UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

September 26, 1990

OFFICE OF THE
INSPECTOR GENERAL

MEMORANDUM FOR: Chairman Carr

FROM: David C. Williams
Inspector General

SUBJECT: STAFF HANDLING OF THE UNIVERSITY OF CINCINNATI HOSPITAL INCIDENT

Enclosed is an Office of the Inspector General (OIG) Report of Investigation concerning an allegation of NRC staff misconduct related to a radiopharmaceutical incident at the University of Cincinnati in August and September 1984. The OIG inquiry was initiated based on information provided by [redacted], Office of the General Counsel. [redacted] alleged that the staff acted improperly by accepting the hospital's representations concerning the incident and by concluding that the incident did not meet the requirements of the NRC misadministration rule.

The OIG investigation did not substantiate the allegation that the staff acted in bad faith or with malfeasance. However, the investigation determined that the staff made an error in accepting the hospital's representations without having sufficient information to make a determination as to whether the misadministration reporting requirement had been violated.

This report is furnished for whatever action you deem appropriate. Please contact this office if further assistance is required.

Enclosure:
Report of Investigation

cc: W. Parler, OGC
J. Taylor, EDO

FREEDOM OF INFORMATION/PRIVACY ACT EXEMPTION (b)(6)(7)(C) + 7(F)

Information in this record was deleted in accordance with the Freedom of Information Act, exemptions 6+7C+7F
FOIA- 92-277

