Title: EDWARD HINES, JR., VETERANS ADMINISTRATION MEDICAL CENTER

ALLEGED WILLFUL FAILURE TO REPORT DIAGNOSTIC MISADMINISTRATIONS AND ALLEGED WILLFUL MATERIAL FALSE STATEMENTS

Licensee:

Edward Hines, Jr. Veterans Administration Medical Center
Hines, IL 60141

Docket No. 030-01391

Reported by:

Mary Kay Fahey, Investigator
Office of Investigations
Field Office, Region III

Case Number: 3-87-003

Report Date: November 4, 1987

Control Office: OI:RIII

Status: CLOSED

Reviewed by:

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Field Office, Region III

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Harold G. Walker, OI:RIII
Gary L. Shear, Radiation Specialist, RIII

WARNING

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SYNOPSIS

On February 10, 1987, the Office of Investigation (OI) Field Office, Region III (RIII), received a Request for Investigation from the RIII Acting Administrator. The request evolved from anonymous allegations that three unreported misadministrations involving diagnostic radiopharmaceuticals occurred at Edward Hines, Jr., Veterans Administration Medical Center (HMC) during the [redacted]. An HMC Board of Investigation (BI) concluded that only one misadministration may have occurred and requested NRC assistance. Due to the conflicting statements received during the NRC:RIII inspection of this matter, the case was referred to OI.

The first alleged diagnostic misadministration involved the administration of Technetium-99m diethylenetriaminepentaacetic (Tc-99m DTPA), a brain scanning agent, rather than the one intended, Technetium-99m medronate diphosphonate (Tc-99m MDP), a bone scanning agent. Evidence revealed that the alleged misadministration was brought to the attention of the HMC Section Chief of Clinical Nuclear Medicine (SCCNM) (a physician Board-certified in nuclear medicine) by the Acting Chief Technologist (ACT). It was further revealed that after the SCCNM became aware of the alleged misadministration, the SCCNM claimed that he had changed the prescribed bone scan to a brain scan. The SCCNM then identified and represented the brain scan to the patient's referring physician as the originally prescribed bone scan, never indicating to the referring physician that the SCCNM had at any time changed the original order or that a misadministration had occurred.

The second alleged diagnostic misadministration involved the administration of a radiopharmaceutical, gallium-67 citrate, not regulated by the NRC, to the wrong patient. Again, the alleged misadministration was brought to the attention of the SCCNM by the ACT. After the SCCNM was notified of the alleged misadministration, the SCCNM obtained a Consult (an HMC physician's order form for a diagnostic study) from an HMC staff physician ordering a scan to validate the injection of the wrong patient. The staff physician had no knowledge that the patient had already been allegedly misadministered when he completed the requested Consult for the SCCNM.

The third alleged diagnostic misadministration involved the administration of a radiopharmaceutical (Tc-99m MDP) rather than the intended gallium-67 citrate. This alleged misadministration was also brought to the attention of the SCCNM by the ACT. Following the third alleged misadministration, the ACT also informed the HMC Chief of Nuclear Medicine (CNM) of the alleged misadministrations and advised the CNM that reports had not yet been initiated, although the ACT had previously reported the incidents to the SCCNM.

The SCCNM directed a technologist to support the SCCNM's explanation of the events regarding the alleged first misadministration when the technologist was questioned by the CNM. The technologist admitted that he had lied to the HMC:BI and to the RIII inspectors regarding the facts of the first alleged misadministration out of fear of contradicting the SCCNM. Further evidence revealed that the Chief Technologist observed the SCCNM remove and discard a key document relative to the alleged first misadministration from the patient's nuclear medicine file just prior to the RIII inspection.

During this investigation, evidence also revealed that several nuclear medicine staff members obstructed the HMC:BI. One former staff member refused to testify to the HMC:BI; another staff member admitted concealing pertinent information; and a third staff member admitted lying to the HMC:BI and to the RIII inspectors.

The OI investigation identified evidence which allowed the NRC to conclude that three patients received diagnostic misadministrations, two of which, though reportable, were not reported to the NRC. It was established that the misadministrations were brought to the timely attention of the SCCNM, who willfully failed to report the misadministrations as required by the NRC. It was also established that the SCCNM made material false statements by denying that the misadministrations occurred; destroyed evidence of one of the misadministrations by removing a key document from a nuclear medicine file prior to the RIII inspection; and impeded the NRC by directing a technologist to make false statements to the NRC. The SCCNM also attempted to influence the testimony of the ACT by suggesting that the ACT not recall pertinent facts when questioned by the HMC:BI or the NRC.

ACCOUNTABILITY

The following portions of this Report of Investigation (Case No. 3-87-003) will not be included in the material placed in the PDR. They consist of pages 3 through 36.

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APPLICABLE REGULATIONS

10 CFR 35.43, Reports of Diagnostic Misadministrations
Atomic Energy Act, Chapter 18, Section 223, Violation of Sections Generally

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LIST OF INTERVIEWEES

AGRAWAL, Shashi, M.D., [redacted] referring physician
ARGUIJO, Rachelle Turano, Acting Chief Technologist
BLEYBERG, Michael, M.D., [redacted] referring physician
BUSHNELL, David L., M.D., Section Chief of Training, Nuclear Medicine Service
CASE, Lawrence F., Jr., Radiation Safety Officer
CHINTAM, Rani S., M.D., [redacted] referring physician
EASTMAN, Gary R., Chief Technologist
FREEMAN, Maynard L., M.D., Section Chief of Clinical Nuclear Medicine and Assistant Chief, Nuclear Medicine Service
GRECO, Joseph, Administrator, Nuclear Medicine Service and Educational Coordinator, School of Nuclear Medicine
KAPLAN, Ervin, M.D., Chief, Nuclear Medicine Service
[redacted] 6, 7C
LaPORTE, Constance, R.N., Ward 2B
LEUNG, June, former technologist, Nuclear Medicine Service
MICHELS, Elizabeth, Secretary to Dr. KAPLAN
NIEMIRO, Mark, technologist, Nuclear Medicine Service
PANTALEON, Frank, M.D., staff physician
PHILLIPS, Arnold G., M.D., resident physician, Nuclear Medicine Service
PICACHE, Alicia M., M.D., [redacted] referring physician
ROMYN, Antonie M., M.D., resident physician, Nuclear Medicine Service
SHAUGHNESSY, Theodora E., R.N., Head Nurse, Ward 2D
SHIRAZI, Parvez, M.D., physician, Nuclear Medicine Service
THOMAS, Mitchell, student technologist, Nuclear Medicine Service
VARGAS, Ruben, Secretary, Ward 2B

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ORGANIZATIONAL CHART

NUCLEAR MEDICINE SERVICE - - - RADIATION SAFETY OFFICER

Lawrence F. CASE, Jr.

Chief

Ervin KAPLAN, M.D.

Assistant Chief/Section Chief, Clinical

Maynard L. FREEMAN, M.D.

Chief Technologist

Gary R. EASTMAN

Technologists

Rachelle Turano ARGUIJO
Mark NIEMIRO
June LEUNG

Student Technologist

Mitchell THOMAS

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DETAILS

Purpose of Investigation

This investigation was initiated to determine whether any member of the staff at Edward Hines, Jr., Veterans Administration Medical Center (HMC), Hines, Illinois, willfully failed to report to the NRC diagnostic misadministrations that allegedly occurred during [redacted] in violation of 10 CFR 35.43, the NRC regulation in effect at that time.

Background

On August 14, 1986, an anonymous alleger [redacted], notified NRC Region III (RIII) that allegedly three diagnostic misadministrations had occurred at HMC and had not been reported to the NRC as required. It was explained to [redacted] by RIII Enforcement Specialist B. W. STAPLETON that the quarterly reporting deadline would be September 30, 1986; therefore, no action could be taken to resolve the allegations until after that reporting deadline. Accordingly, at that time, this matter was assigned to the RIII Division of Radiation Safety and Safeguards. It was concluded on August 19, 1986, that an investigation by the Office of Investigations (OI) would not be undertaken until such time as it was established that a suspected willful violation of 10 CFR 35.43, Reports of Diagnostic Misadministrations, occurred.

On October 20, 1986, RIII received a call from the hospital Radiation Safety Officer (RSO), Lawrence F. CASE, Jr., stating that the HMC administration had just become aware of the allegations. CASE requested an extension of the misadministration reporting requirement if the misadministrations were proven to have occurred. On October 21, 1986, it was determined after a telephone discussion between W. L. AXELSON, RIII Chief of Nuclear Materials Safety and Safeguards Branch; E. T. Pawlik, Director, OI:RIII; and Philip B. DOBRIN, M.D., HMC Assistant Chief of Staff, that the HMC would convene an in-house investigation to determine if the allegations identified by [redacted] could be substantiated. The HMC Board of Investigation (BI) consisted of Ron FLINK, Chairman; Mark VAN DRUNEN, M.D., Diagnostic Radiology Service; and Nirmal BHOOMPALAM, M.D., Medical Service. CASE was not a member of the HMC:BI, but participated in the investigation as the hospital RSO.

