Title: BLOOMINGTON HOSPITAL

(1) ALLEGED WILLFUL FAILURE TO REPORT DIAGNOSTIC MISADMINISTRATIONS; AND (2) ALLEGED WILLFUL IMPEDIMENT TO NRC INSPECTORS THROUGH MATERIAL FALSE STATEMENTS AND THROUGH THE WITHHOLDING OF RECORDS REQUESTED BY NRC INSPECTORS

Licensee:

Bloomington Hospital
Bloomington, Indiana

Docket No. 030-01644

Case Number: 3-85-002

Report Date: April 28, 1986

Control Office: OI:RIII

Status: CLOSED

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SYNOPSIS

On December 31, 1984, NRC Region III (RIII) requested that an investigation be initiated regarding the results of an October 1984 NRC RIII inspection of the Bloomington Hospital Nuclear Medicine Department, Bloomington, Indiana. The inspection was prompted by allegations that the Bloomington Hospital Radiation Safety Officer (RSO) had willfully disregarded NRC reporting requirements regarding diagnostic misadministrations. Further allegations were received by NRC RIII that the Bloomington Hospital RSO had willfully impeded the NRC RIII inspection by directing Bloomington Hospital staff technologists to mislead the NRC inspectors. It was further alleged that the Bloomington Hospital RSO willfully impeded the NRC inspectors by failing to provide for review certain nuclear scans requested by the NRC inspectors, which were, in fact, available at the time of the inspection activity.

The Office of Investigations (OI) investigation revealed that four patients were misadministered between the dates of October 14, 1983, and August 3, 1984. It was further revealed that the required NRC reports regarding the diagnostic misadministrations were not performed.

The investigation further revealed that Bloomington Hospital's RSO is an experienced medical doctor, knowledgeable in the field of nuclear medicine and familiar with NRC reporting requirements. It was learned that appropriate reports regarding diagnostic misadministrations had been made prior to the questioned time period (October 14, 1983, to August 3, 1984) and following the questioned time period.

Regarding the allegations of the RSO impeding the NRC inspectors during the October 1984 NRC RIII inspection, the following was revealed. The RSO directed the Bloomington Hospital staff technologists to respond to the NRC inspectors by denying that unreported misadministrations had occurred. This action by the technologists would have corroborated the RSO's false statements to the NRC inspectors denying unreported diagnostic misadministrations. One of the technologists responded to the NRC inspectors as directed by the RSO.

It was further revealed that the RSO was observed, by a Bloomington Hospital technologist during the October 1984 inspection, removing nuclear scans from a patient's file and placing said film into the patient's x-ray file. The film had been requested by the NRC inspectors for review. Regarding this particular patient, the RSO denied that a misadministration had occurred and was observed by the NRC inspectors altering the date on the patient's file from the date of the alleged misadministration to the date of the administration of the properly prescribed radiopharmaceutical for which scans were provided. A subsequent search by Bloomington Hospital records personnel revealed the nuclear scans, which revealed the misadministrations, were found inside the patient's x-ray folder.

On a separate occasion, during the NRC RIII October 1984 inspection, the RSO was observed by a second technologist reviewing nuclear scans from the file of another patient which had been requested by the NRC inspectors. The inspectors were subsequently informed by the RSO that the requested film was unavailable. However, a subsequent search by hospital personnel revealed the requested film

was available for immediate inspection by the NRC inspectors. The film, when reviewed against the referring physician's request, revealed evidence of a misadministration.

The RSO was also observed by a technologist altering a patient's history card during the NRC RIII inspection to reflect the administration of a radiopharmaceutical which had not been prescribed by the patient's referring physician. The personal history card, according to the hospital's records chief, is a key to the patient's file and reflects the referring physician's order. The cards are maintained by records personnel, not the medical staff, and ordinarily reflect only the referring physician's orders. The effect on the NRC inspector of altering the personal history card, was to provide legitimacy to the nuclear scans found to have been evidence of misadministrations. The NRC inspectors recognized the discrepancy on the patient's personal history card between the time of the October 1984 inspection and the subsequent requested OI investigation.

In a November 1, 1984, response to a NRC RIII request for an investigation to be conducted by the President of Bloomington Hospital, one particular patient's alleged misadministration was denied by the President, who referenced the patient's referring physician as justification for his findings. Subsequent investigation revealed that the patient's referring physician denied the statements attributed to him by the President and further supported the original allegation that a misadministration appeared to have occurred.

The RSO, who initially had denied any unreported misadministrations to the NRC inspectors, acknowledged to NRC:OI Investigators that he was aware of the misadministrations and had not, for a variety of reasons, reported to the NRC as required. The RSO denied any attempt to mislead or impede the NRC inspectors, stating that the inspection was unexpected, stressful, and that he could not recall what was said during the inspection.

ACCOUNTABILITY

The following portions of this Report of Investigation (Case No. 3-85-002) will not be included in the material placed in the PDR. They consist of pages 3 through 37.

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APPLICABLE REGULATIONS

Chapter 18, Section 223 of the Atomic Energy Act, Violation of Sections (generally):

10 CFR 30.52: Inspections
10 CFR 35.44: Records of All Misadministrations
10 CFR 35.43: Reports of Diagnostic Misadministrations

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DETAILS OF INVESTIGATION

Purpose of Investigation

This investigation was initiated to determine the facts surrounding alleged material false statements made by Dr. Glen MATHER regarding alleged unreported diagnostic misadministrations at Bloomington Hospital's Nuclear Medicine Department. Subsequent allegations were that MATHER impedcd the NRC inspectors by directing technologists in his staff to misinform the NRC inspectors during an October 1984 NRC:RIII inspection effort, and that MATHER withheld requested nuclear scans from the NRC inspectors which revealed evidence of diagnostic misadministrations.

Background

On December 31, 1984, the RIII Regional Administrator requested an OI investigation to determine if MATHER and Bloomington Hospital willfully violated 10 CFR 35.43 in failing to make the required reports of diagnostic misadministrations. It was further requested that OI determine if MATHER and Bloomington Hospital impeded the NRC inspection into allegations by willfully not furnishing records requested during the inspection in violation of 10 CFR 30.52.

Allegation 1: Alleged Willful Failure to Report Diagnostic Misadministrations

[redacted] identified to the NRC patients who allegedly were misadministered and for which no required reports were made to the NRC (Exhibit 1; Exhibit 2).

[redacted] from approximately September 1983 through October 1984, identified the following patients as having received injections of radioisotopes other than that prescribed by the patients' referring physician (Exhibit 1):

1. [redacted] October 14, 1983
2. March 28, 1984
3. August 3, 1984
4. August 3, 1984

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[redacted] from August 1982 through October 23, 1984, identified the following patients as having received injections of radioisotopes other than that prescribed by the patients' referring physician (Exhibit 2):

1. [redacted] March 28, 1984
2. August 3, 1984
3. August 3, 1984

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.. Regarding [redacted] stated that Rex HASTINGS, a Nuclear Medicine Technologist, misadministered to [redacted] on October 14, 1983. Upon HASTINGS informing Dr. Glen MATHER (Director of Nuclear Medicine and Ultrasound at Bloomington Hospital) of the misadministration, MATHER allegedly instructed HASTINGS to inform [redacted] that the injection of October 14, 1983 did not "take" and that [redacted] should return on October 17, 1983 (Monday), for a reinjection. [redacted] allegedly received technetium (Tc-99m) instead of the prescribed technetium methylene di phosphonate (Tc-MDP) (Exhibit 1).

II. Regarding [redacted] stated that on March 28, 1984, [redacted] was scheduled to receive a renal scan (which required an injection of technetium gluco heptonate). Instead, [redacted] was injected with technetium sulphur colloid, which produces a liver scan (Exhibit 1).

[redacted] stated, in corroboration of [redacted] statement, that [redacted] also witnessed events surrounding [redacted] misadministration. [redacted] stated that HASTINGS mistakenly administered the technetium sulphur colloid to [redacted] and upon realizing his mistake, reported the misadministration to MATHER. According to [redacted] MATHER allegedly instructed HASTINGS to "reinject [redacted] because a renal scan could still be read (Exhibit 2).

[redacted] stated that HASTINGS, upon realizing his mistake in administering the wrong radioisotope to [redacted] stated, "Oh my God, I gave [redacted] the wrong dose." HASTINGS had allegedly administered technetium sulphur colloid, producing a liver scan instead of a renal scan. The renal scan is created by the prescribed technetium gluco heptonate isotope (Exhibit 1).

[redacted] further stated that MATHER, after being informed of the misadministration to [redacted] instructed HASTINGS to "give [redacted] the other injection." According to [redacted] MATHER made the comment that reporting the misadministration to the NRC would require "too much paperwork and red tape."