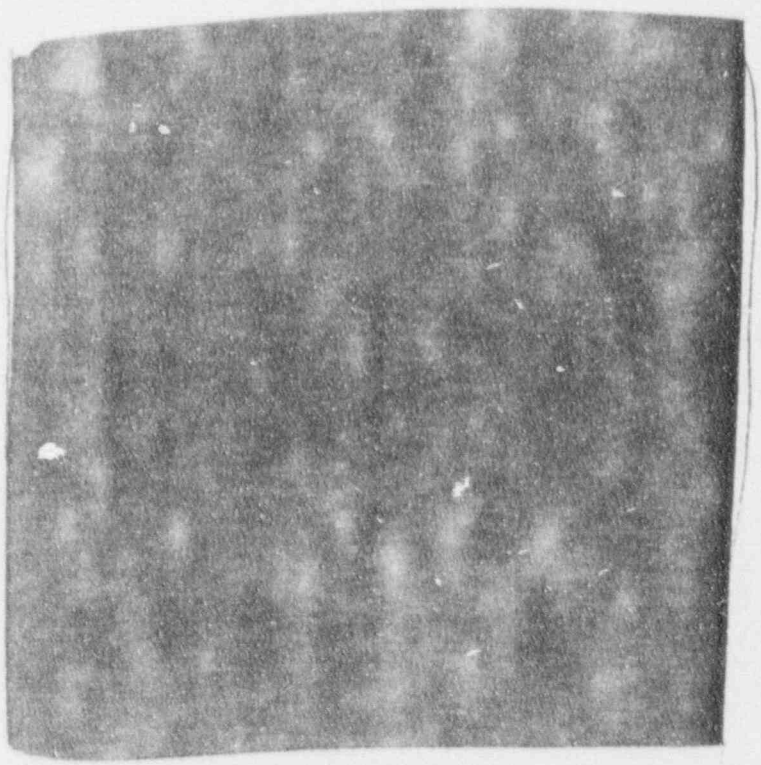
FOIA-92-277
B-1

OFFICE OF THE INSPECTOR GENERAL

REPORT OF INVESTIGATION

# STAFF HANDLING OF UNIVERSITY OF CINCINNATI HOSPITAL INCIDENT

CASE NO.: 87-24 D



INDEX


Page

SUBJECTS ..... 3

STATUTES ..... 4

SYNOPSIS ..... 5

BASIS ..... 7

DETAILS

ALLEGATION 1 ..... 10

ALLEGATION 2 ..... 15

ALLEGATION 3 ..... 16

FINDINGS

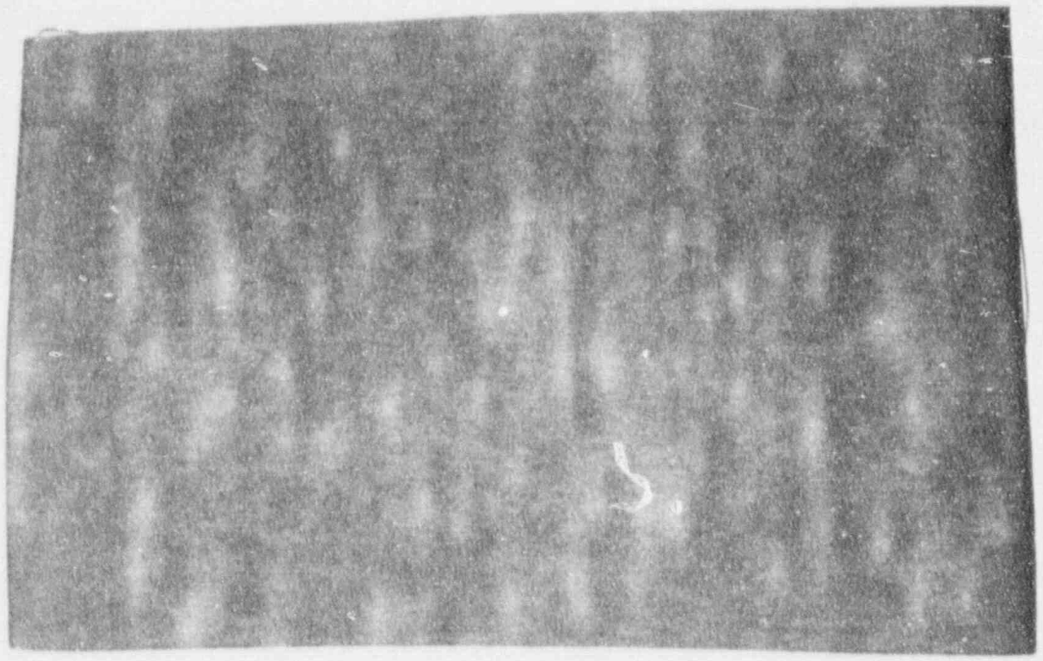
ALLEGATION 1..... 14

ALLEGATION 2..... 16

ALLEGATION 3..... 17

LIST OF EXHIBITS ..... 18

SUBJECTS



STATUTES

10 CFR Part 0.735-49a(f) - Conduct of Employees

SYNOPSIS

This investigation was initiated based on a July 6, 1987, letter from [redacted], Office of the General Counsel, concerning a radiopharmaceutical incident at the University of Cincinnati Hosptial. On August 28, 1984, a terminally ill patient was implanted with sealed sources (seeds) containing radioactive iodine 125. After the seeds were removed on September 1, 1984, the hospital determined that one of the eight seeds had leaked into the patient and had irradiated the thyroid. [redacted] alleged that the staff acted improperly by accepting the hospital's representations concerning the incident and by concluding that the incident did not meet the requirements of the NRC misadministration rule. [redacted] alleged that after the Commission requested a determination from the Office of Investigations (OI) concerning whether NRC rules had been violated, staff compromised the investigation by contacting the licensee. [redacted] also alleged that on November 28, 1986, and December 15, 1986, the staff reported the same inaccurate information to the Commission and Commissioners' Assistants, which the licensee had previously reported to the NRC in 1984.

The investigation revealed that the staff failed to question the hospital regarding the specific events and actions undertaken during the incident. The staff assumed that the hospital made a medical decision based on the knowledge that a sealed source was leaking inside the patient. Yet, the hospital subsequently maintained that they did not definitely know, but rather only suspected the seeds were leaking inside the patient.

The staff deferred to the hospital's argument that the incident was not a misadministration because they had made a medical decision to continue treatment. However, the staff did not question when the hospital made the decision and why the determination was made. The staff maintained that whether the decision was made on the first or last day of treatment was irrelevant, as long as it occurred during the treatment process. The staff subsequently inferred that the decision was made early in the treatment. However, review of the incident revealed that the decision was made just prior to the scheduled explant of the sealed sources.

The staff did not obtain a legal opinion concerning whether the incident was a misadministration. By not doing so, the staff reached an erroneous conclusion that the misadministration rule did not apply.

The investigation disclosed that shortly after the Office of Investigations initiated its investigation, OI requested the staff to ascertain whether the patient was alive. The staff accordingly contacted the hospital. OIG concluded that OI

authorized the contact and in OI's opinion this action did not compromise the investigation.

The investigation also disclosed that the November 1986 memorandum to Chairman ZECH and the December 1986 briefing paper to the Commissioners' Assistants did not identify the correct date and circumstances surrounding the hospital's medical decision. Because the staff failed to adequately review the incident, it incorporated inaccurate information which the hospital had provided in 1984.

BASIS

This investigation was initiated based on a letter from [redacted], Office of the General Counsel (OGC), concerning a contamination incident at the University of Cincinnati Hospital (UCH), an NRC licensee, which occurred in August and September 1984 (Exhibit 1). On August 27, 1984, a patient was implanted with sealed sources containing radioactive iodine 125 (I-125) to treat a malignant brain tumor. After the sources were removed on September 1, 1984, the university determined that one of the sources (seeds) was inadvertently punctured and had irradiated the patient's thyroid. The hospital subsequently advised NRC that they made a medical decision to continue the patient's treatment after it had discovered a contamination problem in the brachytherapy source storage room.