The HMC:BI concluded its investigation on December 2, 1986, and forwarded their report to the NRC (Exhibit 1). The HMC:BI concluded that of the three alleged misadministrations, two were not misadministrations, and the third appeared to be a misadministration, but a definite conclusion could not be made due to their inability to interview June LEUNG, a former employee of the hospital. For this reason, HMC requested the assistance of the NRC:RIII staff.

A special inspection was initiated by RIII on December 16, 1986, to review the allegations. The announced, special inspection was conducted by Gary L. SHEAR, RIII Radiation Specialist, and David M. GALANTI, RIII Special Projects Inspector, from December 16, 1986, through January 22, 1987 (Exhibit 2).

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Due to conflicting statements received during the inspection, the allegations could not be substantiated and the case was referred to OI for further action. A Request for Investigation was made to the OI:RIII Field Office Director on February 10, 1987, from the RIII Acting Administrator.

The alleger identified three HMC patients who allegedly received what believed were diagnostic misadministrations for which NRC-required reports were never made. identified the following patients as having received injections of radiopharmaceuticals other than that prescribed by the patient's referring physician (Exhibits 3 and 4).

1. received an injection of Technetium-99m diethylenetriaminepentaacetic (Tc-99m DTPA), a brain scanning agent, instead of the ordered Technetium-99m medronate diphosphonate (Tc-99m MDP), a bone scanning agent.

2. received an injection of gallium-67 citrate intended for (This misadministration was not reportable under NRC regulations.)

3. received an injection of Tc-99m MDP when gallium-67 citrate was ordered to be injected.

Misadministration 1

The first alleged misadministration occurred on and involved patient The Nuclear Medicine Service had received a Consult (an HMC physician's order form for a diagnostic study) prepared by Dr. Michael BLEYBERG, referring physician, requesting a scan to rule out (Exhibit 1, Attachment DD, p. 1). The specific type of scan was left blank on the Consult, thereby leaving that determination to the Nuclear Medicine Service. The Nuclear Medicine Service made a determination that a bone scan was to be performed. Dr. Arnold G. PHILLIPS, a nuclear medicine resident physician, admitted completing the Consult with instructions for the technologist to perform a three-phase bone scan (Exhibit 5, p. 8). BLEYBERG stated that he was notified of the bone scan decision by the Nuclear Medicine Service (Exhibit 6, p. 5). Technologist Mark NIEMIRO stated that after had been injected, he realized he (NIEMIRO) had mistakenly requested a brain dose, Tc-99m DTPA, from Mitchell THOMAS, a nuclear medicine student technologist (Exhibit 7, pp. 5-8). NIEMIRO also stated that upon realizing his error, he injected on his own initiative with Tc-99m MDP, a bone dose. NIEMIRO further stated that he then informed Acting Chief Technologist (ACT) Rachelle Turano ARGUIJO that a misadministration had occurred and that had received two doses, Tc-99m DTPA and Tc-99m MDP (Exhibit 7, pp. 6-13).

The next day, ARGUIJO brought the misadministration to the attention of Dr. Maynard L. FREEMAN, Section Chief of Clinical Nuclear Medicine (SCCNM), who had been the attending Nuclear Medicine Service physician

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of the previous day. FREEMAN stated that ARGUIJO had notified him that she believed NIEMIRO had given [redacted] two doses (Exhibit 9, p 20).

ARGUIJO stated that later during the day of [redacted] a telephone call was received in the Nuclear Medicine Service from [redacted] referring physician (BLEYBERG) asking for the results of his patient's bone scan. ARGUIJO referred the call to FREEMAN, who spoke to the referring physician on the telephone (Exhibit 8, pp. 21-22). BLEYBERG stated that he spoke to both PHILLIPS and FREEMAN on the telephone to verify the preliminary findings of the [redacted] bone scan. BLEYBERG also stated that he was present when FREEMAN examined the films, and FREEMAN explained the scan and their findings as a bone scan. BLEYBERG stated, "Actually, it was a wet reading. The film was still coming out of the processor" (Exhibit 6, pp. 11-12 and 15-16).

ARGUIJO, when interviewed by OI, stated that s[redacted] had been the ACT during [redacted] (Exhibit 8, p. 6). She further stated that on [redacted] she took part in a conversation with FREEMAN and PHILLIPS in which they discussed the appropriateness of a bone scan for [redacted] (Exhibit 8, pp. 8-9). ARGUIJO also stated that the daily schedule shows that [redacted] had originally been scheduled for a gallium-67 citrate scan. The notation on the schedule indicates that the gallium-67 citrate injection, "GM-INJ," was crossed out and changed to "bon-fid," a three-phase bone scan. Further notation indicates that the referring physician was notified of the change at approximately 11:15 a.m. (Exhibit 1, Attachment DD, p. 2; Exhibit 8, pp. 22-23). During her April 28, 1987, interview, ARGUIJO stated that to her knowledge there had never been any discussion within the Nuclear Medicine Service of a brain scan as possibly being considered prior to the injection of [redacted] (Exhibit 8, p. 12). ARGUIJO further stated that FREEMAN gave her a verbal order, "...we're going to do a bone scan." She testified that she, in turn, then advised NIEMIRO of the bone scan decision (Exhibit 8, pp. 12-13).

In a signed statement to NRC:RIII inspectors dated January 8, 1987, ARGUIJO stated that she observed NIEMIRO inject [redacted] and that NIEMIRO then admitted to her that he had injected two doses (Exhibit 2, Attachment C). ARGUIJO reiterated this in her OI interview, stating that NIEMIRO admitted to her that he had injected [redacted] with Tc-99m MDP after the Tc-99m DTPA had already been injected and he had stated to ARGUIJO, "I gave the wrong stuff" (Exhibit 8, p. 14-16).

ARGUIJO further stated that before she left work on [redacted] she had told NIEMIRO to tell FREEMAN what had happened (Exhibit 8, p. 17). She stated that when she reached home, she called NIEMIRO and again told him to notify FREEMAN. She stated that even though NIEMIRO had told her that he had not yet brought the misadministration to anyone's attention, he would do so. ARGUIJO stated that later that evening she received a recorded telephone message from NIEMIRO that "...he had given the right stuff, and he'd see me tomorrow" (Exhibit 8, p. 20).

ARGUIJO stated that the next day [redacted] NIEMIRO explained to her that he had actually given two bone doses (Exhibit 8, p. 20). ARGUIJO told RIII Inspectors SHEAR and GALANTI that by this time she was positive a misadministration had occurred and that NIEMIRO had either given [redacted] a brain dose and a bone dose or two bone doses (Exhibit 2, Attachment C).

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ARGUIJO told OI that later during the day of [redacted] she spoke to FREEMAN about the [redacted] misadministration. She stated that she told FREEMAN that she felt NIEMIRO was lying, that she could not prove it, and that perhaps FREEMAN should look at the scan (Exhibit 8, p. 21).

ARGUIJO stated that after she had spoken to FREEMAN, a telephone call was received in the Nuclear Medicine Service from [redacted] referring physician asking for the results of his patient's bone scan. ARGUIJO referred the call to FREEMAN, who spoke to the referring physician on the telephone. ARGUIJO stated that she overheard FREEMAN clearly explain why he had decided to do a brain scan (Exhibit 8, pp. 21-22).

FREEMAN stated during his June 30, 1987, OI interview that he had decided that a brain scan would provide more specific information concerning the nature of [redacted] FREEMAN stated that he instructed NIEMIRO, "...if you haven't given the bone injection, make it a brain." FREEMAN testified that he then returned to his office (Exhibit 9, pp. 18-19).

FREEMAN stated that he did not discuss the decision to change [redacted] scan with BLEYBERG, the referring physician (Exhibit 9, pp. 28-29). FREEMAN stated that he did have a discussion with PHILLIPS concluding that a brain scan would be just as appropriate. "And I asked Arnie (PHILLIPS), I said what do you think of the chances of him getting a [redacted] And he says quite good. And I said don't you think the brain scan would be just as good, and he concurred" (Exhibit 9, p. 30). However, FREEMAN admitted that this discussion with PHILLIPS ensued after the injection had been given (Exhibit 9, pp. 30-32).