III. Regarding [redacted] stated that [redacted] received Tc-MDP, a bone scanning agent, instead of the prescribed Tc-99m, which produces a meckels diverticulum scan. [redacted] stated that HASTINGS injected [redacted] while [redacted] performed the scan. [redacted] observed that [redacted] "couldn't see the stomach" (which is what one would expect to scan if the proper isotope to produce a meckels diverticulum scan had been administered). [redacted] stated that [redacted] informed MATHER that the scan was not revealing the stomach, at which time MATHER allegedly stated, "go back out there and reposition [redacted] you must see the stomach" (Exhibit 1).

[redacted] stated that [redacted] also witnessed events surrounding the alleged misadministration to [redacted] According to [redacted] HASTINGS prepared an incorrect dose and administered Tc-MDP, a bone scanning agent, instead of the prescribed Tc-99m to [redacted] (Exhibit 2).

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IV. According to [redacted] was injected with Tc-MDP (the bone scanning agent) instead of the prescribed Tc-99m for a meckels diverticulum scan requested by the referring physician. The misadministration was allegedly committed by [redacted] (Exhibit 1).

[redacted] stated that [redacted] informed MATHER of the misadministration [redacted] at which time MATHER instructed [redacted] to tell [redacted] mother that the first injection had not taken and that a reinjection would be necessary. [redacted] was unaware of any subsequent attempt by MATHER to report the August 3, 1984, misadministrations to the NRC (Exhibit 2).

On October 23, 1984, NRC Radiation Specialists R. J. CANIANO and G. L. SHEAR, conducted an unannounced special inspection (Inspection Report No. 030-01644/84-01(DRSS)) to review facts surrounding the allegations by [redacted] and [redacted] (Exhibit 3).

During this special inspection, MATHER, the Radiation Safety Officer (RSO), stated that only one diagnostic misadministration had occurred, September 5, 1984. It was reported to the NRC as required. MATHER was given the name of those alleged to have been misadministered, however, he maintained that no other misadministrations had occurred. MATHER was requested on October 23, 1984, by the NRC inspectors to provide both scans and dose records for the patients who allegedly were misadministered (Exhibit 3, page 4 and Attachment B).

During the course of the inspection, the inspectors were provided, through various means, nuclear medicine films of the following patients:

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]

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I. Regarding [redacted] MATHER provided the NRC inspectors a folder dated October 14, 1983, containing nuclear medicine film. However, enclosed in the [redacted] folder was only a bone scan dated October 17, 1983 (the date of the alleged misadministration of [redacted] was October 14, 1983). MATHER, when questioned by CANIANO regarding the discrepancy between the date of the film provided (October 17, 1984) and the date on the folder (October 14, 1983) "quickly changed the date on the folder to October 17, 1983" (Exhibit 3, page 6).

MATHER stated to the NRC inspectors following his action of altering the date of the folder that on October 17, 1983, one of the technologists indicated to him (MATHER) that [redacted] may have been administered Tc-99m instead of the prescribed Tc-MDP dose. However, MATHER stated that the patient [redacted] was given the proper Tc-MDP dose and the technologist was mistaken. Therefore, MATHER stated that no misadministration occurred with [redacted] (Exhibit 3, page 6).

II. Regarding [redacted] film, MATHER stated that a misadministration did not occur. The referring physician's reviewed by CANIANO and SHEAR revealed that [redacted] was scheduled to receive a kidney scan. However,

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However, upon review of the scan by CANIANO and SHEAR, it was noted by the NRC inspectors that [redacted] film revealed, in addition to the kidneys, both the spleen and liver. MATHER, when questioned regarding the appearance of the additional organs on the scan, stated only that the prescribed technetium gluco heptonate (producing a kidney scan) was administered (Exhibit 3, page 7).

III. Regarding [redacted] MATHER provided nuclear medicine films dated August 3, 1984 which were reviewed by CANIANO and SHEAR. Upon reviewing the films, the inspectors noted two different types of scans. One appeared to be an abdominal scan, and one appeared to be a bone scan. MATHER, when asked specifically if two radiopharmaceuticals were administered, denied that two radiopharmaceuticals were administered and stated that only Tc-MDP was mistakenly administered (Exhibit 3, page 6).

INVESTIGATOR'S NOTE: Tc-MDP is a radiopharmaceutical. Therefore, MATHER's statement that technetium MDP was mistakenly administered is by definition a misadministration, and should have been reported.

MATHER then stated to Inspectors CANIANO and SHEAR that technically this should have been considered a diagnostic misadministration, but was not since a clinical diagnosis was made (Exhibit 3, page 6).

INVESTIGATOR'S NOTE: 10 CFR 35.41(a) defines a misadministration as "the administration of a radiopharmaceutical or radiation from a sealed source other than the one intended." The definition does not address whether or not a clinical diagnosis was possible as a mitigating factor in reportability. 10 CFR 35.43 states in part that "when a misadministration involves a diagnostic procedure, the licensee shall notify, in writing, the referring physician and the appropriate NRC regional office." MATHER stated (in contradiction to the above cited 10 CFR 35.43) that he verbally notified [redacted] referring physician (Exhibit 3, page 6).

IV. Regarding [redacted] MATHER recalled that (following the NRC inspectors' review of [redacted] scans) [redacted] was misadministered to on August 3, 1984. CANIANO and SHEAR recognized upon review of [redacted] scans, what appeared to be an abdominal scan and a bone scan. As with [redacted] scans of the same date, MATHER stated that although [redacted] received Tc-MDP a clinical diagnosis was made once the correct isotope (Tc-99m) was administered. MATHER stated that the misadministration was not reported because a clinical diagnosis was made, and that the referring physician was notified verbally of the misadministration (Exhibit 3, page 7).

INVESTIGATOR'S NOTE: MATHER's definition of what a misadministration and the reportability requirements are inconsistent with 10 CFR 35.41(a) and 10 CFR 35.43 (see page 23 of this report).

It was at this point in the inspection process that MATHER finally acknowledged that [redacted] and [redacted] had received misadministrations that were not reported to the NRC due to MATHER's alleged belief that if a diagnosis is possible, no misadministration occurred. Therefore, there is no requirement to report to the NRC. MATHER, however, had not as yet acknowledged any alleged misadministrations to [redacted]

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It was at this point in the inspection process (being carried out by NRC Inspectors CANIANO and SHEAR), that MATHER finally acknowledged that [redacted] and [redacted] had received misadministrations which were not reported to the NRC due to MATHER's alleged belief that if a diagnosis is possible, no misadministration occurred. Therefore, there is no requirement to report to the NRC. MATHER, however, had not as yet acknowledged any alleged misadministrations to [redacted]

[redacted] stated that on October 23, 1984 (the first day of the NRC inspection), MATHER approached [redacted] and HASTINGS and told them, "[redacted] has turned us in, and this is what we're going to tell them [NRC]. You (HASTINGS and [redacted]) tell them (the NRC) that the misadministrations didn't occur" (Exhibit 2).

Later that day, according to [redacted] while both CANIANO and SHEAR were in MATHER's office, MATHER came to [redacted] leaving the two inspectors in his office. MATHER requested [redacted] assistance in locating [redacted] files requested by CANIANO and SHEAR. [redacted] stated that upon locating the requested files and providing said files to MATHER, MATHER was observed by [redacted] removing nuclear medicine film from the [redacted] file. According to [redacted] MATHER removed the (October 14, 1983) nuclear film revealing the misadministration from the "nuclear folder" placing the (October 14, 1983) film inside the [redacted] x-ray folder." MATHER then, according to [redacted] carried the nuclear film folder to the NRC inspectors, minus the (October 14, 1983) film. He had removed and placed in the "x-ray folder" (Exhibit 2).

CANIANO and SHEAR were informed by [redacted] at the time of the inspection (October 23, 1984) that the nuclear film removed by MATHER was that of [redacted] which was taken on October 14, 1983. The film removed by MATHER would have revealed that on October 14, 1983, [redacted] was administered Tc-99m rather than the prescribed dose of Tc-MDP. On October 17, 1983, according to [redacted] the proper Tc-MDP dose was administered. The inspectors had only been allowed by MATHER to see the October 17, 1983, film, revealing the correct dosage as ordered by the referring physician (Exhibit 3, pages 8-9).

HASTINGS (at the time of the unannounced inspection and in response to questions by the NRC inspectors) stated that the only misadministrations which had occurred were those of [redacted] HASTINGS denied any knowledge of alleged misadministrations to [redacted] HASTINGS further (in response to a request by the NRC inspectors) provided a brief written statement to the NRC inspectors stating that he had not been directed by MATHER to conceal any information from the NRC inspectors (Exhibit 3, page 9 and Attachment B).

MATHER also denied (after having acknowledged that "technically" [redacted] and [redacted] received misadministration) that [redacted] received misadministrations (Exhibit 3, page 9).