[redacted] alleged that it was malfeasance on the part of the staff to be misled by the licensee into believing that the university knew of the inadvertent I-125 exposure before it actually did and, that it made a deliberate medical decision during the treatment process to allow the exposure to continue. [redacted] maintained the university did not know that the seed was leaking until after the treatment process. Therefore, the hospital could not have made a medical decision to allow a leaking seed to remain in the patient. As evidence of the staff's acting in bad faith, [redacted] maintained the staff concluded that the incident was not a misadministration in spite of a legal opinion from [redacted] that it was. [redacted] alleged possible collusion between the staff and the licensee because the staff accepted the hospital's representations notwithstanding that during a telephone conference call, the licensee told NRC that they would have left the seeds in the patient "even if they had known the seeds were leaking during the treatment."

[redacted] alleged that after the Commission authorized OI to conduct an investigation, the staff contacted the hospital to discuss the incident and thereby compromised the investigation. [redacted] also alleged that the staff provided inaccurate information to the Commission in an EDO memorandum, dated November 28, 1986, and in a Commissioners' Assistants briefing paper, dated December 15, 1986. Specifically, these documents provided an account of the incident that repeated the same inaccurate information which the licensee had reported in 1984.

BACKGROUND

University of Cincinnati Incident

On August 27, 1984, physicians at the University of Cincinnati Medical Center temporarily implanted eight sealed iodine 125 (I-125) sources into the brain of a terminally ill patient. The sources were scheduled to be removed on September 1, 1984. On

August 28, 1984, wipe testing of containers in the brachytherapy source storage room revealed I-125 contamination. The room was subsequently sealed and decontaminated. On August 29, 1984, the patient's lead hat and bandage was wipe tested and did not reveal any I-125 leakage. Tests of the technicians responsible for loading the implanted I-125 seeds were scheduled. On August 30, 1984, thyroid counting showed that one of the technicians had measurable uptakes of iodine. Thyroid counts were ordered for all personnel at risk. Approximately 60 persons were tested between August 30 and September 10, 1984. Urine samples were taken from the patient on August 31, 1984. Results of the patient's urine sample were obtained on September 4, 1984.

After the conclusion of the prescribed therapy, the seeds were removed on September 1, 1984. Survey of the patient's thyroid revealed that the thyroid had been irradiated. It was subsequently determined that one of the seeds was punctured prior to being implanted in the patient. On September 4, 1984, the patient returned to the university for further tests (Exhibit 2).

NRC Region III Inspection

NRC Region III was initially notified of the contamination in the brachytherapy room, the thyroid contamination in hospital personnel and the patient's thyroid on September 4, 1984 (Exhibit 2 at 3). [redacted] NRC Region III requested the hospital to provide a written summary of the incident (Exhibit 3 at 5; 4 at 19).

On October 10-12 and October 30, 1984, [redacted] conducted a special announced inspection to review the facts surrounding the damaged I-125 source that was removed from the patient. [redacted] held an exit conference on October 12, 1984. During this meeting, [redacted] and the hospital personnel discussed whether the incident was a misadministration. The hospital told [redacted] that a medical decision had been made to continue the treatment as planned. After discussing the misadministration issue with Region III management, NRC and hospital personnel conducted a telephone conference call to resolve the issue on October 30, 1984. The hospital again advised that they made a medical decision to continue the treatment process. [redacted] Region III, requested the hospital to document the medical decision (Exhibit 2; 3 at 15, 19; 5 at 11, 12; 6 at 31).

On November 2, 1984, [redacted] documented the hospital's medical decision. The letter stated that "When it was noted that there was iodine leakage a conference was held between [redacted] It was felt that because of the significant medical problem, recurrent malignant brain tumor, the patient's implant should be continued to achieve full dose" (Exhibit 7).

On December 17, 1984, Region III released an inspection report which summarized the inspection and findings and included a summary of the events leading to the leaking I-125 seed. The inspection summary stated "on August 29th, a wipe test of the patients lead and bandage revealed no contamination"; the attached narrative stated "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 with the treatment" (Exhibit 2).

Attachments to the NRC inspection report included the hospital's chronology and documentation concerning the incident. The hospital chronology reflected: August 29, 1984, "Wipe testing of patient's hat and bandage revealed no leakage, and it was therefore decided not to remove the sources." Also, reflected was that on August 30th the hospital conducted thyroid counting of the technicians and that "there was 557 uCi found in the patient (see Appendix B)." According to Appendix B, thyroid counting of the patient occurred on September 5 (Exhibit 8).