FREEMAN stated that he recalled ARGUIJO speaking to him about a problem. According to FREEMAN, ARGUIJO had asked him to speak to NIEMIRO, but she refused to provide any additional information. FREEMAN stated that when he questioned NIEMIRO, he admitted to FREEMAN that he had given a brain dose (Exhibit 9, p. 19-20). During his testimony, FREEMAN corroborated that ARGUIJO had in fact told him that she believed NIEMIRO had given two doses to [redacted] FREEMAN stated that he informed ARGUIJO that if she believed a misadministration had occurred, they should complete the appropriate forms and notify the RSO. FREEMAN stated that ARGUIJO was hesitant to do so because she had no proof. FREEMAN testified that he suggested to ARGUIJO that when the delayed films became available, and if they showed any bony activity, they would prepare the necessary paperwork involved in reporting a misadministration (Exhibit 9, pp. 20-21).

FREEMAN admitted that during the interpretation and dictation of the [redacted] scan he failed to mention to PHILLIPS that ARGUIJO had brought to FREEMAN's attention the possibility of two doses being administered (Exhibit 9, p. 36). After reviewing the films, FREEMAN testified that, "..it looked like a brain scan to me." FREEMAN did admit that the [redacted] film had been mislabeled as a bone study, and he had corrected that error by handwriting "DTPA BRAIN" on the film (Exhibit 1, Attachment DD, p. 6; Exhibit 9, pp. 21-22). FREEMAN stated that both he and PHILLIPS interpreted the [redacted] scan as a brain study and the report was dictated as such (Exhibit 1, Attachment D, p. 7).

When first questioned on October 20, 1986, by Dr. Ervin KAPLAN, Chief of Nuclear Medicine (CNM), regarding the [redacted] misadministration, NIEMIRO

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stated that he had injected [redacted] for a brain scan (Exhibit 1, Attachment W). Again in his statement to the HMC:BI on November 26, 1986, NIEMIRO reiterated that he had been verbally instructed by FREEMAN to perform a brain scan rather than a bone scan. He further stated that no misadministration had occurred as far as he knew (Exhibit 1, Attachment D-9). On January 6, 1987, when questioned by NRC:RIII inspectors, NIEMIRO again stated that he had been verbally instructed by FREEMAN to perform a brain scan rather than a bone scan. During that January 6, 1987, interview, NIEMIRO denied giving two injections to [redacted] (Exhibit 2, pp. 5-6).

During the OI interview with NIEMIRO, however, he admitted that he gave inaccurate testimony to KAPLAN on October 20, 1986 (Exhibit 10); he admitted that he gave inaccurate testimony to the HMC:BI on November 26, 1986 (Exhibit 1, Attachment D-9); and NIEMIRO also admitted that he gave inaccurate testimony to NRC:RIII Inspectors SHEAR and GALANTI on January 6, 1987 (Exhibit 2, pp. 5-6). In each previously documented interview, NIEMIRO corroborated that FREEMAN had requested a brain scan for [redacted] However, NIEMIRO admitted to the OI investigators that he had given inaccurate testimony because he had been afraid to admit that the error had occurred, that he had been afraid to contradict FREEMAN, and that he had been afraid of the NRC investigation (Exhibit 7, pp. 22). NIEMIRO stated that he followed the order indicated on the Consult, that being a bone scan, and he did not receive any verbal order from FREEMAN (Exhibit 7, pp. 4-5). He admitted that the reason [redacted] had received a brain dose was because he (NIEMIRO) had made a mistake when the dose was requested from THOMAS, a nuclear medicine student technologist (Exhibit 7, pp. 6-7).

NIEMIRO stated that he was having trouble injecting the patient and ARGUIJO actually injected [redacted] (Exhibit 7, p. 6). However, NIEMIRO admitted in his testimony that he then injected a bone dose in an attempt to cover up the error of the first misadministration (Exhibit 7, p. 7). ARGUIJO denied to OI that she had injected [redacted] (Exhibit 11).

SHEAR and GALANTI found no brain dose calibration ticket (a ticket used to record a measured dose of the prepared radiopharmaceutical) for [redacted] in the [redacted] nuclear medicine file during their December 16, 1986, inspection (Exhibit 2, pp. 10-11). When NIEMIRO was questioned regarding the whereabouts of the brain dose calibration ticket, NIEMIRO admitted that he honestly could not remember, but there was the possibility one had never been made or it may have been destroyed to cover up the error (Exhibit 7, p. 10-11).

INVESTIGATOR'S NOTE: The facts substantiate that regardless which technologist misadministered, ARGUIJO and NIEMIRO both stated unequivocally that they were not aware of FREEMAN changing the order to a brain scan. A brain dose was injected when both technologists had understood the order to be a bone scan, thereby being a misadministration in that the patient received a radiopharmaceutical other than the one intended. The admission of NIEMIRO in giving a second injection, a bone dose, also verifies the fact that NIEMIRO felt that an error had been made when the brain dose was injected.

NIEMIRO stated that after the [redacted] misadministration, he was under the impression that since ARGUIJO was [redacted] immediate supervisor that day, he felt that she would notify FREEMAN of the error (Exhibit 7, p. 13). NIEMIRO

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recalled having a conversation with FREEMAN regarding [redacted] NIEMIRO stated that FREEMAN never broached the subject of a bone dose being injected. NIEMIRO stated that throughout his conversation with FREEMAN, "...he kept stating that he can change a scan if he wants to and that he told me to inject the DTPA" (Exhibit 7, p. 18).

During his OI interview, NIEMIRO recalled and described his October 20, 1986, meeting with KAPLAN. He stated that he was present in KAPLAN's office along with several other HMC staff members. When questioned about the [redacted] case, NIEMIRO stated that, "...before I had a chance to answer the question, Dr. FREEMAN stepped in and said 'this is what happened.' At that point, I just froze with an open mouth and said 'yes, sure'" (Exhibit 7, p. 24).

ARGUIJO stated that in October 1986, soon after the Nuclear Medicine Service became aware of the allegations made to the NRC, FREEMAN had telephoned her at home several times one evening. She stated that she did not return his calls, and FREEMAN spoke to her the next day at work regarding [redacted] "He made statements to the effect that I would not have been aware that He had given Mark NIEMIRO orders to change it to a brain scan, and it's nobody's business to question a doctor's decision" (Exhibit 8, p. 50).

THOMAS, a nuclear medicine student technologist, stated in his OI interview that NIEMIRO had requested a brain dose and THOMAS had handed NIEMIRO both the brain dose and a brain dose calibration ticket, which shows the dosage of the prepared radiopharmaceutical (Exhibit 12, pp. 3-4 and 10). THOMAS further stated that he did not witness the injection of [redacted] but when he returned from lunch, NIEMIRO had told THOMAS that he (NIEMIRO) had requested the wrong dose (Exhibit 12, p. 4).

BLEYBERG, [redacted] referring physician, stated during his June 4, 1987, OI interview that after a consultation with the Department of Infectious Diseases (ID), ID concluded that a gallium-67 citrate scan would be most appropriate to determine the cause of [redacted] (Exhibit 6, p. 4). BLEYBERG stated that he disagreed, and after a discussion with the Nuclear Medicine Service, it was determined that a bone scan would be performed. "After the discussions with Nuclear Medicine, they felt that a bone scan would be best and that, if we wanted to do a gallium scan and then a bone scan, this would prolong patient stay and therefore, it would be better to do the bone scan prior to the gallium scan" (Exhibit 6, p. 5).

BLEYBERG contradicted FREEMAN's contention that he never spoke to BLEYBERG either before or after the scan. BLEYBERG stated that he spoke to both PHILLIPS and FREEMAN via telephone to verify the preliminary findings of the [redacted] bone scan. BLEYBERG also stated that he was present during the scan reading session when FREEMAN examined the "wet" scan film, explaining the scan and their findings to BLEYBERG as a bone scan. BLEYBERG stated that FREEMAN never represented the scan as that of a brain scan (Exhibit 6, pp. 11-12 and 15-16). Furthermore, BLEYBERG stated that he never saw the typed Consult of the interpretation of the [redacted] scan (which referred to a brain scan) since he had received the results of the scan verbally. The typed Consult was sent directly to the ward and placed in the patient's chart. [redacted] (Exhibit 6, pp. 9-10).

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During his June 30, 1987, interview, PHILLIPS confirmed that it was his notation on the left side of the Consult requesting a three phase bone scan of the skull for [redacted] (Exhibit 1, Attachment DD, p. 1; Exhibit 5, p. 7). Initially during the interview, PHILLIPS recalled having a discussion with BLEYBERG that a brain scan would be more appropriate for [redacted] However, PHILLIPS later admitted in the same interview that he could not recall if he or FREEMAN spoke with BLEYBERG regarding the change in order to a brain scan (Exhibit 5, pp. 16-17).