INVESTIGATOR'S NOTE: At the beginning of the unannounced special inspection by CANIANO and SHEAR, MATHER stated unequivocally that the four patients in question had not been misadministered. It was only after the NRC inspectors reviewed the nuclear medicine scans of [redacted] and questioned MATHER regarding their observations that MATHER acknowledged the misadministrations of [redacted]

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[redacted] presented to the NRC inspectors copies of the nuclear medicine films of [redacted] dated October 14, 1983, which were subsequently analyzed by Dr. Stephen PINSKY, a NRC consultant (Exhibit 3, pages 8-10).

INVESTIGATOR'S NOTE: MATHER stated to the NRC inspectors on October 23, 1984, that [redacted] had been administered technetium MDP on October 17, 1983, and that there had been no misadministration in the case of [redacted] (Exhibit 3, page 6).

W. L. AXELSON, Chief, Nuclear Materials Safety and Safeguards Branch, NRC Region III, requested in writing that Roland KOHR, President of Bloomington Hospital, determine whether misadministrations did occur regarding the four patients in question, and if so, whether and when referring physicians of the patients were notified in writing in accordance with 10 CFR 35.43. Pursuant to Section 182 of the Atomic Energy Act of 1954, KOHR's response was requested by AXELSON to be under oath or affirmation (Exhibit 3, Attachment C).

On November 1, 1984, KOHR responded to AXELSON as follows (Exhibit 3, Attachment D):

I. Regarding [redacted] Dr. James SCHAEFER, referring physician of [redacted] stated that MATHER notified him of [redacted] misadministration.

II. Regarding [redacted] the referring physician, Dr. Diane WELLS, was npt available, therefore, KOHR delayed reporting.

III. Regarding [redacted] KOHR stated that Dr. James TOULOUKIAN had "actually participated with MATHER in the study," and that there were "no problems and no misadministrations." Further, KOHR reported TOULOUKIAN as stating that [redacted] scans "were perfectly good in all respects," and that TOULOUKIAN would "dispute any argument that a misadministration had occurred."

IV. Regarding [redacted] KOHR reported that the referring physician and patient were notified of the misadministration of [redacted]

KOHR further stated that MATHER is a highly respected physician on the Bloomington Hospital medical staff, referring to MATHER as a "man of integrity" with a "strong dedication to a high level of medical practice." KOHR stated that MATHER "makes a conscientious effort to observe all of the laws, rules, and regulations related to the practice of medicine, including those that are a part of this medical speciality" (Exhibit 3, Attachment D).

KOHR, by letter dated November 20, 1984, to the NRC, presented findings (by L. Gene PERRY, Vice President, Professional Services, Bloomington Hospital, dated November 19, 1984) to AXELSON relevant to [redacted] (Exhibit 3, Attachment E).

According to PERRY, Dr. Diane WELLS [redacted] referring physician) had "no recall" of MATHER informing her of a misadministration (Exhibit 3, Attachment E). As a result of PERRY's effort, a list of all nuclear studies conducted on [redacted] revealed studies conducted on both October 14 and 17, 1983. According to PERRY, Phil Lewis (the Chief of X-Ray) discovered nuclear studies dated October 14, 1983, among the x-ray film of [redacted] both of which (x-ray film and nuclear studies) are maintained in the same folder (Exhibit 3, Attachment E).

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INVESTIGATOR'S NOTE: [redacted] informed NRC inspectors on October 23, 1984 (during the unannounced special inspection), of MATHER's removal of the [redacted] October 14, 1983 nuclear study revealing a misadministration and placement of the study into the [redacted] x-ray folder (Exhibit 2). On October 23, 1984, MATHER, when questioned by NRC inspectors regarding [redacted] alleged misadministration of October 14, 1983, would only address the October 17, 1983, nuclear study. MATHER changed the October 14, 1983 date on the nuclear study folder to that of October 17, 1983, in the presence of the NRC inspectors (Exhibit 3, page 6).

Dr. Diane WELLS, according to PERRY, stated that she had ordered only one nuclear study, a bone scan, on October 13, 1983. The October 17, 1983, nuclear study was a bone scan according to PERRY's letter, however, the October 14, 1983 nuclear study was not identified and written reports on the study were missing (Exhibit 3, Attachment E).

MATHER, when approached by PERRY with his findings, reportedly stated "that it was obvious that a misadministration had taken place" and that the October 14, 1983 study looked as though Tc-99m had been given rather than the appropriate agent for a bone scan. MATHER, according to PERRY, denied any recollection of the misadministration (Exhibit 3, Attachment E).

PERRY's report further identified Virginia DECKARD (a Nuclear Assistant in the Nuclear Medicine Department of Bloomington Hospital) as having overheard MATHER talking to [redacted] about the misadministration (Exhibit 3, Attachment E).

PERRY offered an explanation as to why the October 14, 1983 [redacted] film was found in the x-ray film. PERRY speculated (along with LEWIS and MATHER) that the October 14, 1983 nuclear film was pulled from the nuclear jacket when the nuclear studies were sent to another hospital because it was a misadministration and therefore of no clinical value, and rather than destroying it, it was thrown in with the x-rays.

INVESTIGATOR'S NOTE: The nuclear film folder is placed inside the x-ray folder at Bloomington Hospital, and even if the misadministration film (October 14, 1983) were removed from the nuclear film (October 17, 1983) and allegedly sent to another hospital, the October 14, 1983 film would have been available for review inside the x-ray film folder. Also, MATHER, according to PERRY's findings, acknowledged the [redacted] misadministration only after LEWIS' discovery of the October 14, 1983 studies, which MATHER had not made available to the NRC inspectors during the previous October 1984 inspection effort. At this point in time (November 1984) MATHER had acknowledged three of the four alleged misadministrations, which on October 23, 1984, he denied had occurred. [redacted] is the only remaining patient that MATHER, at this time, had not acknowledged as having received a misadministration.

The nuclear studies presented to NRC inspectors CANIANO and SHEAR by [redacted] during the October 1984 inspection were presented to PINSKY of Michael Reese Medical Center for review and analysis. The results of PINSKY's analyses of [redacted] nuclear scans revealed a technetium sulphur colloid administration of the renal agent (Exhibit 3, Attachment F, Patient 1).

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INVESTIGATOR'S NOTE: MATHER denied to the NRC Inspectors CANIANO and SHEAR that a misadministration to [redacted] had occurred, stating that only the prescribed dosage (technetium gluco heptonate, producing a renal scan) was administered. This position by MATHER was not supported by PINSKY's analysis. PINSKY's interpretation does support both [redacted] observations.

On December 4, 1985, HASTINGS was interviewed regarding his knowledge of events surrounding both the alleged misadministrations and the NRC unannounced special inspection. HASTINGS exhibited little or no recall regarding the alleged misadministrations of [redacted] However, regarding [redacted] HASTINGS recalled that he had been admonished by MATHER [redacted] (Exhibit 4).

KOHR was interviewed on December 18, 1985, regarding his November 1, 1985, response to a NRC request for information. KOHR demonstrated a correct knowledge of what constitutes a diagnostic misadministration (Exhibit 5, page 8, lines 1-4).

Regarding [redacted] (the only one of the original four patients alleged to have received misadministrations for which no required report was forwarded to the NRC), KOHR stated that he talked with TOULOUKIAN [redacted] (referring physician) by telephone. TOULOUKIAN stated that he was present during the nuclear study itself and that there were no problems, that the scans were perfectly good scans, satisfactory in all respects, and that he (TOULOUKIAN) would actually dispute if any misadministration occurred (Exhibit 5, page 11, lines 4-22).

On December 5, 1985, TOULOUKIAN was questioned regarding his knowledge of events surrounding the nuclear study of [redacted] on March 28, 1984. In view of TOULOUKIAN's exhaustive schedule, TOULOUKIAN was allowed to respond to questions by letter (Exhibit 6).

TOULOUKIAN responded to the NRC by letter dated December 20, 1985. TOULOUKIAN stated (upon his review of copies of the [redacted] scan) that apparently two radiopharmaceutical administrations must have occurred. TOULOUKIAN stated that as of the date of this letter (December 20, 1985), he had received no written notification of a misadministration; however, TOULOUKIAN stated that the [redacted] misadministration had been verbally brought to his attention by Bloomington Hospital's Nuclear Medicine Department (Exhibit 7).

INVESTIGATOR'S NOTE: As of December 5, 1985, TOULOUKIAN had not been notified of misadministration by Bloomington Hospital's Nuclear Medicine Department (Exhibit 6).

Regarding other points in KOHR's November 1, 1984, response, TOULOUKIAN states:

1. "I was just an observer" and "was not present at the actual time of the administration of the isotope."

2. "I could not state that there were no problems and no misadministrations."