The NRC inspection report identified two violations: (1) the unauthorized opening of a sealed source (the I-125 seed); and (2) the failure to perform an adequate survey to detect low level contamination. The report stated that based on [redacted] letter the NRC determined that no misadministration occurred "since a medical decision and evaluation was achieved and the patient's implant was continued to achieve treatment" (Exhibit 2).

10 CFR Part 35 defines a misadministration in part as, " a radiopharmaceutical or radiation by route of administration other than that intended by the prescribing physician." The reporting requirements of 10 CFR 35.42, now incorporated in 35.33, requires notification to the NRC within a prescribed period following the discovery of a misadministration.

**Investigation by the Office of Investigations, Region III**

The Office of Investigations was requested to review whether the licensee misrepresented facts surrounding the contamination incident to the NRC. On October 27, 1988, OI concluded that the evidence did not support a finding that the hospital willfully failed to report a misadministration to the NRC. However, OI determined that the hospital's chronology contained inaccurate information. Specifically, it was determined that the medical decision did not occur on August 29, 1984. OI concluded that on or about August 31, 1984, [redacted] and [redacted] discussed the "possibility" that the patient might be the source of the contamination problem and therefore a decision was made to continue the planned treatment until September 1, 1984 (Exhibit 9 at 2, 19).

Differing Professional Opinion Panel

On May 21, 1990, a Differing Professional Opinion Panel (DPOP) was established because [redacted] disagreed with OI's conclusion. On July 12, 1990, the DPOP concluded that the contamination incident was a misadministration. They also concluded that there was insufficient evidence the licensee "significantly misstated facts regarding the incident and misled the NRC" (Exhibit 10 at 3).

The DPOP stated that the hospital chronology included inaccurate statements for August 29th and 30th but that the inaccuracies were inadvertent. They further stated they could not have been used to mislead NRC because [redacted] did not rely on the chronology to reach the regulatory conclusion that no misadministration had occurred. Similarly, the DPOP stated that the information concerning the wipe test could not have been used to mislead NRC to believe that the hospital knew the seeds were leaking on August 29, or that a medical decision was made on this date knowing that the patient's thyroid would be irradiated. The DPOP commented that it was not convinced that the hospital "ever claimed having actual knowledge of a leaking source in the patient" (Exhibit 10 at 38, 36, 35, 43).

DETAILS - ALLEGATION # 1

Medical Decision Issue

Review of the NRC inspection report did not indicate when the hospital determined that the seeds were the source of the contamination problem. The attached hospital chronology did not identify when the hospital knew the seeds were leaking in the patient. Both the NRC inspection report and the hospital's chronology reflected that after the seeds were removed on September 1, 1984, testing of the patient's thyroid revealed that the thyroid was contaminated (Exhibit 2).

The NRC inspection report also did not indicate whether there had been an inquiry as to when a medical decision was made to continue the treatment. Although [redacted] letter did not state when the decision was made, the NRC inspection summary stated that the decision was made after the wipe test was conducted on August 29, 1984. However, both [redacted] and [redacted] advised that they never asked the hospital when the medical decision was made (Exhibit 2; 4 at 34; 5 at 15, 36).

[redacted] stated that [redacted] concern during the inspection was to determine the extent of the contamination event and whether procedures were violated. The hospital chronology was accepted without question, although it was not intended to be a final document. [redacted] understanding of the chronology was that the hospital initially suspected a leaking seed on August 29th

and therefore a wipe test was performed. assumed that the medical decision was made based on the results of the wipe test (Exhibit 4 at 34, 25, 26, 27, 33).

stated that a misadministration was the "last thing on my mind when I did the inspection," and it did not become an issue until after the inspection. advised never focused on the medical decision. Moreover, never thought of asking when the decision was made and probably never asked who made the decision. The misadministration issue was initially discussed at the exit conference. stated that during the meeting, the hospital put on the defensive and made it clear they did not view the incident as a misadministration. The hospital advised that regardless of whether the seed was leaking, the patient was going to receive the full therapy (Exhibit 4 at 34, 3 at 12, 16; 4 at 28, 29, 30).

said that NRC conducted the October 30, 1984, conference call to resolve the misadministration issue. During the call, the hospital advised that after they determined there was a leakage problem, they decided to continue the treatment because of the patient's condition. stated that the wipe test was a useless test and was not the basis for making the decision to leave the seeds in or to take them out of the patient. said assumed the decision was made sometime during the treatment, "probably near the end, probably the 29th, 30th, 28th" (Exhibit 5 at 11; 6 at 30, 31; 5 at 30, 27 15).

stated that November 2, 1984, letter convinced that the hospital made a deliberate medical decision to continue treatment. advised that the doctors made the decision recognizing that the thyroid would be irradiated. Further, in opinion, the hospital had enough "preponderance of evidence" to conclude that the seeds were leaking in the patient. interpretation of letter was that the hospital knew the seeds were leaking and that the "iodine leakage" referred to the leaking in the patient's head (Exhibit 5 at 12, 17, 45; 6 at 24, 26, 33; 5 at 34, 36).