PHILLIPS contradicted ARGUIJO's testimony that she had received an order from FREEMAN to perform a bone scan. PHILLIPS stated that he was present and heard FREEMAN tell ARGUIJO to perform a brain scan (Exhibit 5, p. 19). However, later during the same interview, PHILLIPS recalled that ARGUIJO may have told FREEMAN that the bone scan had already been performed (Exhibit 5, p. 24).

PHILLIPS stated that he did not believe that BLEYBERG was present during the scan reading session in which PHILLIPS and FREEMAN interpreted [redacted] scan. PHILLIPS stated that he interpreted the films [redacted] as that of a brain study, thereby concurring with FREEMAN (Exhibit 5, pp. 17-18). PHILLIPS did admit to OI that there was a possibility of two radiopharmaceuticals being administered based on his review of the [redacted] brain study. However, he also stated that it would require somebody with more experience than he had to make a positive determination (Exhibit 5, pp. 25-26).

INVESTIGATOR'S NOTE: The following opinions were obtained concerning a review of the [redacted] scan and the possibility of two radiopharmaceuticals being administered:

> HMC:BI had W. Earl BARNES, Physicist, HMC Nuclear Medicine Service, review the [redacted] brain study. In BARNES' conclusion dated November 18, 1986, he stated that he was unable to draw any conclusion concerning the nature of the radiopharmaceuticals being administered (Exhibit 1, Attachment HH).
>
> RIII Inspector SHEAR submitted copies of the [redacted] brain study to Dr. Steven PINSKY, Director of the Division of Nuclear Medicine, Michael Reese Medical Center, a renowned expert in the nuclear medicine field. On January 22, 1987, PINSKY stated that while no definite conclusion could be reached, "the possibility of a second injection with a different isotope cannot entirely be ruled out" (Exhibit 2, Attachment G).
>
> During the interview with KAPLAN, HMC CNM, KAPLAN stated that he doubted there is an expert in the world who could conclude that both a brain and bone scanning agent had been given, without a great deal of specialized information. KAPLAN stated that it would be exceedingly difficult or impossible to determine, since "one covers up the other" (Exhibit 13, p. 20).

Misadministration 2

INVESTIGATOR'S NOTE: The alleged [redacted] misadministration involved the radiopharmaceutical gallium-67 citrate, which is not required to be reported

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to the NRC. However, the facts surrounding the alleged misadministration are included in this Report of Investigation since there is a similar fact pattern involved in FREEMAN's failure to report this second incident. None of the witnesses interviewed have ever indicated to the NRC that they had any knowledge that gallium-67 citrate was a radiopharmaceutical not required to be reported to the NRC.

The second alleged misadministration also occurred on involving patients and . Based on a Consult dated July 29, 1986, a gallium-67 citrate scan was requested for (Exhibit 1, Attachment CC, p. 1). was scheduled for a gallium-67 citrate injection on and based upon the Nuclear Medicine Service schedule, telephoned Ward 2B and requested be sent down for the scheduled gallium-67 citrate injection (Exhibit 1, Attachment CC, p. 2). stated that did not recall specifying the patient by his first name (Exhibit 14, p. 20). Progress notes made by a nurse on Ward 2B indicate that on was sent to the Nuclear Medicine Service at 10:00 a.m. for a gallium-67 citrate injection (Exhibit 15).

ARGUIJO stated that on LEUNG brought to ARGUIJO's attention the fact that had been injected on in error. ARGUIJO stated that the misadministration was discovered when LEUNG had called the ward to have return to nuclear medicine for the first set of gallium-67 citrate pictures--a day's delay from the injection. The ward personnel indicated that had never received a gallium-67 citrate injection. ARGUIJO further stated that after reviewing both charts, she confirmed that had received the gallium-67 citrate injection intended for (Exhibit 8, p. 30).

ARGUIJO stated that she adjusted the nuclear medicine Consults and dose calibration ticket to reflect the correct sequence of events for and (Exhibit 8, p. 32). ARGUIJO stated that she reported the misadministration to FREEMAN on (Exhibit 8, p. 30). FREEMAN then obtained a Consult from a staff physician requesting a gallium-67 citrate scan for (Exhibit 1, Attachment BB, p. 3; Exhibit 9, pp. 42-43).

During her OI interview, ARGUIJO stated that she informed FREEMAN of the misadministration at the same time that she brought the misadministration to his attention (Exhibit 8, p. 30). ARGUIJO further stated that at the time received the gallium-67 citrate injection, there was no Consult in the Nuclear Medicine Service, nor was there an order in chart from the referring physician ordering a gallium-67 citrate scan (Exhibit 8, pp. 34-35).

ARGUIJO stated that after she informed FREEMAN, he stated that he had spoken with the patient's physician concerning the matter and FREEMAN returned with a Consult ordering a gallium-67 citrate scan for ARGUIJO stated that she dated and initialed the right side of the Consult to indicate the date she received it from FREEMAN (Exhibit 8, p. 33).

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FREEMAN admitted that ARGUIJO spoke to him regarding the [redacted] incident. He stated that he then questioned technologists LEUNG and NIEMIRO about the incident. FREEMAN admitted that after questioning them, he examined both [redacted] patient charts and verified that there was no consult for [redacted] FREEMAN indicated that he discussed the incident with ARGUIJO, LEUNG, and NIEMIRO, telling them that they were all responsible for the mistake (Exhibit 9, pp. 40-48). In his HMC:BI testimony, FREEMAN stated he believed he "...took all the right steps including notifying the ward and verbally reprimanding all three technologists involved" (Exhibit 1, Attachment D-1). After a review of the [redacted] patient charts on May 5, 1987, and a review of the Ward (2B and 2D) appointment/log books on May 15, 1987, no record or notation could be found of any notification by FREEMAN of the patient "mix-up" (Exhibits 16 and 17).

FREEMAN stated that LEUNG and NIEMIRO had shown FREEMAN on [redacted] the daily schedule where both [redacted] were scheduled. FREEMAN stated that [redacted] was scheduled for a gallium-67 citrate scan on [redacted] and [redacted] was scheduled for a gallium-67 citrate scan on [redacted] (Exhibit 9, pp. 41-51). FREEMAN stated that as far as he was concerned, it was not a misadministration because it was the right patient, right pharmaceutical, and right dose. "It was just a wrong time, and that's how I interpreted the rule" (Exhibit 9, p. 44).

ARGUIJO explained the daily schedules during her second OI interview on July 8, 1987. The original computer-generated schedule, or "tech" copy, is used by the technologists to make notations and indicate which patients have been administered. This "tech" copy from [redacted] showed that [redacted] was not listed on the schedule. [redacted] was checked off as being present for his gallium-67 citrate injection ("GAL-INJ") at 9:30 a.m. [redacted] when actually, [redacted] had been injected. The final schedule entered into the data base for [redacted] was corrected to reflect that [redacted] was injected and [redacted] was not present on [redacted] (Exhibit 1, Attachment BB, p. 6).

The "tech" copy for [redacted] shows [redacted] scheduled and checked off as having gallium-67 citrate delay films. [redacted] name does not appear (Exhibit 11). The final schedule entered into the data base for [redacted] was corrected to reflect that [redacted] had gallium-67 citrate delay films ("GAL-DLY"), and [redacted] was not present on that day (Exhibit 1, Attachment BB, p. 8). The "tech" copy of [redacted] shows [redacted] handwritten onto the schedule as receiving gallium-67 citrate delay films ("GAL-DLY"). [redacted] is shown scheduled for and received a gallium-67 citrate injection ("GAL-INJ") on [redacted] (Exhibit 11). The final schedule entered into the data base reflects the same (Exhibit 1, Attachment BB, p. 11). The "tech" copy for [redacted] reflects [redacted] also scheduled for gallium-67 citrate delay films ("GAL-INJ"). The final schedule entered into the data base reflects the same (Exhibit 1, Attachment BB, p. 13-14).

FREEMAN also stated that he telephoned the staff physician, whose name he did not know, and explained the "mix-up" between [redacted] FREEMAN stated that the physician specifically told FREEMAN that a gallium-67 citrate scan

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was ordered for [redacted] there should have been a Consult requesting the scan, but he did not have a problem with completing another (Exhibit 9, pp. 41-51). FREEMAN stated that after lunch on [redacted] he returned to the Nuclear Medicine Service with a Consult for [redacted] dated [redacted] signed by the staff physician (Exhibit 1, Attachment BB, p. 3).

