid gland.

Crane asserts Dr. Aron formulated a fall back story where the doctors come up with a "what if" scenario of "even if the seeds were leaking, we wouldn't take them out." Supposedly, the doctors' story claimed that they were unsure that the contamination might be from the seeds in the patient, however, the importance of the treatment to the patient outweighed the possible contamination that the patient might receive if in fact the seeds were leaking and the decision was made that the implant be continued.

Crane claimed Ho, at one point, agreed with the story. He asserts the story lacks credibility especially when Dr. Aron states that what evidence they had during treatment indicated the patient herself was not contaminated.

2. The OI Position

OI found ample reason for Drs. Aron and Ho to hold a discussion on August 31, 1984 based on uncertainty as to the cause of contamination affecting staff. This led them to consider it might be from the seeds in the patient and as a consequence made a "medical decision" to continue the implant because the need to treat the patient outweighed her possible contamination.

It found that it was not until removal of the I-125 seeds on September 1, 1984 that it was known with any certainty that the seeds had been leaking in the patient. However, prior to that point, the known area of contamination from which I-125 emanated was the brachytherapy room. An ongoing search was made for the source and it was not known as late as August 30, 1984 that the origin of the contamination was the seeds implanted in the patient.

OI did not consider it unreasonable for the physicians to hold the discussion they claimed they had on August 31. It asserted that there was sufficient reason for a "what if" discussion based upon the source of contamination being unknown.

OI did not find evidence to suggest that the "medical decision" was not made as stated by the physicians. It claimed

that mere suspicion cannot be used as evidence to suggest otherwise.

3. DPOP Findings

We find that there is insufficient evidence to support a finding that the "medical decision" claimed to have been made by hospital officials during the incident was not as it was represented to the NRC.

We conclude this despite the fact that Crane's allegations, that the hospital learned only after treatment was over that a seed had leaked in the patient and that there were numerous facts that were inconsistent with the hospital having prior knowledge of a leaking seed, were fully borne out by the record.

Our examination of the record failed to convince us that the hospital officials ever claimed to NRC that they had actual knowledge of a leaking source in the patient and that they considered it as part of a "medical decision" to continue treatment prior to scheduled explant. That concept was one that originated with Crane and was not proffered by hospital officials in describing the "medical decision" they had made.

Crane derived the idea that the physicians claimed to know that the seed was leaking in the patient's head and decided to leave it there anyway from his interpretation of the November 2, 1984 Aron letter and a similar staff interpretation reported in November, 1986, two years after the event.

Crane asserted that Aron's reference in the letter to "iodine leakage" could only refer, in the context of the letter,

to leakage in the patient. He concluded that there would be no other reason for him to mention the effect on the patient's thyroid gland.

We disagree with that assertion. There was an ongoing investigation into I-125 contamination in the brachytherapy room. Hospital staff had contaminated thyroids. The seeds in the patient were the only ones in the hospital that had not been ruled out as a source of the environmental contamination. Dr. Ho had been subject to thyroid counting and a small amount of contaminants were found. Under those circumstances, it is evident that the doctors, although having no knowledge of a leaking seed, had good reason to consider the possibility that the patient's thyroid might be contaminated. Those factors provide ample reason for the doctors to consider possible thyroid contamination absent knowledge that a seed was leaking in the patient.

There is no evidence that the doctors knew or focused on the possibility that the patient had a dose commitment of over 2000 rad to the thyroid when they made their decision. Dr. Ho stated to the investigator: "...treatment was going to outweigh the slight contamination she was going to get..." Aron said "any contamination from the iodine was minuscule for the patient's health..." (Emphasis added) The doctors expected that if the patient were contaminated, the amount would be small.

Crane's interpretation of the letter did not approach the plausibility of the explanation of Dr. Aron. In the first

instance, the Crane interpretation was wholly incompatible with the situation that existed in the hospital during treatment. Further, the Aron letter makes no mention of leakage in the patient. As to Crane's conclusion that the referenced concern over the patient's thyroid could only indicate leaking seeds in the patient, it is without merit.

The Crane interpretation was contrary to the hospital officials' position that they always maintained that they did not know of a leaking seed until after explant and that their "medical decision" was based on the generalized contamination in the hospital's brachytherapy room and the possibility of a leaking seed. Their position was consistent with what the overall situation at the hospital was.