3. "I would not be able to say 'they (the nuclear studies) were perfectly good in all respects' as it is obvious from the scan that liver, spleen, and kidneys are all imaged on the same scan, which would not be the case

in a properly executed renal scan" (Exhibit 7).

INVESTIGATOR'S NOTE: TOULOUKIAN, point by point, refuted KOHR's November 1, 1984, response to the NRC, that addressed [redacted] nuclear scan and attributed alleged remarks by TOULOUKIAN in support of MATHER's statement to NRC inspectors that [redacted] had not received a misadministration.

KOHR stated (regarding questions of any findings as of the date of this interview, December 18, 1985, which might cause Bloomington Hospital to conclude that [redacted] had or had not received a misadministration) that, "it appears that there may have been a misadministration with [redacted] (Exhibit 5, page 14, line 24 through page 15, line 1).

According to KOHR, "from my listening to him (MATHER), there is no certainty that one (a misadministration) did take place and there is certainly no way of saying one did not take place" (Exhibit 5, page 15, lines 16-19).

INVESTIGATOR'S NOTE: KOHR stated on the one hand, "it appears that there may have been a misadministration." And at the same moment states that from listening to MATHER, it is difficult to determine. PINSKY's analysis refutes that it is difficult to determine, and in fact, states that two radiopharmaceuticals were administered to [redacted]

INVESTIGATOR'S NOTE: On December 17, 1985, Investigator Walker, Radiation Specialist CANIANO, Guy R. LOFTMAN, Esq. (on behalf of HASTINGS), and Ken FOSTER, Assistant U.S. Attorney, Indianapolis, Indiana, met in the offices of the U.S. Attorney, Indianapolis, Indiana. The purpose of this meeting was based upon HASTINGS' desire to tell the truth regarding facts surrounding the NRC special unannounced inspection of October 23-24, 1984, of Bloomington Hospital's Nuclear Medicine Department. During the meeting, LOFTMAN was assured that HASTINGS' previous interview dated December 4, 1985, by OI was viewed as a preliminary information gathering interview. HASTINGS (according to LOFTMAN) was concerned that his October 1984 false written response to CANIANO and SHEAR, in concert with his acknowledged false responses to OI, would cause him to loose his license.

It was also learned through John J. HOLLINDEN, a nuclear consultant for the Nuclear Medicine Department at Bloomington Hospital, that on or about December 11, 1985, HASTINGS expressed a concern that records or files were missing during the October 1984 NRC inspection (Exhibit 8A).

On December 18, 1985, HASTINGS addressed the following patients:

I. [redacted] No recollection.

II. [redacted] HASTINGS stated that he misadministered to [redacted] on March 28, 1984, and told both [redacted] and MATHER. MATHER, according to HASTINGS, told him to just go ahead and do the scan that was ordered. MATHER, HASTINGS acknowledged, instructed HASTINGS to readminister the proper dosage (Exhibit 8, page 7, lines 13-25).

III. [redacted] HASTINGS stated that he misadministered to [redacted] HASTINGS presented a copy of a "Oral Discussion/Written Notice of Instruction" dated August 3, 1984,

signed by MATHER. The notice documents that MATHER recognized the misadministration and so stated in the August 3, 1984 notice, "one more misadministration will result in immediate dismissal" (Exhibit 8, page 10, lines 19-25, page 11, line 17, page 12, lines 4-24; Exhibit 9).

IV. [redacted] HASTINGS stated that he drew the doses for both [POZZATTI] and [redacted] According to HASTINGS, both patients were to receive technetium [redacted] for meckels diverticulum). However, they were administered MDP (Exhibit 8, page 11, line 19, page 12, line 1).

INVESTIGATOR'S NOTE: MATHER's statements to NRC Inspectors CANIANO and SHEAR during their October 1984 inspection is contradicted by HASTINGS' sworn statement as reported. HASTINGS stated that MATHER had direct knowledge of the misadministrations of [redacted] and [redacted] misadministrations denied by MATHER to the NRC inspectors in October 1984. HASTINGS, however, had no recall of [redacted]

On December 18, 1985, Virginia DECKARD, an employee of Bloomington Hospital, was interviewed regarding her knowledge of events surrounding the alleged misadministration of [redacted] (Exhibit 10).

DECKARD stated that she was standing within the proximity of MATHER and overheard MATHER tell [redacted] that [redacted] had been misadministered [October 14, 1983]. MATHER, according to DECKARD, asked [redacted] to "come back the next day or so and have it done" (Exhibit 10, page 5, lines 3-12).

INVESTIGATOR'S NOTE: DECKARD's statement corroborates [redacted] regarding the alleged [redacted] misadministration.

Allegation 2: Alleged Willful Impediment to NRC Inspectors Through Material False Statements and Through the Withholding of Records Requested by NRC Inspectors

[redacted] stated that on October 23, 1984 (the first day of the NRC unannounced special inspection effort), MATHER allegedly notified both [redacted] and HASTINGS that an NRC inspection was imminent and directed both [redacted] and HASTINGS to "tell them (the NRC inspectors) that the misadministration didn't occur." MATHER also allegedly informed the two technologists that [redacted] has turned us in" (Exhibit 1, page 5, Technologist D; Exhibit 2).

HASTINGS stated that MATHER told him that [redacted] turned in some names." MATHER also told HASTINGS that the scans for [redacted] were ordered. HASTINGS stated that he knew the scans were not ordered, but told the NRC inspectors that he had "heard they were ordered" (Exhibit 8, page 14, line 8 through page 15, line 7).

HASTINGS clarified himself by again acknowledging that MATHER directed him to indicate to the inspectors if asked, "that the bone scans were ordered." HASTINGS acknowledged that by "being ordered" would mean that there had not been misadministrations (Exhibit 8, page 15, lines 10-23).

NRC Inspector SHEAR stated that he recalled on October 23, 1984, HASTINGS making the comment that he (HASTINGS) had "heard they (the bone scans for [redacted] had been ordered" (Exhibit 11).

INVESTIGATOR'S NOTE: HASTINGS corroborates, in his statement, [redacted] allegation regarding MATHER's attempts to impede and mislead the NRC inspectors. SHEAR corroborates HASTINGS' comments regarding HASTINGS response to the NRC inspectors' questions (Exhibit 8A).

[redacted] stated that MATHER (on October 23, 1984) removed from [redacted] film file an October 14, 1983, nuclear film revealing a misadministration to [redacted]. The film dated October 17, 1983 (which revealed no misadministration) was provided by MATHER to the NRC inspectors (Exhibit 1; Exhibit 2).

KOHR's response to the NRC request regarding an investigation into events surrounding the four patients allegedly misadministered, specifically [redacted] was prepared by L. Gene PERRY, Vice President, Professional Services (Exhibit 3, Attachment F).

PERRY's findings addressed the assistance of Chief Radiological Technologist, Phil LEWIS. As a result of LEWIS' search into [redacted] x-ray film jacket where the nuclear film are maintained, LEWIS found the October 17, 1983, nuclear film (Exhibit 3, Attachment E).

LEWIS reportedly found the October 14, 1983, nuclear film intermingled with [redacted] x-ray film and not inside the 8" x 10" nuclear film jacket (the x-ray film jacket is a large folder, large enough that the 8" x 10" nuclear film jacket is retained inside the larger x-ray film jacket) (Exhibit 3, Attachment E).

LEWIS' attention was directed to the small 8" x 10" nuclear medicine folder which contained [redacted] nuclear studies. The date October 14, 1983, had been altered, [redacted] to a "7". This made it appear that only an October 17, 1983, nuclear study was performed. LEWIS had no knowledge of how the change in dates was accomplished (Exhibit 12, pages 29-30).

PERRY stated in his November 19, 1984, letter that he discussed the circumstances of the October 14, 1983, film "being in with the x-ray films" with both MATHER and LEWIS. It was concluded by PERRY that "when the nuclear studies were sent to another hospital, the October 14, 1983, film was pulled from the nuclear jacket because it was a misadministration and thus of no clinical value. Rather than destroy it, it was thrown in with the x-rays" (Exhibit 3, Attachment E, page 2).

LEWIS recalled having found the nuclear film "mixed up with the other films." LEWIS discussed at length the process by which nuclear film traceability is maintained. However, he stated regarding the October 14, 1983, nuclear film) that on August 31, 1984, [redacted] the daughter of [redacted] signed out for x-ray on nuclear film of [redacted] LEWIS stated that "it (the nuclear film) may have gone to another hospital, although it does not indicate it" (Exhibit 11, pages 14-15; Exhibit 12, page 31).

LEWIS, when asked his opinion of why the October 14, 1983, nuclear film was not made available to the NRC inspectors, responded as follows: "I assume that these were pulled." LEWIS speculated that "whoever released the film (to [redacted] would have pulled them out [the October 14, 1983, film] and looked at them and said well, this one is not of clinical value...[and] send the ones we know are accurate and take the other one and stick it back in this jacket."