This handwritten Consult that was obtained by FREEMAN was prepared by Dr. Frank PANTALEON on [redacted] ordering a gallium-67 citrate scan for [redacted] PANTALEON's only explanation during his OI interview was that he possibly may have been approached by a nuclear medicine physician when it was discovered that a gallium-67 citrate scan Consult was missing on the patient. Possibly, in Dr. Rani S. CHINTAM's [redacted] referring physician) absence, PANTALEON, as staff physician, had completed the requested Consult. PANTALEON contradicted FREEMAN's testimony and stated that he had no knowledge of whether CHINTAM had ordered a gallium-67 citrate scan, nor did he have knowledge that the patient had already been injected on [redacted] with gallium-67 citrate when the request had been made (Exhibit 18, pp. 8-13).

[redacted] CHINTAM, referring physician for [redacted] made a notation in the patient's chart ordering a gallium-67 citrate scan. (Exhibit 1, Attachment BB, p. 1). In her OI interview, CHINTAM stated that she then changed her mind and she prepared a handwritten Consult ordering a bone scan, which was performed on [redacted] "I was requesting on [redacted] on my order sheet a gallium scan, but in my Consult sheet I am taking a bone scan, because a bone scan is the first step to do [redacted] infection of the bone" (Exhibit 19, p. 3). After a review of [redacted] patient chart and nuclear medicine file, CHINTAM stated that to the best of her recollection, she did not complete a Consult ordering a gallium-67 citrate scan for her patient on [redacted] (Exhibit 19, pp. 6-7). CHINTAM stated that she was not notified by any nuclear medicine physician that an unordered gallium-67 citrate scan was performed on her patient in [redacted] (Exhibit 19, p. 11-12).

RIII Inspectors SHEAR and GALANTI were told by NIEMIRO that he drew up a gallium-67 citrate dose based upon a dose calibration ticket showing [redacted] name. NIEMIRO stated that LEUNG actually injected [redacted] with gallium-67 citrate on [redacted] even though NIEMIRO had initialed the dose calibration ticket (Exhibit 2, p. 5).

NIEMIRO admitted during his OI interview that he drew up the gallium-67 citrate dose, but was called away for some reason prior to injecting the patient. NIEMIRO stated that LEUNG was standing nearby and she told NIEMIRO that she would inject the patient for him. He further stated that he had not yet verified the identity of the patient, but LEUNG must have assumed that he had. NIEMIRO stated, "At that point, I had not checked his arm band yet. Maybe she assumed I did and she didn't also and went ahead and injected" (Exhibit 7, p. 31).

When NIEMIRO and LEUNG realized the error the next day, NIEMIRO stated they informed ARGUIJO, who in turn notified FREEMAN of the misadministration. NIEMIRO stated that it was his understanding that [redacted] also needed a gallium-67 citrate scan, so "...we lucked out" (Exhibit 7, p. 32). NIEMIRO

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stated that he had no knowledge of how the Consult for [redacted] was obtained (Exhibit 7, p. 36). NIEMIRO told NRC:RIII inspectors that FREEMAN verbally counseled him about the mistake following the incident (Exhibit 2, p. 5).

LEUNG stated during her June 27, 1987, interview that she did not recall misadministering [redacted] nor did she recall any of the events following the [redacted] misadministration (Exhibit 20, pp. 8-10).

INVESTIGATOR'S NOTE: Both the HMC:BI and the RIII inspection team determined that LEUNG would be a primary witness, and after LEUNG rebuffed their attempts to interview her, it was agreed HMC would obtain a Veterans Administration administrative subpoena. LEUNG failed to acknowledge receipt of the subpoena, which had been sent to her by certified mail, and failed to appear at the scheduled date and time. Upon commencing the OI investigation, an NRC administrative subpoena was obtained (Exhibit 21). LEUNG was served in person on June 22, 1987 [redacted] At the interview with LEUNG on June 26, 1987, she provided an unsworn statement. LEUNG was uncooperative and stated that she was unable to recall most of the circumstances surrounding the events during [redacted] (Exhibit 20).

Misadministration 3

The third alleged misadministration occurred on [redacted] involving patient [redacted] ARGUIJO stated that she became aware of the misadministration when LEUNG advised ARGUIJO that she had just injected patient [redacted] with a bone scanning agent, when [redacted] had been scheduled for a gallium-67 citrate scan (Exhibit 8, p. 38). A Consult dated [redacted] had been prepared by Dr. Shashi AGRAWAL, [redacted] referring physician, requesting a gallium-67 citrate scan for [redacted] (Exhibit 1, Attachment FF, p. 1). ARGUIJO stated that LEUNG told her that the patient chart on [redacted] bed had the name [redacted] on it, and LEUNG had injected [redacted] with the bone scanning agent intended for patient [redacted] Furthermore, ARGUIJO stated that LEUNG asked her to inform FREEMAN. ARGUIJO stated that after she told FREEMAN, he made a comment to the effect that, "I'll have to report this one." ARGUIJO stated during her OI interview that FREEMAN told her that he would speak to LEUNG (Exhibit 8, pp. 38-41).

RIII inspectors reviewed the [redacted] nuclear medicine file during their inspection. One bone flow film dated [redacted] was found along with gallium-67 citrate films. No bone dose calibration ticket was found (Exhibit 2, p. 12). The "tech" copy of the patient schedule shows that gallium-67 citrate injection ("GAL-INJ") was crossed out and "bon-fid" was written in on the schedule, indicating that [redacted] had actually received an injection of a bone scanning agent rather than a gallium-67 citrate injection (Exhibit 1, Attachment FF, pp. 2 and 5).

In her OI interview, ARGUIJO stated that on [redacted] LEUNG brought it to her attention that she (LEUNG) had injected [redacted] for a bone scan that was intended for [redacted] LEUNG had told ARGUIJO that the patient chart on [redacted] bed had the name [redacted] on it, and LEUNG had injected [redacted] with Tc-99m MDP, a bone scanning agent, assuming him to be [redacted] (Exhibit 8, p. 40). ARGUIJO

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stated that there was no Consult ordering a bone scan for [redacted] but there was a Consult ordering a gallium-67 citrate scan (Exhibit 8, p. 39).

ARGUIJO stated that LEUNG asked her to speak to FREEMAN. ARGUIJO personally advised FREEMAN of the misadministration approximately one half to one hour after the incident (Exhibit 2, Attachment C). ARGUIJO testified that FREEMAN was upset when advised of the error. "He said something to the effect that, 'I'll have to report this one.' I questioned him about the other two previous misadministrations. He said, 'Okay.'" ARGUIJO further stated that FREEMAN did not indicate that he would report any of the three misadministrations that had occurred (Exhibit 8, pp. 40-41). ARGUIJO stated that she had previously prepared forms necessary for reporting misadministrations and that she should have been involved in the paperwork if the misadministrations were to be reported. To her knowledge, no paperwork had been discussed or initiated, and no forms had been completed (Exhibit 8, pp. 41-42).

ARGUIJO stated that FREEMAN told her he would speak to LEUNG. She further stated that LEUNG had told her (ARGUIJO) that FREEMAN had spoken to her (LEUNG). LEUNG asked ARGUIJO what she should do with the patient. ARGUIJO told LEUNG to go ahead and take pictures and put them in the patient's file as long as he was there and he had been given the dose already (Exhibit 8, p. 41).

ARGUIJO stated that FREEMAN then told both LEUNG and ARGUIJO to give [redacted] the prescribed gallium-67 citrate injection anyway, but to wait forty eight hours for the delay films instead of the usual twenty-four hours in order to let the bone dose dissipate (Exhibit 11). The films corroborate ARGUIJO's statement that she directed LEUNG to complete the bone scan. The only gallium-67 citrate films found in [redacted] nuclear medicine file were dated [redacted] forty eight hours after the gallium-67 citrate was injected (Exhibit 1, Attachment FF, p. 9). The "tech" copy of the schedule shows "bon-fid" crossed out and gallium-67 citrate injection ("GAL-INJ") inserted. ARGUIJO admitted that she had made the second correction on the "tech" copy (Exhibit 11). ARGUIJO also stated that LEUNG had told her on [redacted] that LEUNG had spoken to CASE (HMC RSO), but did not tell him about the misadministrations because she did not want to incriminate any of the other technologists (Exhibit 8, p. 42).

FREEMAN stated during his OI interview that, "the first time I heard of [redacted] and [redacted] was when Mr. FLINK informed me that [redacted] and [redacted] had 'a misadministration.' And that was sometime in [redacted] I was never informed, to my knowledge, of those two patients before that" (Exhibit 9, p. 51).