Misadministration Issue

prepared the inspection report which was reviewed by Region III and approved by (Exhibit 11 at 5, 6). Before finalizing the report, consulted NRC Region III and the Office of Nuclear Material Safety and Safeguards (NMSS) headquarters staff concerning whether the incident was a misadministration. discussed the issue with NMSS. and the enforcement board advised that the incident was not a misadministration. However, advised that it

was. (Exhibit 5 at 13, 14).

advised that the original inspection report did not address the misadministration issue. After reviewing an internal NMSS document on misadministrations, discussing the incident with the hospital and receiving assistance from headquarters, the staff determined that a physician could change his diagnosis during the treatment process. stated that after discussing the issue with the staff concluded in the inspection report that the incident was not a misadministration (Exhibit 11 at 4, 5, 7, 8, 10).

stated that although ultimately made the decision that the incident was not a misadministration, mistake was in not going back to after receiving conflicting information from the NMSS staff (Exhibit 5 at 14; 6 at 33). stated initially described the incident to but did not tell that the hospital made a medical decision to continue treatment (Exhibit 5 at 13, 14). subsequently discussed the incident with and reviewed the NMSS policy document which described various examples of misadministrations (Exhibit 5 at 13, 6 at 32).

stated, based on discussions with NMSS and the licensee, that was convinced there was a medical decision to continue the patient's treatment. further stated that the doctors changed the prescription for the benefit of the patient and therefore, the incident did not meet the misadministration rule. According to the doctors could have changed the prescription at any time during the therapy and no matter when the decision occurred (i.e., at the beginning or end of the treatment process), it would not have affected NRC's regulatory decision (Exhibit 5 at 13, 14, 43; 6 at 13).

According to advised that the attending physicians made a conscious decision to continue the treatment even though they had knowledge that there was some leaking in the patient. discussed the incident with NMSS, who advised that it was not a misadministration. stated essentially went along with and who was the expert on the misadministration rule (Exhibit 12 at 12, 7).

stated that the misadministration rule had been developed after a clear history of mistakes were documented in clinical procedures that were best characterized as human error. advised that the rule was not intended to apply to the type of incident which had occurred at the university (Exhibit 13 at 6). stated however, that had trouble "buying off" on the theory that the incident was not a misadministration because of a physician's decision to leave the seeds in during the treatment

process. According to [redacted], a doctor's decision after the fact, should not be "used as a basis for determining whether this was a misadministration reportable event" (Exhibit 13 at 13).

[redacted] stated [redacted] did not view [redacted] conversation with [redacted] as an "official OGC" opinion. However, since [redacted] was a [redacted], [redacted] would have expected [redacted] and [redacted] to seek additional OGC advice after obtaining differing views from the staff (Exhibit 14).

[redacted] advised that although there was strong disagreement among the staff concerning the hospital incident, the staff knew the rules. According to [redacted] as long as the licensee gave NRC a reasonable explanation, the staff would "bend over" to find in the licensee's favor. The staff would do so because they did not want to interfere with medical decisions and had "strenuously" disagreed with the rule when it was originally proposed.

Possible Collusion Concerning Staff's Determination That Incident Was Not A Misadministration

Region III did not document the October 30, 1984, conference call, however, the staff reported that the hospital advised "even if they had known the seeds were leaking during treatment, therapy would have continued" (Exhibit 15 at 8).

[redacted] documented the hospital's medical decision and the staff's conclusion that the incident was not a misadministration in a memorandum dated December 11, 1984. The memorandum reflected that "the physicians stated that even had they known if the seeds were leaking, at the time of treatment, therapy would have continued" (Exhibit 16).

As a result of the OI investigation, [redacted] documented [redacted] October 12, 1984 exit conference with the licensee. [redacted] October 9, 1987, memorandum stated that the hospital advised they did not know the patient was the source of contamination during treatment. However, they had not ruled out the possibility. Further, even if they had that evidence during the treatment process, treatment would have continued (Exhibit 17).