The decision of Drs. Ho and Aron was made with erroneous assumptions and apparently without full appreciation of its medical significance. Nevertheless, Aron's letter claimed without added elaboration only that a "medical decision" was made that took possible effect on the thyroid into account. NRC did not inquire and no effort was made to mislead the NRC about his state of knowledge when he made his decision.

When confronted with the hospital acknowledgement that they had no actual knowledge of leaking seeds prior to explant, Crane characterized their position on the event as a reinterpretation and employing a fall back story.

We do not find that Dr. Aron reinterpreted his letter. He offered his explanation of what he had written. The only prior

interpretation was Crane's and not one by Aron. Again, the "what if medical decision" is no fall back from a previous story. It was consistent with the explanation offered by the hospital personnel from the start.

DPOP finds a lack of probative evidence to dispel the claim the physicians made under oath that on the afternoon of August 31, 1984 they decided that irrespective of the general situation of leaking iodine in the area and the possibility of a leaking seed that they would continue with the I-125 implant because of the gravity of her situation and the need for treatment, which outweighed the possible effects from irradiation of the thyroid.

The failure of the hospital to take the preventive actions and to record the medical decision on the patient's chart in the hours prior to explant can raise an inference that the claimed "medical decision" never occurred. However, the failure to act can be equally attributable to what were the practicalities of the situation. It was only a matter of hours between the time the "medical decision" was made and the time for explant. The amount of radiation that was expected was "slight" and the contamination "minuscule". It could equally have been a matter of medical judgement and practice that the action was not taken rather than a case of the "medical decision" never occurring.

The inference that the "medical decision" never occurred is weak and insufficient to overcome the sworn statements of the two physicians that it had occurred. Their credibility had not been successfully impeached.

Crane would not be willing to accept the August 31, 1984 discussion between Dr. Aron and Dr. Ho as a "medical decision" even if he believed it had occurred.

We have found no recognized definition of a "medical decision". It can be considered as one formally arrived at, with consideration of all ramifications and be one with a major consequence. However, we find equally meeting the term, a determination made as to how to treat a patient that was arrived at in passing and was not of a significant consequence. It is the latter which the hospital claimed to have occurred and which was represented to the NRC. The evidence against such a "medical decision" occurring was not sufficiently probative and convincing to find that it did not occur as claimed by the hospital.

There is insufficient evidence to support a finding that the "medical decision" claimed to have been made by hospital officials during the incident was not as it was represented to the NRC.

D. Miscellaneous Matters Relating To The Dispute

Crane, in his memorandum to DPOP of June 11, 1990 raised new matters not previously considered by OI and others that evolved from comments made previously. We will consider them in this section.

1. Crane attacks the hospital's creditability from another angle. From notes he found at the hospital on May 3, 1989, it was disclosed that on October 30, 1984 hospital staff including Dr. Aron and NRC staff reached an understanding by which the

hospital would report its "medical decision" in writing and the NRC would find no misadministration.

Crane asserts that Dr. Aron in 1987 was lying to the OI investigator when he said that his letter of November 2, 1984, as to the "medical decision", had nothing to do "with whether a misadministration would be found to have occurred."

We first wish to comment that an understanding to confirm an oral statement in writing is by itself not improper. It is a neutral occurrence neither indicating propriety nor impropriety.

Our review of the record disclosed that Dr. Aron truthfully stated in 1987 that the request for his letter was made by NRC. Some hand written notes of a conference call with NRC on October 30, 1984 obtained by Crane, show that the relationship between the medical decision and misadministration was discussed. Aron participated in the call. The notes establish that Aron was not naive about the purpose of the letter when he prepared it. Contrary to Crane's assertion, he did not purport to be so in his statements to the OI investigator.

Aron answered a compound question by the investigator that inquired whether the relationship was brought to his attention and what he discussed. It appears that he narrowly interpreted the question in light of what was requested of him during the call. He answered that he limited his discussion in the letter to a description of the "medical decision" because that was what he was requested to do. The nature of the question and answer were such that we cannot conclude Aron was untruthful in his

answer as asserted by Crane. We can draw no conclusion from this that it reflects adversely on Dr. Aron's credibility on the "medical decision".