During a telephone conversation on November 10, 1986, FREEMAN told ARGUIJO that regarding the third misadministration, a bone scan film was found in one of the patients' charts. FREEMAN stated, "...I have no idea where this occurred and that's the only thing, without that one piece of film, then the whole damn thing, that whole damn thing would fall apart, too" (Exhibit 22, pp. 17-18). FREEMAN also stated that, "okay, they've got the film with bone and if it's a bone and it turns out to be a misadministration the worst that will happen is that nothing will happen. Okay, the worst that will happen is that the department may get a citation. Okay, but that's all that's going to happen. But I think what probably happened was during that one lousy week, a

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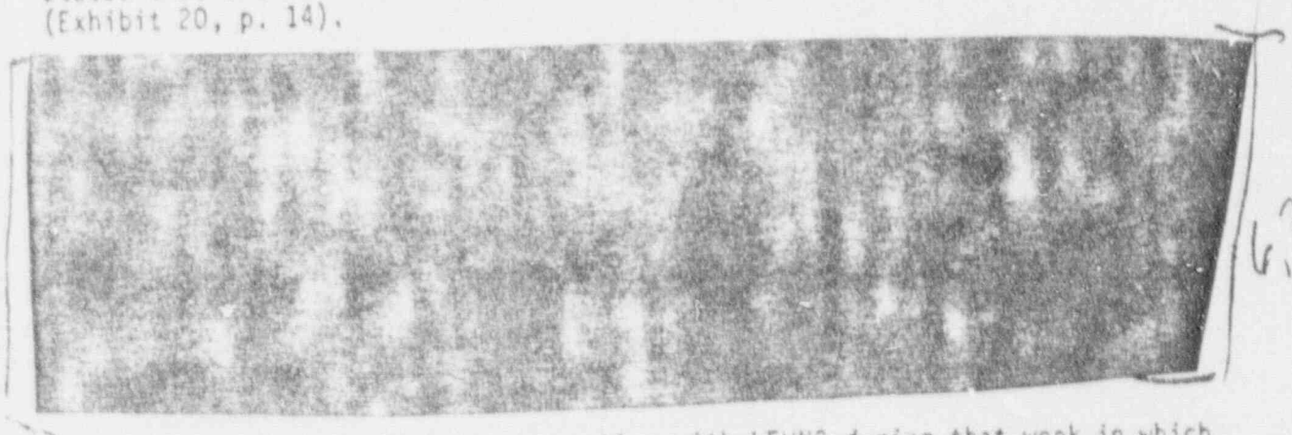
lot of communication was given back between, back and forth between everybody and maybe there was miscommunication" (Exhibit 22, p. 13). The next day, November 11, 1986, during another telephone conversation between FREEMAN and ARGUIJO, FREEMAN implied that LEUNG had altered films and doctored the [redacted] film for [redacted] to make it appear to be a bone flow study. FREEMAN told her that, "...I'm thinking about it now and I think what June did was she altered the studies to make it look like something happened that didn't happen" (Exhibit 22, pp. 25-26). Yet, during his OI interview, when questioned about this assertion, FREEMAN stated only that there had been some "locker room talk" that LEUNG had altered the [redacted] films (Exhibit 9, p. 64).

LEUNG stated that she did not recall a misadministration to [redacted] nor did she recall bringing the misadministration to ARGUIJO's attention (Exhibit 20, p. 26). She did admit that she injected [redacted] with gallium-67 citrate on [redacted] as the dose calibration ticket indicates (Exhibit 20, p. 26). LEUNG denied being responsible for altering any scan films, nor was she aware of anyone else altering any scan films (Exhibit 20, pp. 13 and 24). LEUNG stated that she made no attempt to notify CASE regarding any misadministrations (Exhibit 20, p. 14).



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CASE verified that he had a conversation with LEUNG during that week in which she had asked for amnesty or anonymity if she divulged information to CASE. However, CASE stated that LEUNG never told him what was on her mind. He stated that he did not force the issue with LEUNG, because she refused to give him any specific information (Exhibit 23, pp. 43-45).

CASE stated that he first became aware of the allegations when Joseph GRECO, HMC Education and Administrative Coordinator, advised CASE on [redacted] that [redacted] had revealed to GRECO that [redacted] had notified the NRC of unreported misadministrations. CASE notified the HMC administration and RIII on October 20, 1986 (Exhibit 23, pp. 10 and 28).

Chronology

ARGUIJO stated that the same day, [redacted] she spoke separately to Dr. Antonie ROMYN, Nuclear Medicine Service resident physician, and Dr. Parvez SHIRAZI, Nuclear Medicine Service physician, asking each doctor what she should do about the misadministrations. She stated that both advised her to speak to KAPLAN, CNM (Exhibit 8, p. 47).

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SHIRAZI confirmed that ARGUIJO had advised him on [redacted] He stated that ARGUIJO had told him that there had been a misadministration two days prior and that FREEMAN had been the attending physician in the Nuclear Medicine Service that day (Exhibit 24, p. 4). SHIRAZI stated that on [redacted] he later confronted FREEMAN saying, "I hear there was a misadministration." SHIRAZI stated that FREEMAN responded that he had taken care of it. SHIRAZI testified that he assumed FREEMAN meant that he had reported the incident (Exhibit 24, pp. 4-5).

ROMYN also confirmed ARGUIJO's statements. He stated that he recalled overhearing the technologists talking in the break room about misadministrations. ROMYN could not recall the date of the conversation, but ARGUIJO had asked him what should be done. ROMYN advised ARGUIJO to notify the proper authorities and report it. He also recalled advising ARGUIJO that she had better get to the "bottom of it" (Exhibit 25).

Elizabeth MICHELS, KAPLAN's secretary, stated that she recalled that sometime during the [redacted] ARGUIJO had asked her what she should do about the misadministrations. MICHELS stated that she told ARGUIJO that if she was worried, she should speak to KAPLAN. MICHELS confirmed that ARGUIJO had a conversation with KAPLAN in his office (Exhibit 26, p. 3-4).

ARGUIJO stated that she spoke to KAPLAN on [redacted] and told him specifically that there had been three misadministrations in the last few days, that she had told FREEMAN, and FREEMAN did not appear to be doing anything about them.

She further stated that she told KAPLAN that she was afraid CASE (HMC RSO) would find out about the misadministrations and she did not want to go over FREEMAN's head by going to CASE. ARGUIJO stated she asked KAPLAN how he wanted her to handle the situation. Furthermore, ARGUIJO stated that she specifically identified the technologists involved in the misadministrations to KAPLAN; however, she did not recall identifying any of the patients by name to KAPLAN at that time. ARGUIJO stated that KAPLAN assured her that he would look into the matter and he would discuss it with FREEMAN (Exhibit 8, p. 44; Exhibit 11).

ARGUIJO stated that KAPLAN later told her that he had spoken to FREEMAN, "...and from now on things would be reported and that everything was okay." ARGUIJO stated that after the short conversation with KAPLAN, she felt that things were going to be left as they were, even though she felt KAPLAN had acknowledged that the misadministrations had occurred (Exhibit 8, p. 45).

KAPLAN stated that ARGUIJO came to see him in [redacted] indicating that she thought there had been some mistake with isotopes, but nothing more specific. However, KAPLAN testified that ARGUIJO did state to him that she had spoken to FREEMAN several days prior regarding the matter (Exhibit 13, p. 5-9). KAPLAN stated in his Voluntary Witness statement to the HMC:BI that ARGUIJO indicated three episodes but gave no names, dates, or details. KAPLAN also told the HMC:BI that he personally did not examine any of the nuclear medicine files at that time nor did he further discuss the issue with ARGUIJO following her initial disclosure to him (Exhibit 1, Attachment D-6).

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KAPLAN further stated to the HMC:BI that he felt ARGUIJO was a very reliable technician who was not prone to making unwarranted reports to the Chief of Service (Exhibit 1, Attachment D-6). Yet, KAPLAN later stated in his OI interview that ARGUIJO wa[redacted] (Exhibit 13, pp. 44-46).

KAPLAN stated during his OI interview that after ARGUIJO spoke to him, he had FREEMAN followup and investigate the allegations. KAPLAN stated that he did not know the extent to which FREEMAN may have investigated the allegations, but he stated that he believed that FREEMAN may have looked over some records, and was unable to find anything wrong (Exhibit 13, pp. 9-11).

KAPLAN stated in his testimony to the HMC:BI that FREEMAN told him there had been no recent misadministrations. KAPLAN stated that FREEMAN later reaffirmed that there were no misadministrations. KAPLAN was told by FREEMAN that in the case of [redacted] FREEMAN had verbally changed the order from a bone scan to a brain scan, and the incident involving the [redacted] was a "clerical error" (Exhibit 1, Attachment D-6).