[redacted] and [redacted] were questioned concerning the apparent discrepancy between NRC's conclusion that the hospital made a medical decision based on the knowledge or suspicion that the seeds were leaking, and their memorandums reflecting that the hospital had advised NRC that they did not know the seeds were leaking. In [redacted] opinion, the statements were not contradictory. [redacted] interpretation was that the hospital probably meant if the wipe test had shown contamination or if they had known with "a high degree of certainty," treatment would have continued. [redacted] commented that although the hospital made this statement, it was made prior to [redacted] letter. [redacted]

reiterated that the letter convinced [redacted] that the hospital made a medical decision, regardless of the leaking (Exhibit 5 at 33, 34, 37; 6 at 25, 32, 33).

In [redacted] opinion, the hospital did not provide contradictory information. According to [redacted] after the wipe test, the hospital probably did not know with "100% certainty" where the iodine was coming from. But the hospital had consistently maintained they made a conscious decision prior to explant that whether the seeds were leaking or not, they were remaining in the patient. [redacted] acknowledged that the hospital's representations were made after they knew that one of the seeds had leaked. Yet, [redacted] stated that [redacted] thought the incident was a misadministration from "day one" (Exhibit 3 at 16, 19; 4 at 8, 10). According to [redacted] never expressed this view, although [redacted] had ample opportunity to do so (Exhibit 5 at 23). [redacted] also stated that it was [redacted] and [redacted] who initially told [redacted] that based on NMSS criteria, doctors could decide to change a prescription if they found an error during the treatment process, and in light of a medical decision that was in the best interest of the patient, it would not be a misadministration (Exhibit 5 at 8, 9, 6 at 5).

Hospital staff members, [redacted] participated in the October 30, 1984, conference call. [redacted] did not recall the conversation, but [redacted] handwritten notes reflected in part: "treatment of tumor was continued for the best interest of the patient; NRC requested that the hospital put this in writing. NRC will not consider this a misadministration since the medical decision was to continue treatment." [redacted] stated that [redacted] vaguely recalled the conversation. [redacted] notes reflected in part: "provide in writing -no difference in treatment if leakage found earlier (8-29-84) - medical decision made" (Exhibit 18 at 36, 18a; 19 at 6; 19a).

FINDING - ALLEGATION #1

The investigation failed to substantiate the allegation that the staff acted in bad faith or with malfeasance. However, the investigation determined that staff did not adequately review the incident and made an error in accepting the hospital's representations.

The staff incorporated the hospital's chronology into NRC documents without, in some cases, an appropriate inquiry as to the facts which supported the chronology. The staff apparently did not focus on the medical decision. [redacted] advised that [redacted] was primarily concerned with the contamination issue and not with whether or not the incident was a misadministration. Because the staff did not determine when the decision occurred, they later inferred that it was made after the wipe test.

The staff accepted the hospital's representations concerning the medical decision without having sufficient information to make an appropriate determination as to whether the misadministration reporting requirement had been violated. The staff assumed that the physicians could make a decision to change a prescription during the treatment. They also assumed that the doctors could make the decision on the first or last day of treatment, as long as it occurred during the treatment process. Accordingly, the staff maintained that the timing of the medical decision was irrelevant. The staff failed to question the plausibility of a medical decision that occurred the night before the scheduled removal of the seeds. The staff did not seek an official OGC opinion after receiving conflicting opinions from NRC staff. As a result, the staff erroneously concluded that the incident was not a misadministration.

The investigation failed to disclose any evidence of collusion between the staff and the hospital concerning the staff's predecisional representations that the NRC would determine the incident was not a misadministration. Although [redacted] handwritten notes of October 30, 1984, may suggest possible collusion, they are not conclusive proof. The staff was correct in requesting the hospital to document the medical decision. However, the staff may have inappropriately advised the hospital of what NRC's conclusion would be as a result of the hospital's documented medical decision. The DPOP noted that [redacted] was "not naive about the purpose of the letter when he prepared it." [redacted] letter omitted specific information concerning when the hospital initially determined that the patient was the source of the contamination and when the hospital made the medical decision. As previously stated, [redacted] interpretation of the letter was that the "iodine leakage" referred to the leaking in the patient. [redacted] explanation that the "iodine leakage" referred to the general contamination in the environment, and not the patient, occurred well after the allegations were made. While the staff had no apparent motive in reaching a determination that the incident was not a misadministration, there could have been legal ramifications for the hospital.

DETAILS - ALLEGATION # 2

[redacted], Region III conducted the OI investigation concerning the hospital's alleged misrepresentations to NRC. [redacted] stated that after receiving the request for the investigation, [redacted] asked [redacted] whether the patient was still alive. [redacted] subsequently advised [redacted] that the patient had died. According to [redacted] contact did not compromise the investigation (Exhibit 20 at 5, 6).