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LEWIS further stated, referring to the October 14, 1983, film, "I don't know why it (the October 14, 1983, film) wasn't stuck in here (in the nuclear film jacket)?" LEWIS stated "somebody else will have to answer that one" (Exhibit 12, pages 31-33).

INVESTIGATOR'S NOTE: LEWIS' speculation included a possible clinical diagnosis and a determination regarding the value of forwarding the October 14, 1983, film. However, any such diagnosis concluding that the October 14, 1983, film was a misadministration could only be made by a person trained in reading nuclear scans, and with knowledge of what was prescribed by the referring physician.

LEWIS speculated that "our staff would not know to search [the x-ray file] for a nuclear film that should be in [the] small [nuclear] jacket."

INVESTIGATOR'S NOTE: The film search was initially conducted on October 23, 1984, by [redacted] not a "stenographer." LEWIS is apparently unaware of events surrounding the "mis-filing" of the October 14, 1983, nuclear film. The October 1983 film was available at the time of the October 1984 inspection effort and within the confines of the x-ray file of [redacted] according to LEWIS' statement.

Regarding the [redacted] nuclear study, HASTINGS stated, in his December 18, 1985, statements that during the October 23-24, 1984, NRC inspection, MATHER requested HASTINGS to pull the file for [redacted] HASTINGS observed MATHER pull the film out, look at it, and replace the film (Exhibit 4, page 16).

NRC Inspectors CANIANO and SHEAR documented in their inspection report that MATHER informed them (during the October 1984 inspection) that the films pertaining to this patient were not available and may have been sent to Indiana University Medical Center. A technologist, however, subsequently located the [redacted] film for the NRC inspectors during the October 1984 inspection (Exhibit 3, pages 6-7).

In his sworn statement, HASTINGS stated that MATHER typed additional information on a personal history card of one of the patients in question during the NRC inspection effort. HASTINGS could not recall the identity of the patient, nor did he at that time inform either NRC inspector of the incident.

LEWIS provided for review, 3" x 5" typed personal history cards used to identify the four patients, their types of exams, and their referring physicians (Exhibit 11, page 16; Exhibit 13; Exhibit 14; Exhibit 15; Exhibit 16).

LEWIS stated that the cards are typed by seven or eight scheduling people in radiology. When the schedulers are off duty, according to LEWIS, orderlies and technicians work on the cards. LEWIS stated that normally, administrative personnel, not technologists or medical personnel, work on the cards (Exhibit 11, page 17).

According to LEWIS, the information typed on the 3" x 5" personal history card is taken directly from the referring physician's requisition. The card reflects the requisition and usually would be completed long before the patient is examined (a nuclear study conducted). LEWIS described the personal history card as "the key." "If we don't have this we can't find anything" (Exhibit 11, page 17).

LEWIS identified the 3" x 5" personal history cards of the patients in question and stated that to his knowledge, there had been no altering of the cards since their origination (Exhibit 11, page 23).

Further examination of the 3" x 5" personal history cards by LEWIS revealed four dates reflecting x-rays or nuclear studies for [redacted] as follows:

1.	Chest x-ray	September 23, 1983
2.	Nuclear study	October 14, 1983
3.	Nuclear study	October 17, 1983
4.	Tomogram	October 28, 1983

(Exhibit 3, Attachment E; Exhibit 12, page 28).

A discrepancy noted on [redacted] card was that both nuclear studies dated October 14 and 17, 1983, in the November 19, 1984, letter are not reflected on [redacted] 3" x 5" personal history card (Exhibit 12, page 29; Exhibit 13).

A point of contradiction is seen by examination of the 3" x 5" personal history card of [redacted] (who was allegedly misadministered on the same date as [redacted]. The [redacted] card reflects an August 3, 1984, bone scan in addition to an August 3, 1984, abdominal scan (Exhibit 12, page 39; Exhibit 16).

The requisition form in [redacted] file reflects a request for only an abdominal scan for meckels. The noted discrepancy between the [redacted] personal history card could not be explained by LEWIS other than that an order/requisition for a bone scan for [redacted] would have been worked up at the registration desk and processed, and that the requisition for [redacted] bone scan must be missing for some reason (Exhibit 12, pages 39-40).

INVESTIGATOR'S NOTE: There never had been a bone requisition for either [redacted] MATHER's entry on the [redacted] card of the bone scan was not part of the hospital's routine as outlined by LEWIS.

During the October 23-24, 1984, NRC inspection, CANIANO noted that [redacted] 3" x 5" personal history card revealed only one nuclear study conducted on [redacted] on August 3, 1984, a meckels scan. The additional entry of a bone scan was not present when reviewed by CANIANO in October 1984 (Exhibit 17).

HASTINGS stated the following regarding his written comment requested by the NRC inspectors during the October 23-24, 1984, inspection (in which he denied that MATHER had directed him to mislead the NRC inspectors), "I worked there and I was scared for my job" (Exhibit 3, Attachment B; Exhibit 8, page 20).

HASTINGS stated that "pressure and surprise" were also elements which caused him to deny any prompting by MATHER to mislead the NRC. HASTINGS stated that he did not think that [redacted] deserved the right to call the NRC. HASTINGS said, "I didn't think [redacted] earned it." HASTINGS cited both pressure and confusion for his conduct. HASTINGS defined the pressure as "the pressure was what would happen to me if I didn't [corroborate the Doctor]" (Exhibit 8, pages 20-21).

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HASTINGS stated that during or after the inspection of October 1984, he was "pretty worried" and MATHER told him (HASTINGS) that the lawyer advised him (MATHER) that "it's not against the law not to remember things" (Exhibit 8, page 21).

HASTINGS stated that following the NRC inspectors leaving the hospital, he talked with [redacted] via telephone, and following his discussion with [redacted] called MATHER. HASTINGS said that he told MATHER that [redacted] had told them everything." HASTINGS said that the next day, MATHER went to confer with the hospital's lawyer (Exhibit 8, pages 22-23).

[redacted] stated that [redacted] had a telephone conversation with HASTINGS following the NRC inspection, during which HASTINGS surmised that [redacted] had told the NRC inspectors the truth regarding the activities of MATHER. HASTINGS, according to [redacted] said that he had provided a false statement to the NRC inspectors. [redacted] stated that [redacted] told HASTINGS he had done the wrong thing, at which time HASTINGS responded by saying, "if I hadn't lied, I could have lost my job" (Exhibit 2).

INVESTIGATOR'S NOTE: HASTINGS' fear of losing his livelihood had he not corroborated MATHER's story appeared to be self-induced.

HASTINGS stated that MATHER did not confide in him regrading MATHER's meeting with the hospital lawyer (which occurred following the October 1984 NRC inspection), which according to HASTINGS, "bummed me out." HASTINGS said that he felt as though he was "left out on a limb to be a little scapegoat." This is when HASTINGS made the decision to obtain an attorney (Exhibit 8, page 23).

MATHER, Director of Nuclear Medicine and Ultrasound at Bloomington Hospital, was interviewed on December 19, 1985. MATHER described his background in the nuclear medicine profession as follows. MATHER stated that he has been with Bloomington Hospital since July 10, 1964. He is board-certified in pathology and trained in his pathology residence in aspects of nuclear medicine. In 1965, MATHER stated that a limited nuclear medicine service was started [at Bloomington Hospital] which consisted largely of thyroid uptakes. MATHER stated that in 1967, the first scanner was obtained and patient scanning began. In 1973, MATHER passed the board examination from the American Board of Nuclear Medicine. In 1977, MATHER left the pathology group and joined the radiology group in the hospital, and since that time has limited his practice to nuclear medicine and diagnostic ultrasound (Exhibit 18, pages 3-4).

MATHER demonstrated his understanding of what constitutes a diagnostic misadministration by defining the term as "the administration of a radiopharmaceutical other than the one designated for the procedure to be done on the patient" (Exhibit 18, pages 4-5).

INVESTIGATOR'S NOTE: MATHER's understanding of what constitutes a diagnostic misadministration is in concert with 10 CFR 35.41(a).

MATHER also exhibited an understanding and comprehension of the NRC's reporting requirements regarding diagnostic misadministrations. MATHER stated that "a report is required to be sent to the regional office of the NRC describing the incident and the reasons for it, if known, and steps that have been taken to prevent future misadministrations. These are due in the hands of the NRC

within the first ten days of the quarter following the event." MATHER also stated that "the attending physician is to be notified in writing" (Exhibit 18, page 5).

INVESTIGATOR'S NOTE: MATHER's understanding of NRC reporting requirements regarding diagnostic misadministrations is in agreement with 10 CFR 35.43.

MATHER stated that his understanding of what records are to be maintained is, "we are required to keep copies of the reporting that we have done and copies of the letters to the physicians, and any other incident reports or documents appropriate to the incident" (Exhibit 18, pags 6).