Another reason Crane points out to be wary of taking the hospital's statement on faith relates to his claim that the 3M Company vigorously disputed the hospital's claim that the company admitted that the incident was the fault of the seeds.

Dr. Saenger reported to NRC that the seed was damaged during hospital manipulation. His report to NRC on this matter was candid and it did not mislead the investigators. Thus any dispute that may exist between the hospital and 3M Company is one for them to resolve as manufacturer and user. This aspect of the matter does not affect our findings and conclusions.

2. Crane alleges impropriety on the part of the staff in speaking to Drs. Aron and Ho on November 24, 1986, to discuss the events of the incident. This contact allegedly put the hospital on notice of continuing NRC interest in the subject even if OI's involvement was not mentioned. (The OI interviews were begun in September and finished in early December, 1987.) In Crane's opinion, this contact was improper and it presented the opportunity for the staff and the hospital to engage in collusion in advance of the pending OI investigation.

DPOP has no basis to believe one way or another that the staff contact in November, 1986 resulted in collusion between the NRC staff and the hospital or that the contact tainted the OI investigation that took place one year later in 1987. That

matter is within the jurisdiction of the IG which is investigating actions of the staff in this case. DPOP has conducted its review under the assumption that the statements of persons interviewed by OI were as they were purported to be. If other evidence subsequently shows that this was not the case our conclusions would have to be reconsidered.

3. Crane faults OI for having relied almost exclusively on the testimony of Drs. Ho and Aron as to the "medical decision" and to have ignored other evidence that suggested that the "medical decision" might have been a story concocted after the fact or at least greatly exaggerated.

Crane is correct that OI basically reached its conclusion on the oral interviews with the participants. It can be argued that the evidence was sufficiently convincing and this was all that was required. However, we believe Crane made a positive contribution to determining all of the facts by pursuing and obtaining the patient's and other hospital records. It provided a separate means for examining the truthfulness of the information provided. Although the records did not provide sufficient information to alter the conclusions reached, they foreclosed having an unexplored avenue for determining what occurred.

As to the question raised by Crane of whether OI, with the information in its possession, pursued the investigation appropriately or instead stopped short prematurely, it is not really one for us to answer. It becomes a question of the

effectiveness of OI which is not part of our task. One would have to be fully apprised of OI's investigative policies, and whether the policies were appropriately followed.

We can state it was a more complete investigation after Crane obtained the hospital records. The incident appears now to be fully reviewed. In a sense, this conclusion was confirmed by the IG interviews of 1989 that were made available to us. They did not provide anything substantially different that would alter the prior findings.

4. Crane contends in the June 11, 1990 memorandum that the OI investigation contained enough evidence to meet the low threshold for a referral. DPOP disagrees.

Contrary to the Crane allegation that the hospital misled the NRC by representing it knew of the patient's radioactive exposure well before it actually did the preponderance of the evidence was that the NRC was not misled. Although there were two incorrect statements, they did not represent any attempt to mislead and no misleading occurred.

As to Crane's claim that there is sufficient evidence for a finding that the licensee misrepresented the claimed "medical decision", we have found that the inferences raised by Crane that the "medical decision" did not occur as described were not of sufficient weight to overcome the evidence of the hospital that it occurred as described.

To forward a case to the Department of Justice for enforcement action, the evidence should provide reasonable ground

that the offense was committed. The evidence that an offense occurred should outweigh the evidence that it did not happen.

Here the evidence that the offense did not happen is more convincing.

18 U.S.C. 1001 makes it a crime to make false statements to an agency of the United States. Generally, the crime is knowingly and willfully falsifying a material fact, or making false statements, or using false documents knowing them to contain false statements.

Sufficient probative evidence was not provided for one to believe that the hospital engaged in false representations to the NRC, let alone that it was done knowingly and willfully.

The decision of OI to close the file and not make a referral to the Department of Justice was correct.

The foregoing finding does not lessen the importance of Peter Crane's efforts that resulted in correcting the erroneous conclusion of the staff investigation that no misadministration occurred and making clear the NRC regulatory requirements on misadministrations.

V. ULTIMATE CONCLUSION AND RECOMMENDATION

We find that there is a lack of substantial evidence to support a conclusion that the licensee significantly misstated the facts regarding the misadministration incident at the University of Cincinnati Medical Center.