[redacted] contacted [redacted] to determine whether or not the patient was living. [redacted] asked [redacted] about the iodine leakage and if [redacted] and [redacted] had a discussion regarding continuation of treatment.

[redacted] did not view the contact as improper because [redacted] had requested the information (Exhibit 5 at 41, 42).

FINDING - ALLEGATION # 2

The investigation concluded that [redacted] requested [redacted] to obtain information concerning the patient. Therefore, [redacted] contact with the licensee was authorized by OI and in OI's opinion did not compromise the investigation.

DETAILS - ALLEGATION # 3

As a result of [redacted] allegations, Chairman ZECH requested the EDO to respond to several questions concerning the contamination incident. The November 28, 1986, EDO memorandum concluded that after further staff and OGC review, the incident "would be more appropriately classified as a misadministration" (Exhibit 21). The memorandum recounted the medical decision and stated that the incident had been thoroughly discussed with the licensee. It referenced a discussion with the [redacted] on November 24, 1984. The memorandum stated that the hospital suspected leaking seeds on August 28 or 29, 1984; and the attached summary of the incident reflected that on August 29, 1984, a medical decision was made to continue treatment knowing that the patient's thyroid would be irradiated. The statement concerning the medical decision was not included in an earlier draft of the attachment (Exhibit 21 at 2; 22).

The briefing paper for the Commissioners' Assistants, dated December 15, 1986, documented the chronology of events leading to the ruptured I-125 seeds; the licensees' actions and corrective measures; and NRC enforcement actions (Exhibit 15). With respect to the medical decision, the document reflected that: on August 28 or 29, 1984, [redacted] and [redacted] "met to discuss the iodine leakage" ... and that "on August 29, 1984, wipe testing of the patient's lead hat and bandage revealed no leakage, and it was decided not to remove the sources."

James SNIEZEK, Deputy Executive Director, Nuclear Regulations, Regional Operations & Research was the final approving official before the EDO's signature. SNIEZEK stated that he did not specifically recall discussing the memorandum with staff or whether the summary of events was attached prior to his concurrence. SNIEZEK did not know that the information concerning the medical decision was inaccurate. SNIEZEK stated the staff ultimately concluded that the incident should have been a misadministration. Therefore, the timing of the medical decision would not have altered or have made a difference with respect to the regulatory conclusion (Exhibit 23).

[redacted] NMSS, was responsible for coordinating the

preparation of the November 28, 1986, EDO memorandum and the December 15, 1986, briefing paper. [redacted] was not involved in the initial determination of the contamination incident. NMSS headquarters, OGC, OE and Region III staff were principally involved in preparing the EDO memorandum (Exhibit 24 at 4, 5, 12). [redacted] prepared the briefing paper at [redacted] request and essentially made the presentation to the Commissioners' Assistants (Exhibit 5 at 26).

Although the EDO memorandum referenced a November 24, 1986, telephone call with the [redacted] stated that [redacted] did not recall having a conversation with NRC (Exhibit 25 at 31). [redacted] stated that [redacted] did not call [redacted] and presumed Region III made the call (Exhibit 24 at 8). [redacted] stated that the only conversation [redacted] had was with [redacted] concerning whether the patient was still alive (Exhibit 6 at 38).

[redacted] stated that [redacted] did not discuss when the medical decision was made with the staff. [redacted] assumed that the decision occurred after the wipe test. [redacted] stated that the EDO memorandum did not focus on this issue, nor did it specifically state when it occurred. [redacted] acknowledged that the briefing paper did state when the decision was made. However, [redacted] stated that the timing of the decision was immaterial to the staff's determination that the incident should have been a misadministration. According to [redacted] the staff's documentation of when the incident occurred did not make any difference because a misadministration was not "tied" to a medical decision. Further, [redacted] advised that the important issue was when the doctors had positive indication that the thyroid had been irradiated and therefore the hospital should have known that a misadministration had occurred (Exhibit 24 at 23, 37, 34, 20, 23, 24, 30, 37).