INVESTIGATOR'S NOTE: MATHER's understanding of what records must be maintained by the licensee of misadministrations is in agreement with 10 CFR 35.44.

MATHER identified a diagnostic misadministration report dated October 8, 1982, documenting an incident of misadministration which occurred September 27, 1982, and bearing MATHER's signature (Exhibit 18, pages 6-7; Exhibit 19).

INVESTIGATOR'S NOTE: MATHER's identification of the September 27, 1982, misadministration and subsequent October 8, 1982, report of said misadministration provides evidence of MATHER's understanding regarding what constitutes a diagnostic misadministration and the NRC's reporting requirements.

MATHER was asked to address each of the four patients in question.

1. Regarding [redacted] MATHER stated that [redacted] was referred to the Bloomington Nuclear Department for a bone scan and was given instead, pertechnetate (Exhibit 18, page 8).

INVESTIGATOR'S NOTE: MATHER told NRC inspectors on October 23, 1984, that there had not been any misadministrations regarding the four patients in question, one of which was [redacted]

MATHER stated that he (on October 23, 1984) did not recall the [redacted] administration at all when NRC inspectors, on that day, asked him (MATHER) about [redacted] MATHER was reminded by CANIANO that only [redacted] October 17, 1983, film was made available to the NRC inspectors that day. MATHER stated, in response to CANIANO, that "we did not find any--these films [October 14, 1983, misadministration film of [redacted] were not in the nuclear medicine jacket when you were here." MATHER explained that the film in question [October 14, 1983] were found in the x-ray jacket intermingled with x-ray film (Exhibit 18, pages 9-10).

INVESTIGATOR'S NOTE: LEWIS (Chief Radiological Technologist and Record Custodian for Bloomington Hospital's Nuclear and X-ray Departments) found the missing [October 14, 1983] nuclear studies which revealed the misadministration of [redacted] intermingled with the x-ray film of [redacted] as MATHER stated (Exhibit 3, Attachment E, page 2; Exhibit 11, pages 14-15).

MATHER addressed the apparent change of the date [October 14, 1983] to October 17, 1983, which appears on the [redacted] 8" x 10" nuclear film folder, as follows, "the 14th after reviewing all the films, was the day of the misadministration. [redacted] was rescheduled back, then I

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would assume, on the 17th for the procedure that was supposed to have been done" (Exhibit 19, page 10).

MATHER stated in response to the question "did you [MATHER] change it [the date on the folder] from the 14th to the 17th?" MATHER responded "no, sir" (Exhibit 18, page 11, lines 1-3).

INVESTIGATOR'S NOTE: MATHER was observed by NRC Inspectors CANIANO and SHEAR changing the date October 14, 1983 to October 17, 1983 (Exhibit 3, page 6, 'Patient 2').

11. MATHER described the type of nuclear study performed on [redacted] MATHER described a renal scan (kidney scan) requested by TOULOURIAN (the referring physician). MATHER concluded that "activity in the liver and in the spleen ... should not be there," leading MATHER to believe the patient [redacted] "was probably given the material designed to be given for liver-spleen imaging." According to MATHER, he did not recall having observed it (the misadministration) "under the pressure of the circumstances." MATHER did not, to his recollection, make a written referral to TOULOUKIAN.

INVESTIGATOR'S NOTE: MATHER still would not acknowledge that a misadministration took place with [redacted] HASTINGS, however, had already stated that he told MATHER about the misadministration of [redacted] at which time, MATHER instructed HASTINGS to re-administer [redacted] (Exhibit 8, page 7, lines 13-25)

MATHER emphasized that he thinks "probably" there were two injections, however, "it was late in the day, and it was a very busy day. I do not recall specifically that there was." MATHER stated that the probability is high that there was a misadministration (Exhibit 18, page 15).

MATHER was reminded by NRC Inspector CANIANO that at the time of the initial request by the NRC inspectors (October 23, 1984) for MATHER to provide the nuclear films of [redacted] that they (the inspectors) were informed by MATHER that the film was not available, and they (the film) had been sent to another hospital. MATHER was asked "did you personally look for those films, or did one of your technologists?" MATHER responded, "no; I asked someone to look for them" (Exhibit 18, page 15).

INVESTIGATOR'S NOTE: HASTINGS, a Nuclear Medicine Technologist, stated that he was asked by MATHER (on October 23, 1984) to pull the file for [redacted] and observed MATHER pull the nuclear film out, look at it, and then replace it in the file. The nuclear film was subsequently found by a technologist in the [redacted] file and reviewed by the NRC inspectors during the October 23-24, 1984, inspection at Bloomington Hospital (Exhibit 3, page 7, paragraph 2; Exhibit 4, page 16).

INVESTIGATOR'S NOTE: MATHER theorized that [redacted] records were forwarded to the Crane Naval Depot. However, there were no records to support MATHER's theory, and an eyewitness and subsequent find of the requested records contradict MATHER (Exhibit 18, page 16).

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MATHER was questioned regarding TOULOUKIAN's knowledge about the [redacted] nuclear study. MATHER stated that "Dr. TOULOUKIAN is a gastro-enterologist, and he is not informed about nuclear medicine; he (TOULOUKIAN) knows kidneys when he sees it, but the other activity would not mean anything to him" (Exhibit 18, page 17, lines 1-4).

INVESTIGATOR'S NOTE: MATHER prefaced the above comment by stating that he had talked with TOULOUKIAN following the December 5, 1985, OI interview with TOULOUKIAN, wherein TOULOUKIAN stated that it appeared to him that [redacted] scans exhibited signs of a dual administration, therefore, a misadministration (Exhibit 6; Exhibit 19, page 16, line 22).

MATHER further acknowledged that TOULOUKIAN was not an expert in the field, and would not be able to look at the nuclear film and make a determination based on his professional background (Exhibit 19, page 17, lines 5-9).

III. MATHER was questioned about the 3" x 5" personal history card of [redacted] which reflects both a bone scan and meckels scan appearing to have been ordered for the same day, August 3, 1984. MATHER stated that "when a misadministration occurs...it's important to note someplace in the records...that a bone scan was in fact done on this patient" (Exhibit 16; Exhibit 18, page 18).

MATHER states that the 3" x 5" personal history card, at the time of [redacted] misadministration, was used to reflect what was done and not what was ordered (Exhibit 18, page 19, line 23 through page 20, line 12).

MATHER stated that he either typed the bone scan information on [redacted] card or had it done (Exhibit 18, page 36).

INVESTIGATOR'S NOTE: HASTINGS pulled the card and MATHER made the additional entry.

LEWIS stated that he had responsibility for maintaining records such as x-ray folders and nuclear file folders for individual patients. This responsibility was bestowed upon him in mid-1983 when the x-ray and nuclear files began to be merged. This process was complete in mid-1984, prior to the NRC inspection. Regarding the 3" x 5" personal history cards, LEWIS stated that the cards reflect the order/requisition and is usually completed long before the patient is examined or scanned (Exhibit 11, pages 4-5 and 17).

MATHER further stated that (as of August 3, 1984) "LEWIS was not involved in our department (the Nuclear Medicine Department) to the extent that he is now" (Exhibit 18, page 20, lines 3-4).

INVESTIGATOR'S NOTE: LEWIS' statement that the merger of x-ray and nuclear files was complete in mid-1984, in addition to the procedure that the 3" x 5" cards reflect what is ordered/requisitioned, is in direct conflict with MATHER's statement regarding what is recorded on the 3" x 5" personal history cards. [redacted] nuclear study was on August 3, 1984, which could have been well within the time frame in which LEWIS' procedure regarding the 3" x 5" card was being carried out. This would contradict MATHER's statement.

IV. Regarding [redacted] MATHER stated that [redacted] was misadministered on the same day that [redacted] was misadministered, August 3, 1984. MATHER stated that after his initial recollection (on October 23, 1984) that there had been no misadministrations, he reviewed the images and did recall the misadministration (Exhibit 18, page 22).

MATHER identified (for the record) his signature on HASTINGS' August 3, 1984 "Oral Discussion/Written Notice of Instruction," which provided evidence of MATHER's immediate knowledge of the [redacted] misadministration. MATHER attributed his failure to report the misadministration of [redacted] and [redacted] as an "oversight" (Exhibit 9, Exhibit 18, page 22).

At this point, MATHER was questioned regarding the events surrounding the inspection effort itself.

I. Regarding the missing October 14, 1983 nuclear film of [redacted] during the October 1984 NRC inspection, MATHER stated that he went to search for the film himself, and [redacted] was with him (Exhibit 18, page 24).

MATHER stated that he removed the small folder (the 8" x 10" nuclear folder) from the larger x-ray folder. MATHER stated that "not all films were in it; that was clear from the list of films on the front."