Our recommendation is that the Executive Director For Operations accept the conclusion of OI that the file by closed and that it not be referred to the Department of Justice.

Respectfully submitted:

Morton B. Margulies, Chairman
Administrative Law Judge

Jerry R. Kline
Administrative Judge

Harry Foreman by MBM
Harry Foreman
Administrative Judge

July 12, 1990

APPENDIX A

LIST OF MATERIALS FURNISHED TO DPOP

From Deputy Executive Director Hugh L. Thompson, Jr.

DPO Panel Task Assignment
Memo dated 8/27/86 from P. Crane on University of Cincinnati Incident
Memo dated 8/4/89 from H. Walker, OI, Region III to Pawlik
Memo from Eugene Pawlik, Region III
Note for Ben Hayes from Peter Crane dated 5/26/89
OI Report, Case No. 3-86-014
Memo for B. Kennedy from Peter Crane dated 3/9/90
Memo for H. Thompson from Peter Crane dated 8/4/89
Talking Points to H. Thompson from Peter Crane dated 9/26/89
Memo for E. Pawlik Director, OI Region III dated 10/10/89

From Director Ben B. Hayes

Memo, Hayes to DPOP, 6/5/90

From Assistant Inspector General for Investigation Leo J. Norton

Investigative Interview Transcripts Aaron, Breneman, Fritz, Saenger and Sodd

From Peter G. Crane, Office of the General Counsel

Memo, Crane to DPOP, 6/11/90
Patient's chart, 8/27/84 through 9/2/84
Handwritten notes of K. Fritz (RSO), 10/30/84
3M letter to Heltemes, 2/11/86
Memo, Roberts to Hayes, 9/26/86
Memo, Hayes to Commissioners, 10/30/86
Draft memo, Stello to Zech, undated (c. 11/26/86)
Memo, Crane to Malsch, 11/26/86
Memo, Stello to Zech, 11/28/86
Crane's notes in preparation for NRC staff briefing, 12/15/86
NRC staff briefing handout, 12/15/86
Crane memo to files, 12/19/86
Abnormal Occurrence Report, 52 Fed. Reg. 17855, 5/12/87
Memo, Crane to Connelly, 7/6/87
Memo, Crane to Walker, 7/29/87

Memo, Crane to Logan, 2/5/88
Memo, Crane to Logan, 2/19/88
Memo, Crane to Rathbun, 11/7/88
Crane notes on OI interviews, undated (c. 11/15/88)
Memo, Crane to Connelly, 11/20/88
Memo, Crane to Walker, 4/5/89
Memo, Crane to Thompson, 8/4/89
Memo, Crane to Scinto, 9/28/89
Memo, Crane to Williams, 3/10/90
Memo, Taylor to Commissioners, 6/4/90
Miscellaneous documents obtained from U. of Cincinnati Medical Center pursuant to OI subpoena, 5/3/89
Memo, Crane to Margulies, 6/6/90

APPENDIX B

HOSPITAL PERSONNEL NAMED IN REPORT

Bernard S. Aron, M.D., Director, Division of Radiation Oncology

John C. Breneman, M.D., Resident, Division of Radiation Oncology

Kenneth M. Fritz, M.S., Radiation Safety Officer

Peter Y. C. Ho, M.D., Attending Oncologist

Eugene L. Saenger, M.D., Chairman Radiation Safety Committee

Vincent J. Sodd, Ph.D., Nuclear Chemist

3-7-91

(22)

A BRIEF ACCOUNT OF THE U. OF CINCINNATI INCIDENT

The case involved a 26-year-old woman -- "J.H." -- with a recurrent case of highly malignant brain tumor. Her doctors at the University of Cincinnati Medical Center decided to treat her with "brachytherapy" -- that is, a radioactive source placed in the tumor itself. For this purpose, they used tiny "seeds" of highly radioactive Iodine-125, placed in a thin nylon catheter and inserted through a hole drilled into the patient's skull. Though the hospital had considerable experience with I-125 seeds that were designed for one-time use, the seeds implanted in J.H. were of a new kind, of higher potency, and designed to be used in a number of patients. J.H. was the second patient to be treated with this particular group of seeds.