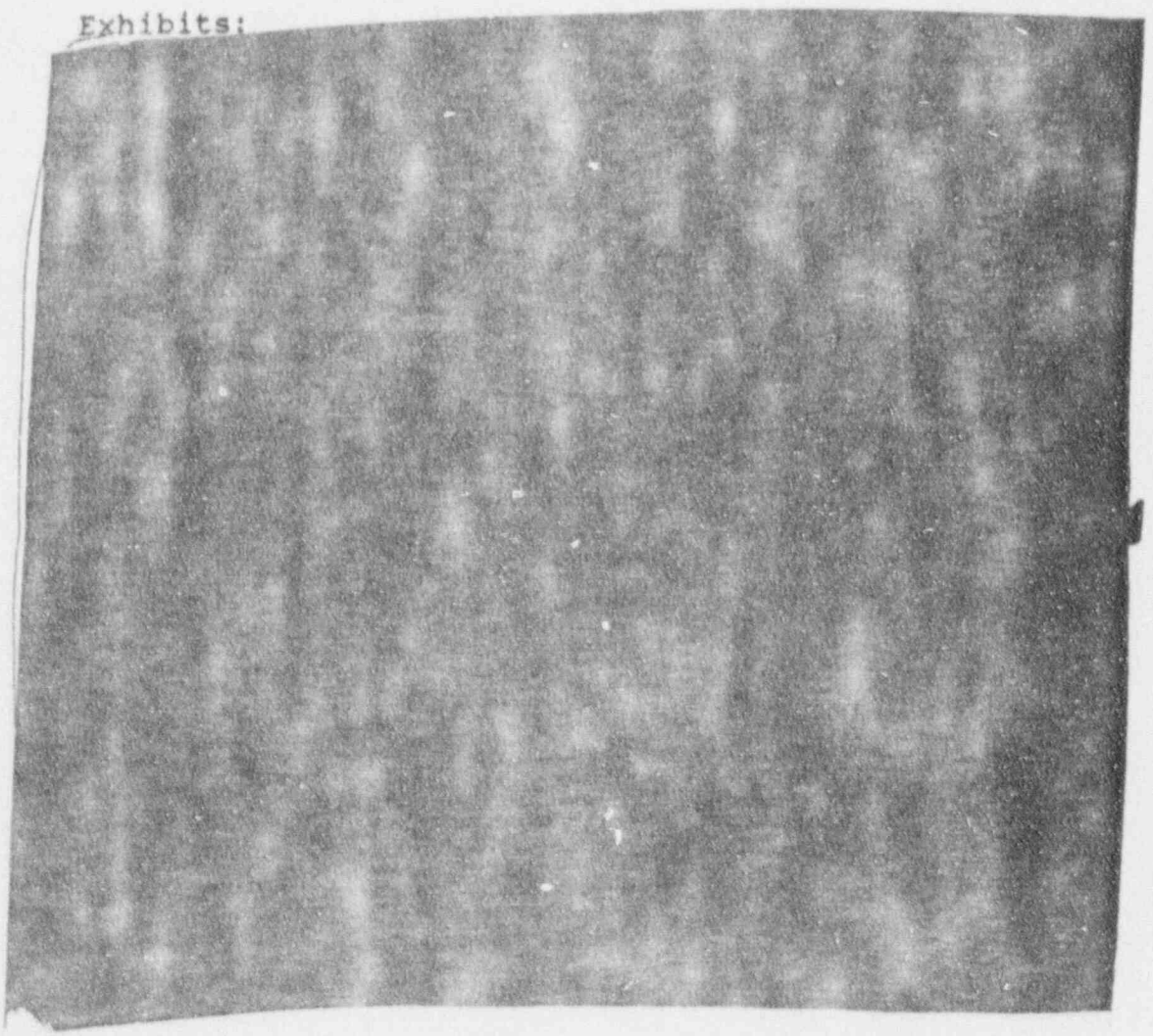
[redacted] advised that the staff tried to explain the circumstances surrounding the incident and reasoning behind their decisions. The staff relied on existing documentation and memory to prepare the information provided to the Commission. The staff did not contact the hospital because of the potential OI investigation. According to [redacted] the information concerning the timing of the medical decision was a result of the October 30, 1984, conference call with [redacted] or [redacted] subsequent discussion with [redacted] acknowledged however, that [redacted] may have combined [redacted] letter with the hospital chronology and assumed that the physicians' discussion and decision occurred on August 28th or 29th (Exhibit 6 at 40; 5 at 68, 72).

FINDING - ALLEGATION #3

The EDO memorandum and the briefing paper for the Commissioners' Assistants did not identify the correct date or circumstances surrounding the medical decision. However, the investigation

failed to substantiate that the staff knew the information was inaccurate. The staff never determined when the hospital initially suspected that the patient was the source of the contamination problem or the timing of the medical decision. Although the EDO memorandum implied that the staff verified the information during a telephone conversation with the hospital, the investigation did not determine who made the call and what was discussed. [redacted] stated that [redacted] definitely called [redacted] once, however, the investigation did not determine whether there were additional calls.

Exhibits:



Outside Loop
0/S