MATHER described how he searched through the film. He stated that he "began leafing through other films in there" and "as I did so, pulling out films that are roughly the same size, saying, 'well, they don't need to see these, they don't need to see these: it's obvious they're x-rays.'" MATHER further stated, "I did not find [redacted] films in here" (Exhibit 18, page 24).

[redacted] stated that on October 23, 1984 (during the NRC inspection) [redacted] was asked by MATHER to locate the [redacted] film. Upon locating the film and notifying MATHER, he removed the film from the 8" x 10" nuclear folder which revealed the October 14, 1983 misadministration and placed the October 14, 1983 film in with the x-ray film. MATHER then carried the 8" x 10" nuclear film folder to the NRC inspectors, minus the October 14, 1983 film (Exhibit 2; Exhibit 3, page 8, paragraph 3).

MATHER further stated that he "overlooked" the film and that he did not take every film out of the [redacted] jacket. He further stated that the films in question "probably were there" (Exhibit 18, page 25, lines 1-3).

INVESTIGATOR'S NOTE: The film was later located by LEWIS. The October 14, 1983 film was in the x-ray film folder where [redacted] said MATHER had placed the film in question.

MATHER denied that he pulled the October 14, 1983 film from the [redacted] nuclear film folder. He stated that he "had nuclear film in my hand, I had x-rays in my hand. No one looking could see which films I was looking at." Regarding the allegation, MATHER also said, "I don't believe they could have told that (that he pulled the October 14, 1983 film) for certain." MATHER denied that he did anything to purposefully deceive the NRC (Exhibit 18, page 25, lines 10-17, page 26, lines 4-6).

MATHER was again asked (regarding the change of the dates on the nuclear folder of [redacted] from October 14 to October 17, 1983) if he knew who changed the dates. MATHER's response was, "no, I do not" (Exhibit 18, page 26, lines 7-10).

At this time, CANIANO told MATHER that he (CANIANO) witnessed MATHER (while in the presence of SHEAR and Tom SCHUMACHER of the State of Indiana) scratch out 14 and put 17. MATHER stated that "I don't remember that, Mr. CANIANO" (Exhibit 18, page 26, lines 13-20).

II. Regarding [redacted] MATHER denied any recollection of a technologist notifying him of [redacted] misadministration, stating, "I do not recall that conversation. It may have taken place, but I do not at this time recall that conversation."

INVESTIGATOR'S NOTE: [redacted] and HASTINGS have all stated that [redacted] had received a misadministration and that MATHER was notified at the time of the occurrence, and directed that [redacted] be re-administered. HASTINGS stated (following the NRC inspection in October 1984) that MATHER advised him "it's not against the law not to remember things" (Exhibit 8, page 21).

When asked specifically if [redacted] had been misadministered, MATHER again stated that "there is a high probability" and "nothing in this business is a certainty; no sir, I think the probability is high that there was." At this time, MATHER was presented the study conducted on the nuclear film in question by Dr. Stephen PINSKY, Director, Division of Nuclear Medicine, Michael Reese Hospital and Medical Center, Chicago, IL (Exhibit 3, Attachment F; Exhibit 18, page 28, lines 19-25).

MATHER compared the film analyzed by PINSKY to the original film in [redacted] nuclear folder and concluded that both were the same. MATHER was then allowed to review PINSKY's November 6, 1984, analysis of the [redacted] nuclear film (Patient 1) of PINSKY's report. PINSKY stated in his report that the nuclear study conducted on [redacted] revealed that "the findings are consistent with technetium sulphur colloid administration prior to the administration of the renal agent" (Exhibit 3, Attachment F, Patient 1; Exhibit 18, page 29, lines 9-14).

MATHER, upon reviewing the analysis prepared by PINSKY, agreed with PINSKY's findings. MATHER also acknowledged that he had denied (to the NRC inspectors) that a misadministration on [redacted] had taken place. MATHER was asked why he denied the [redacted] misadministration, even though the misadministration had been revealed to him at the time of the occurrence, and further, why he had not notified the NRC (Exhibit 18, page 31, lines 2-25).

MATHER's response to the question of "why" was, "I don't believe I can give an excuse for having denied it" (Exhibit 18, page 32, lines 1-2).

III. Regarding [redacted] MATHER was questioned regarding the personal history card which reflects both a bone scan and an abdominal scan for meckels. MATHER's previous explanation for the card reflecting the bone scan was that "it's important to note someplace in the records...that a bone scan was, in fact, done on this patient" (Exhibit 18, page 18).

MATHER had also stated that the personal history card was used to reflect what was done, not what was ordered (Exhibit 18, pages 19-20).

In view of MATHER's explanation, he was asked why [redacted] folder did not reflect the bone scan (the misadministration) as did [redacted] folder and 3" x 5" card. MATHER responded that "it should have been added to [redacted] form" (Exhibit 18, page 32, lines 7-19).

MATHER denied having directed the technologists (HASTINGS and [redacted] to mislead the NRC during the October 23-24, 1984, inspection (Exhibit 18, pages 33-34).

MATHER, in answering the question of "have you made the comment that it was too much red tape and paperwork to report to the NRC?" stated, "I at no time made a comment, to the best of my recollection, that the amount of paperwork would preclude reporting this to the NRC" (Exhibit 18, page 35).

[redacted] stated that MATHER had stated, upon learning of [redacted] misadministration of [redacted] (March 28, 1984) that "it is too much paperwork and red tape to report it to the NRC" (Exhibit 2).

MATHER stated that "I really have no conceivable reason for not doing it (reporting the misadministration). Oversight. And a reluctance to do paperwork. I prefer others do this for me. I don't like to do it" (Exhibit 18, pages 38-41).

HASTINGS stated that he had informed MATHER following the NRC inspection that [redacted] "had told them (the NRC) everything" regarding the misadministration to the patients in question (Exhibit 8, pages 22-23).

MATHER acknowledged the call from HASTINGS, but stated that he could only recall that "Mr. HASTINGS was distraught," but MATHER said, "I do not recall the text of that call."

INVESTIGATOR'S NOTE: According to HASTINGS, soon after the NRC inspection and the phone call, MATHER went to see the hospital attorney. It was after MATHER's alleged meeting with the attorney that he allegedly told HASTINGS "it's not against the law not to remember things" (Exhibit 8, page 21).

MATHER made the following comments regarding his failure to report the four misadministrations in question:

In response to the following questions: (Q) "In these four patients...it was demonstrated earlier in the interview that you are aware and cognizant of all the misadministrations, diagnostic, reporting requirements, record maintenance, and whatever." MATHER responded, "yes, sir." (Q) "And that your (MATHER's) background is extensive enough in the field that you are capable of recognizing what you have demonstrated today. However, the misadministrations did take place. The NRC was not notified in accordance with the 10 CFR requirements. In that regard, I would like to ask you in general, what were the circumstances? What occurred? Why did you all of a sudden stop notifying the NRC?" (Exhibit 18, pages 38-39) MATHER responded to the question as follows: "You are correct that I am, and was, aware of the reporting requirements." MATHER further stated,"this was [my] responsibility to handle. I simply did not do

it" (Exhibit 18, page 39).

MATHER stated that his failure "was not intentional." However, "as time went on, they (the misadministrations) went out of my mind, for whatever reason, but they did. We (Bloomington Hospital Nuclear Department) had in the past reported them, we have since. This was, if this is the proper term, an administrative oversight on my part" (Exhibit 18, pages 39-40).

MATHER further stated "that is the best explanation I have for it: administrative oversight. I know now, and I knew then that a misadministration as such was not, in a sense, contrary to the regulations; not reporting it (the misadministration) is; but having them (misadministrations) is not. I was aware of that. And, I would have had nothing to gain by not reporting them (misadministrations)" (Exhibit 18, page 40).

HASTINGS stated in his deposition that he (HASTINGS) was talking with MATHER (following the October 1984 NRC inspection) about [redacted] and [redacted] (both of whom were misadministered on August 3, 1984) when MATHER allegedly told HASTINGS that he (MATHER) "was sorry about the trouble we (Bloomington Nuclear Medicine Department) got into." HASTINGS said he told MATHER that he (HASTINGS) thought that he (MATHER) reported these (the misadministrations). HASTINGS stated that MATHER responded by saying he (MATHER) started to (to report the misadministrations), but he (MATHER) was scared of a big investigation (Exhibit 8, pages 18-19).

MATHER stated, when attempting to explain his failure to report the misadministrations in question, "granted, a cluster of them might bring Mr. CANIANO or another specialist down to see what was going on" (Exhibit 18, pages 40-41).