The technicians whose job it was to remove the seeds from the catheter after a treatment and put them away in a lead container until their next use had received inadequate training. After the seeds' first use, they had used a knife or a scissors to cut the seeds out of the catheter. Unable to see what they were doing, because the catheter was smeared with blood and other fluids, the technicians inadvertently cut one of the seeds.

At the time that the seeds were taken from storage and implanted in J.H., therefore, one of them was leaking. The implant took place on August 27, 1984, and the treatment was scheduled to last until September 1, 1984, five days later..

On August 28, 1984, the hospital became aware that there was radioactive iodine contamination in the brachytherapy storage room. Looking for the source of the contamination, however, they were unable to find it. Suspicion fell on the seeds in J.H.: was it possible that radioactivity was leaking from J.H.'s head into the hospital environment? The Radiation Safety Department therefore took a wipe test of the lead hat which J.H. had been instructed to wear. The test showed no radioactivity, and one of her physicians wrote in J.H.'s chart, "Sources intact & pt tolerating implant well. Plan 5 days 6 hrs to be removed Saturday 9/1/84 to deliver 8000 R [rads] to tumor."

For the remainder of the treatment period, there were no further notations in the patient's chart or any other hospital records indicating continuing suspicion of the seeds in J.H.'s head. To be sure, Radiation Safety took a urine sample on August 31, but it was not counted for radioactivity until several days after the seeds had been removed from the patient. By that time, the leak had been discovered. It would have taken only 10 or 20 minutes to perform a urine count, so if suspicion of contamination had been high, one could expect the test to have been run immediately after the sample was taken.

In focusing on the possibility that radiation was leaking from the patient's skull, the hospital seems to have overlooked

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the possibility that the seed was leaking before the implant, and that it was now leaking into the patient's system. This was in fact the case. Because the thyroid gland is "avid" for iodine, the leaking iodine was concentrating in J.H.'s thyroid, and delivering to it a substantial dose of radiation.

The hospital was well aware, however, that it had a major release of radiation on its hands, with many staff members contaminated. On August 30, the hospital ordered testing for everyone who might be exposed. The technicians who handled the seeds were examined by an eminent thyroid specialist.

But nothing in the records indicates a continuing concern about contamination of J.H. as of that time. In addition to not ordering an immediate count of her urine, the hospital:

-- failed to give her a thyroid blocker (a harmless form of iodine that would have saturated her thyroid and blocked any further uptake of radioactive iodine);

-- did not have the thyroid specialist examine her;

-- did not warn the nurses who were taking care of her that she might be emitting radiation through her bodily fluids and the pores of her skin;

-- did not prevent her from receiving and having physical contact with visitors, including her 5-year-old daughter; and

-- did not warn the surgeon who would be removing the catheter that one or more of the seeds might be leaking radiation.

On September 1, 1984, the seeds were removed from J.H. When a count was taken of her neck area, and her thyroid was found to be emitting radiation (from absorbed iodine), it became apparent that one or more of the seeds had been leaking while the treatment was going on. On September 4, 1984, the hospital notified the NRC.

The NRC conducted an inspection the following month. The NRC staff, after consulting a lawyer at NRC headquarters, advised the hospital that a "misadministration" had taken place. (The NRC's rules require misadministrations to be reported to the NRC, the patient's referring physician, and the patient. The requirement of patient notification has galled many physicians, who regard it as an encouragement to malpractice suits.) The hospital objected strenuously. On October 30, 1984, a conference call was held between NRC staff and hospital personnel. Two sets of notes, found at the hospital, reveal that the NRC staff

directed the hospital to put in writing that a "medical decision" had been made.
One of the sets of notes says, "The NRC will not consider this a misadministration since the medical decision to continue the treatment."

On November 2, 1984, Dr. Bernard Aron of the hospital wrote a letter to the NRC regional office which said:

> "When it was noted that there was iodine leakage, a conference was held between Drs. Bernard S. Aror 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. This was felt medically to be of primary importance, far overshadowing the effects of iodine 125 irradiation of the thyroid gland."

This letter was forwarded to the NRC by Dr. Eugene Saenger, the head of the hospital's Radiation Safety Committee and a longtime consultant to the NRC staff. He wrote: "I trust that this information is adequate to resolve this problem."