KAPLAN stated that he was not aware of any of the nuclear medicine physicians having knowledge of any of the specific events of the three misadministrations prior to [redacted] yet OI received testimony from FREEMAN, SHIRAZI, and ROMYN that they were all aware of the alleged misadministrations having occurred during the [redacted] (Exhibit 13, pp. 26-27).

FREEMAN verified that KAPLAN informed him of the discussion with ARGUIJO. FREEMAN stated that he reviewed the facts with KAPLAN based on his own (FREEMAN's) recall of the events on [redacted] FREEMAN admitted that he did not review the nuclear medicine files prior to speaking to KAPLAN (Exhibit 9, pp. 38-39).

Gary R. EASTMAN, Chief Technologist who had been on vacation [redacted] stated to OI that upon his return, ARGUIJO had told him to speak to FREEMAN about some problems they had had (Exhibit 27, pp. 3-4). EASTMAN stated in both his HMC:BI Voluntary Witness statement dated November 25, 1986, and to OI that he indicated in strong terms to FREEMAN that if there were any misadministrations, they must be investigated and properly reported. FREEMAN told EASTMAN that it was "no big deal" and "no problem." EASTMAN stated that KAPLAN subsequently advised EASTMAN that he had assigned FREEMAN to investigate the allegations (Exhibit 1, Attachment D-3; Exhibit 27, pp. 3-4).

In an HMC "Report of Contact" dated November 10, 1986, GRECO documented a conversation he had with FREEMAN (Exhibit 28). GRECO stated that FREEMAN told him that FLINK (HMC:BI Chairman) had stated to FREEMAN that the testimony by ARGUIJO to the HMC:BI allegedly placed responsibility on FREEMAN for not taking action with reference to information given to FREEMAN by ARGUIJO. FREEMAN told GRECO that he would deny such an allegation made by ARGUIJO and it would result in FREEMAN's word against ARGUIJO's. FREEMAN suggested that GRECO contact ARGUIJO and suggest to her that she revise the statements she initially made to the HMC:BI specifically with regards to patients [redacted] GRECO further stated in his OI interview of May 13, 1987, that FREEMAN told GRECO during the same conversation that "if he (FREEMAN) goes down, she (ARGUIJO)

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is going down with him." GRECO stated he told FREEMAN that if he (FREEMAN) wanted to discuss anything with ARGUIJO, he should telephone her himself. GRECO stated that he informed KAPLAN of the conversation with FREEMAN that evening (Exhibit 29, pp. 17-20).

FREEMAN denied ever making such a statement, but admitted that he had telephoned ARGUIJO at home after GRECO had asked him to telephone her, as a favor to GRECO (Exhibit 9, p. 60). KAPLAN stated that he did not recall GRECO's telephone call to him that evening (Exhibit 13, pp. 49-50).

ARGUIJO stated that when she arrived home the evening of November 10, 1986, she discovered that FREEMAN had telephoned her several times and left several messages for her to return his calls. ARGUIJO stated that she had a telephone conversation with FREEMAN at approximately 8:00 p.m. that evening. ARGUIJO stated that she recorded this conversation and a second conversation on November 11, 1986, in order to protect herself. She stated that she felt FREEMAN was suggesting that she not recall the circumstances of the misadministrations (Exhibit 8, pp. 53-55). She stated that her decision to record the telephone conversations was based on the fact that she had been receiving pressure from FREEMAN regarding her testimony to the NMC:BI on November 7, 1986 (Exhibit 30).

ARGUIJO stated that during the telephone conversations FREEMAN told her to tell the truth, but he also told her nobody could do anything if she claimed that she did not remember all the details, and that there would be no harm in her saying that she really did not remember exactly what had occurred. ARGUIJO also stated that FREEMAN told her that if he were found to be in error that she would also be responsible (Exhibit 8, pp. 53-58). FREEMAN also stated, "if you say I don't remember and that's it, it's worked in the past...it could work in the future..." (Exhibit 22, p. 17).

INVESTIGATOR'S NOTE: It was at the conclusion of ARGUIJO's OI interview that she advised, off the record, that she had taped the two telephone conversations with FREEMAN at her home and she would be willing to turn the tape over to OI as evidence. After discussions between OI and the NRC Office of General Counsel Attorney Sebastian C. ALOOT; and OI and Assistant U.S. Attorney Pat DEADY, the tape was obtained, inventoried as evidence, and introduced as Exhibit 22 in the OI investigation.

During his OI interview, FREEMAN was questioned about his telephone conversations with ARGUIJO. FREEMAN stated that during his telephone conversation with ARGUIJO, he gave her three instructions. "First, I told her that Mr. GRECO instructed me to talk to her; second of all, I told her to tell the truth; and the third thing I told her is do not make up any stories" (Exhibit 9, p. 60). FREEMAN stated that he had told all the technologists that nobody could fault them for not remembering (Exhibit 9, p. 61).

The OI investigator specifically asked FREEMAN the following questions, which were based upon FREEMAN's statements during the telephone conversations: (1) "Did you tell anybody, hypothetically speaking, that if you had given them orders to cover up a misadministration, that they are required anyway to complete the forms? If they didn't they would be just as guilty as you?" (Exhibit 9, p. 62; Exhibit 22, pp. 7-8); (2) "Do you recall advising anyone

to say that they didn't remember and that this has worked in the past?" (Exhibit 9, p. 62; Exhibit 22, p. 17); and (3) "Did you ever tell any of the technologists to just play ignorant and say it was three months ago?" (Exhibit 9, p. 67; Exhibit 22, p. 5). FREEMAN denied making any of the statements (Exhibit 9, pp. 61-67).

INVESTIGATOR'S NOTE: During his OI interview, FREEMAN did not indicate that he was aware that OI had in their possession a tape recording of the referenced conversations with ARGUIJO.

NIEMIRO also stated that FREEMAN had telephoned him at home prior to the RIII inspection (Exhibit 7, pp. 28-29), yet FREEMAN stated that NIEMIRO had telephoned FREEMAN to discuss the upcoming investigation because NIEMIRO was nervous (Exhibit 9, p. 74).

EASTMAN related that he had had a discussion with FREEMAN just prior to the RIII inspection. EASTMAN stated that FREEMAN had retrieved the nuclear medicine files of three of the patients and was on his way to a meeting with KAPLAN to discuss the misadministrations. EASTMAN stated he observed FREEMAN remove a dose calibration ticket, which EASTMAN believed to be [redacted] bone dose calibration ticket, and throw it in the garbage. EASTMAN stated that it was his opinion that FREEMAN was incensed by the allegations. EASTMAN also stated that he told FREEMAN that there was another copy of the ticket in CASE's office (Exhibit 27, pp. 9-16). EASTMAN stated that he did not retrieve the ticket, nor did he tell KAPLAN, the HMC:BI, or RIII that he had witnessed FREEMAN remove the document (Exhibit 27, pp. 9-16).

When questioned by OI regarding the removal of the [redacted] bone dose calibration ticket, FREEMAN denied that he had removed any document from the file, and further stated that it appeared that it had never been placed in the file in the first place (Exhibit 9, p. 80).

The RIII inspectors verified that the bone dose calibration ticket for [redacted] was missing from the [redacted] file when they examined the file. However, a copy of the ticket was obtained from the RSO (Exhibit 2, pp. 10-11).

Willfulness/Intent

It has been established that FREEMAN, having received timely notification from ARGUIJO, ACT, failed to bring two diagnostic misadministrations to the attention of the RSO, thereby causing the misadministrations to go unreported to the NRC (Exhibit 8, pp. 21 and 40-41). FREEMAN acknowledged that he was aware of the NRC reporting requirements, yet he denied that the misadministrations occurred (Exhibit 9, pp. 7-12).

FREEMAN explained that when instructing technologist NIEMIRO regarding patient [redacted] FREEMAN had changed the order from a bone scan to a brain scan (Exhibit 9, p. 19). NIEMIRO denied receiving an order from FREEMAN for a brain scan and admitted that he (NIEMIRO) had erred when requesting the preparation of Tc-99m DTPA, a brain dose, from student technologist THOMAS (Exhibit 7, pp. 5-20). THOMAS corroborated NIEMIRO's testimony by stating that NIEMIRO had told him of the error after it had occurred

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(Exhibit 12, pp. 4-7). NIEMIRO also admitted that he then gave a second injection of Tc-99m MDP, a bone scan dose, in an attempt to cover up the misadministration (Exhibit 7, pp. 5-20).