In response to questions regarding alleged direction by MATHER to the technologists to mislead or misdirect the NRC inspectors, MATHER stated the following: "The inspection (October 23-24, 1984) of course, was unexpected. It took most of us by surprise...the stress of having unexpected people come in saying these people (allegers) have made allegations is great. We were all somewhat flustered by this...we talked a lot. I don't recall what we said, but we talked a lot" (Exhibit 18, page 43).

MATHER stated that "I did not knowingly say anything of that kind. If something I said was misinterpreted, I regret that very much" (Exhibit 18, page 44).

Willfulness/Intent

Allegation 1: Alleged Willful Failure to Report Diagnostic Misadministrations

It is readily apparent through both eye witness accounts, physical evidence, expert analysis of nuclear scans, referring physicians' interpretation, and admissions by MATHER, that the alleged diagnostic misadministrations of [redacted] did occur. It is further apparent that MATHER was knowledgeable of the required NRC reported requirements, and for various reasons, did not abide by said requirements.

MATHER, in his sworn statement, acknowledged that he was aware of the NRC reporting requirements, but did not comply with said requirements, citing both administrative oversight and a reluctance on his part to do paperwork,

something he preferred others do for him. MATHER further stated that he had no conceivable reason for not reporting the diagnostic misadministrations to the NRC as required.

Allegation 2: Alleged Willful Impediment to NRC Inspectors Through Material False Statements and Through the Withholding of Records Requested by NRC Inspectors

On October 23, 1984, the first day of the NRC RIII inspection effort at Bloomington Hospital, MATHER responded to NRC inspectors by stating that there had been no unreported misadministrations of the patients in question: [redacted] and [redacted] During the NRC inspection effort at Bloomington Hospital, which occurred on October 23-24, 1984, MATHER directed the hospital's two technologists [redacted] and HASTINGS) to mislead the NRC inspectors. MATHER's directions to the technologists was to respond to the inspectors' questions in such a manner that would make it appear that no unreported misadministrations had occurred. The response solicited by MATHER of the technologists also had the effect of corroborating MATHER's denial that unreported diagnostic misadministration had not occurred at Bloomington Hospital. HASTINGS, one of the technologists, lied to the NRC inspectors because he was afraid of losing his job if he had not responded as directed by MATHER.

On two separate occasions during the October 23-24, 1984, inspection, MATHER was observed by a technologist reviewing nuclear scans requested by the NRC inspectors, which MATHER subsequently failed to provide to the NRC. MATHER told the NRC inspectors that the requested films [redacted] October 14, 1983 and [redacted] March 28, 1984) were not available. The requested film was found by hospital personnel subsequent to MATHER's search and provided to the NRC inspectors. [redacted] nuclear scan of March 28, 1984 was found in [redacted] nuclear film file during the inspection effort and following HASTINGS' observance of MATHER reviewing [redacted] file while acting upon the request of the NRC inspectors. MATHER was also observed by [redacted] pulling the October 14, 1983 film of [redacted] from the nuclear film package and placing said film into the x-ray film file of [redacted] It was not until the NRC:RIII requested an investigation be initiated by KOHR that the October 14, 1983 film was found by the Bloomington Hospital staff. The October 14, 1983 film in question was found in [redacted] x-ray film package. Both the March 28, 1984 film of [redacted] and the October 14, 1983 film of [redacted] revealed evidence of a misadministration, contrary to MATHER's October 23, 1984, response to the NRC inspectors.

Associated with [redacted] MATHER, while denying the unreported misadministration in [redacted] case, was observed by NRC inspectors CANIANO and SHEAR altering [redacted] file by changing the October 14, 1983 date to read October 17, 1983. MATHER referred to the October 14, 1983 date as an administrative mistake. It was later documented, as previously indicated, that October 14, 1983 was not an administrative mistake.

MATHER was also observed, and later in his sworn statement admitted, altering [redacted] personal history card by adding to [redacted] card the radiopharmaceutical which had been misadministered. The effect of adding the misadministered radiopharmaceutical to [redacted] card would have the effect of making it appear to the NRC inspectors that the misadministered radiopharmaceutical had

been ordered by the referring physician, thus by definition, making it appear that no misadministration had occurred. MATHER's explanation, that he was adding the misadministered radiopharmaceutical so that a record of the administration of the wrong radiopharmaceutical would be available to future doctors, lacks credibility due to MATHER's failure to document [redacted] who was misadministered on the same day as [redacted] and whose personal history card did not reflect (as [redacted] did) the misadministered radiopharmaceutical.

[redacted] misadministration was well documented despite MATHER's denial of it (October 23, 1984). HASTINGS' personal file reflected HASTINGS having been admonished for [redacted] misadministration on October 23, 1984, for which HASTINGS admitted responsibility. Therefore, to add to [redacted] personal history card, the misadministered radiopharmaceutical would not have obscured the fact that a misadministration had occurred in [redacted] case.

MATHER also, according to HASTINGS (following the October 1984 NRC inspection), apologized to HASTINGS for the trouble caused by MATHER not reporting the misadministration. MATHER further allegedly stated that he had started to report the misadministrations, but was afraid of a big investigation. MATHER's alleged comment to HASTINGS is somewhat supported by MATHER's response in his sworn statement that he felt that a cluster for misadministration might bring an NRC inspector to see what is going on.

On November 1, 1984, KOHR responded in writing to a NRC inquiry regarding the alleged misadministrations. While helping document three of the four alleged incidents, KOHR stated that regarding [redacted] his inquiry supported MATHER's position that no unreported misadministrations had occurred in [redacted] particular case. KOHR went further in [redacted] case by alleging remarks from [redacted] referring physician, TOULOUKIAN, which were later adamantly denied by TOULOUKIAN. The remarks attributed to TOULOUKIAN by KOHR would have supported MATHER's denial of a misadministration in [redacted] incident if TOULOUKIAN would have supported KOHR's characterization of TOULOUKIAN's remarks in KOHR's November 1, 1984, letter to the NRC.

Agent's Conclusion

Regarding Allegation 1, it has been clearly established that the four patients in question did receive unreported diagnostic misadministrations. MATHER also willfully failed to report these diagnostic misadministrations as required by the NRC. MATHER never acknowledged a diagnostic misadministration until forced to by overwhelming evidence presented by either the Bloomington Hospital administrative staff or the NRC.

Regarding Allegation 2, it has been established that MATHER made material false statements to NRC inspectors by denying that unreported diagnostic misadministrations had occurred. It has further been established that MATHER attempted to impede the NRC inspection by directing technologists on his staff to lie to the NRC inspectors. MATHER also failed to provide requested nuclear scan film (that was available) to the NRC inspectors, which revealed diagnostic misadministrations.

KOHR, President of Bloomington Hospital, responded to the NRC with false information regarding the misadministration of one patient, [redacted]

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STATUS OF INVESTIGATION

Evidence developed during this investigation demonstrates that Dr. MATHER, RSO of Bloomington Hospital, made material false statements to NRC Inspectors, failed to provide NRC requested documents material to an NRC inspection, altered records relevant to an NRC inspection, and directed others to lie to NRC inspectors.

This investigation is CLOSED.

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SUPPLEMENTAL INFORMATION

This investigation has developed information indicating possible violation of Federal criminal law by Dr. Glen MATHER. Under the circumstances, a copy of the final Report of Investigation has been referred to the Department of Justice.

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LIST OF EXHIBITS

1. Report of Interview of [redacted] dated October 16, 1985.
2. Report of Interview of [redacted] dated October 16, 1985.
3. Copy of NRC Region III Inspection Report No. 030-01644/84-01.
4. Report of Interview of Rex HASTINGS dated December 4, 1985.
5. Copy of sworn statement of Roland E. KOHR dated December 18, 1985.
6. Report of Interview of Dr. James S. TOULOUKIAN dated December 5, 1985.
7. Copy of letter from Dr. TOULOUKIAN to H. G. Walker dated December 20, 1985.
8. Copy of sworn statement of Rex HASTINGS dated December 18, 1985.
   A. Copy of memorandum from NRC Inspectors R. CANIANO and G. SHEAR dated January 10, 1986.
   B. Copy of memorandum from NRC Inspector Gary L. SHEAR dated February 11, 1986.
9. Copy of "Oral Discussion/Written Notice of Instruction" dated August 3, 1984.
10. Copy of sworn statement of Virginia DECKARD dated December 18, 1985.
11. Copy of sworn statement of Phil LEWIS dated December 18, 1985.
12. Copy of sworn statement of Phil LEWIS dated December 19, 1985.
13. Copy of [redacted] personal history cards.
14. Copy of [redacted] personal history cards.
15. Copy of [redacted] personal history card.
16. Copy of [redacted] personal history card.
17. Copy of memorandum from R. CANIANO dated December 31, 1985 with attachment.
18. Copy of sworn statement of Dr. Glen MATHER dated December 19, 1985.
19. Copy of a Report of Diagnostic Misadministration signed by Dr. MATHER dated October 8, 1982.