Without again consulting the lawyer who had advised that the event was a misadministration, the NRC staff determined that it was <u>not</u> a misadministration. There the matter rested for almost two years. During that period, the patient died -- not, it should be stressed, as a result of the misadministration, but from the cancer that the iodine was used to treat.

In August 1986, the NRC's Office for the Analysis and Evaluation of Operational Data issued a report on the risks posed by reusable iodine seeds. As I read the discussion of the Cincinnati incident in that report, I very quickly reached two conclusions: first, that the incident was a misadministration, regardless of whether there was a medical decision, after the misadministration was discovered, to allow it to continue; and second, that there was serious reason to doubt, based on the totality of the record, that the hospital in fact had made any such "decision" to allow the treatment to continue.

I should add that it seemed to be not improbable that if the hospital <u>had</u> discovered the leak during the treatment period, they would not at that point have cut the treatment short. To emphasize, my point was not that the treatment should have been terminated, but rather that the hospital should have been candid about what it knew -- and didn't know -- while the treatment was going on.

On August 27, 1986, I wrote a memo casting doubt on the hospital's account and urging that the event should be called a misadministration. The NRC staff took extreme exception to the

memorandum. Nevertheless, the Commission sent it to the Office of Investigations, which in a memo dated October 30, 1986, advised the Commission, "We agree with Mr. Crane's assessment that the licensee attempted to deceive the NRC." The memo added that because of high priority cases then underway in the Region III field office of OI, it was unlikely that the case could be conducted before the end of 1986.

On November 28, 1986, the Executive Director for Operations wrote a memo to the Commission, in which he acknowledged (1) that the incident should have been called a misadministration, and (2) explained that the licensee had only suspected (not known) that the seed was leaking during the treatment. The EDO urged that there was no basis for an investigation into the matter.

For reasons still unclear, the regional office of OI closed out the investigation in late 1986 without conducting a single interview. It was only reopened after I pressed the issue with OI headquarters personnel. Despite serious misgivings about the NRC staff's role, I had not made a referral to the Office of Inspector and Auditor initially, believing that the OI investigation would supply the factual predicate. In July 1987, however, with OI's investigation languishing, I made a referral to OIA.

OI finished its investigation late in 1988. After I raised serious questions about it, including the failure of OI even to ask for the hospital's documents on the incident, OI agreed to conduct another round of interviews at the hospital. These took place in May 1989. It was at that time that the NRC for the first time examined the patient's chart and learned of the notes detailing the communications between the hospital and the NRC staff that led to the finding of no misadministration. IT WAS ALSO AT THAT TIME THAT THE NRC LEARNED THAT THOUGH THE HOSPITAL HAD REPORTED ON SOME 60 PEOPLE WHO WERE CONTAMINATED IN THE INCIDENT, IT HAD OMITTED FROM THE LIST THE PATIENT'S 5-YEAR-OLD DAUGHTER.

OI's report, which found no attempt to deceive the NRC, was in my view seriously deficient. My objections to it were turned over to a panel of licensing board judges, sitting as a "Differing Professional Opinion Panel." They upheld OI on all points of substance. The judges announced that if an issue or argument was not mentioned in their opinion, it was because it was "wanting either in consequence or merit." Apparently, the failure to mention the contamination of the patient's daughter fell in this category, in the judges' eyes.

Late in 1989, the Office of the Inspector General issued its report on the staff's role, after an investigation lasting three and a half years. For reasons unknown to me, they did not interview the three higher-ups -- including the former EDO, whose

November 28, 1986 memo included significant inaccuracies -- whose role most needed examination.

It is significant, I think, that when hospital personnel were reinterviewed, at my insistence, in May 1989, Dr. Saenger objected to a question about the "misadministration" by saying that no one at the NRC had ever told him that the incident constituted a misadministration. If this is true, one wonders how the NRC staff could tell the Commission in 1986 that the event was a misadministration -- a concession to me that was supposed to make a further investigation unnecessary -- and the Commission could in turn notify the Congress in 1987 that the event was a misadministration, without anyone in the NRC staff advising the hospital. (It is the finding of a misadministration that triggers the requirement that the patient be notified.)

The patient is long since in her grave. I have no reason to believe that anyone in her family was ever told that a misadministration occurred. Nor do I see any reason to believe that anyone was told of her daughter's contamination.