BLEYBERG, referring physician, stated that he was never informed during conversations with FREEMAN that FREEMAN had changed the order from a bone scan to a brain scan, nor was he advised that a misadministration had occurred to his patient. In fact, BLEYBERG stated that FREEMAN specifically explained the scan to him as a bone scan (Exhibit 6, pp. 11-15). EASTMAN, Chief Technologist, observed FREEMAN remove a dose calibration ticket, which EASTMAN believed to be [redacted] bone dose calibration ticket, and throw it in the garbage prior to the NRC:RIII inspection (Exhibit 27, pp. 9-16). NIEMIRO admitted that he lied to KAPLAN, CNM, the HMC:BI, and NRC:RIII inspectors out of fear of contradicting FREEMAN's version of the [redacted] misadministration (Exhibit 7, pp. 21-24).

Although not required to be reported, the [redacted] misadministration was explained by FREEMAN as only a clerical error, i.e., the patient received the gallium-67 citrate injection two days prior to the scheduled injection (Exhibit 9, p. 44). The day the misadministration was brought to FREEMAN's attention by ARGUIJO, FREEMAN obtained a Consult from staff physician PANTALEON. FREEMAN requested PANTALEON complete the Consult for a gallium-67 citrate scan without informing PANTALEON that the patient, [redacted] had already been misadministered. PANTALEON had no knowledge of whether the scan had been ordered by the patient's referring physician (Exhibit 18, pp. 8-10). The Consult completed by PANTALEON gave the appearance of legitimizing the misadministration.

FREEMAN stated he was not aware of the [redacted] misadministration until October 1986 (Exhibit 9, p. 51). However, ARGUIJO stated that it was brought to his attention on [redacted] at which time FREEMAN instructed her and technologist LEUNG to inject the prescribed gallium-67 citrate after he was already aware that Tc-99m MDP had been injected in error (Exhibit 11). Documentation of the scan films corroborates ARGUIJO's testimony that both a bone and a gallium-67 citrate scan were performed (Exhibit 1, Attachment FF, pp. 5 and 9).

After the HMC:BI was initiated and prior to the NRC:RIII inspection and investigation, FREEMAN attempted to coerce ARGUIJO, during two telephone conversations, by attempting to convince her that she was as guilty as he if misadministrations were uncovered. FREEMAN suggested that ARGUIJO be non-specific and vague in her testimony, that a lack of recall had worked in the past, and nobody would fault her for not remembering the facts (Exhibit 8, pp. 53-55; Exhibit 22).

During his OI interview, FREEMAN was questioned about his telephone conversations with ARGUIJO. The OI investigator specifically asked FREEMAN the following questions, which were based upon FREEMAN's statements during the telephone conversations: (1) "Did you tell anybody, hypothetically speaking, that if you had given them orders to cover up a misadministration, that they are required anyway to complete the forms? If they didn't they would be just as guilty as you?" (Exhibit 9, p. 62; Exhibit 22, pp. 7-8); (2) "Do you recall advising anyone to say that they didn't remember and that this has worked in

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the past?" (Exhibit 9, p. 62; Exhibit 22, p. 17); and (3) "Did you ever tell any of the technologists to just play ignorant and say it was three months ago?" (Exhibit 9, p. 67; Exhibit 22, p. 5). FREEMAN denied making ar. of the statements (Exhibit 9, pp. 61-67).

Besides those involved with the misadministrations, [redacted] additional witnesses: KAPLAN (Exhibit 13, pp. 5-9); SHIRAZI (Exhibit 24, pp. 4-5); ROMYN (Exhibit 25); [redacted] MICHELS (Exhibit 26, pp. 4-5); and THOMAS (Exhibit 12, pp. 3-4 and 10); provided testimony that they were aware of misadministrations during the [redacted]

Agent's Conclusion

Due to conflicting statements received during the NRC:RIII inspection, the inspectors were unable to determine at that time if misadministrations had occurred. As a result of NRC technical staff review of the inspection report and OI investigative evidence, it has been established that two patients received diagnostic misadministrations that were not properly reported to the NRC as required. (A third diagnostic misadministration involved a non-reportable radiopharmaceutical.) The misadministrations were brought to the attention of FREEMAN, SCCNM, who failed to report them to the RSO and failed to initiate the paperwork necessary to report them to the NRC.

Evidence developed during the investigation substantiates that FREEMAN willfully failed to report the two misadministrations even though he was aware of the reporting requirements, and made a conscious attempt to cover up the misadministrations after they occurred. FREEMAN made material false statements to the NRC by denying that unreported diagnostic misadministrations had occurred, and attempted to impede the NRC by destroying documentation and attempting to coerce technologists to lie to the NRC.

Evidence developed during the investigation substantiates that NIEMIRO willfully lied to the HMC:BI and NRC:RIII inspectors out of fear of contradicting FREEMAN, because he had been afraid to admit that an error had occurred, and because he had been afraid of the NRC investigation.

Evidence developed during the investigation substantiates that EASTMAN observed FREEMAN remove a dose calibration ticket from the [redacted] nuclear medicine file prior to the NRC inspection. EASTMAN willfully failed to retrieve the ticket and failed to inform the HMC:BI or NRC:RIII that he had witnessed FREEMAN remove the document.

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SUPPLEMENTAL INFORMATION

The following witnesses were also interviewed during the course of the investigation, but their testimony was not considered relevant to the investigation:

Alicia M. PICACHE, M.D. (Exhibit 32)
Shashi AGRAWAL, M.D. (Exhibit 33)
David L. BUSHNELL, M.D. (Exhibit 34)

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LIST OF EXHIBITS

1. Copy of Edward Hines, Jr., Veterans Administration Medical Center Board of Investigation Report dated December 2, 1986.

2. Copy of NRC:RIII Inspection Report No. 030-01391/87001.

3. Copy of NRC memorandum from Charles H. WEIL to Jack A. HIND dated August 20, 1986.

4. Copy of NRC memorandum from Jack A. HIND to Charles H. WEIL dated January 26, 1987.

5. Copy of sworn statement of Arnold G. PHILLIPS, M.D., dated June 30, 1987.

6. Copy of sworn statement of Michael BLEYBERG, M.D., dated June 4, 1987.

7. Copy of sworn statement of Mark NIEMIRO dated June 11, 1987.

8. Copy of sworn statement of Rachelle Turano ARGUIJO dated April 28, 1987.

9. Copy of sworn statement of Maynard L. FREEMAN, M.D., dated June 30, 1987.

10. Copy of Hines VA Hospital Report of Contact dated October 20, 1986.

11. Copy of Report of Interview with Rachelle Turano ARGUIJO dated July 8, 1987.

12. Copy of sworn statement of Mitchell THOMAS dated May 14, 1987.

13. Copy of sworn statement of Ervin KAPLAN, M.D., dated June 26, 1987.

15. Copy of Report of Interview with Constance LaPORTE, R.N., dated May 15, 1987.

16. Copy of Report of Interview with Ruben VARGAS dated May 15, 1987.

17. Copy of Report of Interview with Theodora E. SHAUGHNESSY dated May 15, 1987.

18. Copy of sworn statement of Frank PANTALEON, M.D., dated May 14, 1987.

19. Copy of sworn statement of Rani S. CHINTAM, M.D., dated May 14, 1987.

20. Copy of unsworn statement of June LEUNG dated June 26, 1987.

21. Copy of NRC memorandum from Mary Kay Fahey to Ben B. Hayes dated July 22, 1987.

22. Copy of transcribed telephone conversations between Rachelle Turano ARGUIJO and Maynard L. FREEMAN dated November 10 and 11, 1986.

23. Copy of sworn statement of Lawrence F. CASE, Jr., dated May 4, 1987.

24. Copy of sworn statement of Parvez SHIRAZI, M.D., dated June 22, 1987.

25. Copy of affirmed statement of Antonie M. ROMYN, M.D., dated June 30, 1987.

26. Copy of sworn statement of Elizabeth MICHELS dated June 4, 1987.

27. Copy of sworn statement of Gary R. EASTMAN dated June 22, 1987.

28. Copy of Hines VA Hospital Report of Contact dated November 10, 1986.

29. Copy of sworn statement of Joseph GRECO dated May 13, 1987.

30. Copy of Report of Interview with Rachelle ARGUIJO dated April 28, 1987.

31. Copy of sworn statement of Michael BLEYBERG, M.D., dated May 13, 1987.

32. Copy of sworn statement of Alicia M. PICACHE, M.D., dated May 13, 1987.

33. Copy of sworn statement of Shashi AGRAWAL, M.D., dated May 14, 1987.

34. Copy of sworn statement of David L. BUSHNELL, M.D., dated June 4, 1987.