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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION V
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CALIFORNIA 94596

John Glenn
P.Lo review

JAN 18 1991

MEMORANDUM FOR: James Lieberman, Director
Office of Enforcement

FROM: John B. Martin
Regional Administrator

SUBJECT: DRAFT ORDER IMPOSING CIVIL PENALTY; TRIPLER ARMY MEDICAL CENTER (DOCKET NO. 030-03537; EA 90-132)

In an October 22, 1990 Notice of Violation and Proposed Imposition of Civil Penalty (NOV), the NRC proposed a civil penalty (CP) of $5,000 for a Severity Level I violation based on Tripler Army Medical Center's administration of I-131 to a nursing mother. The I-131 was administered, contrary to licensee procedures, without a determination prior to the administration that the mother was nursing. The licensee admitted the violation in a December 7, 1990 Reply (attached), but in a December 21, 1990 Answer (attached) requested mitigation or remission of the CP. As explained below, the licensee has submitted no new information that would persuade us to mitigate or or remit the CP.

Tripler argues that several factors support its argument. First, Tripler identified the incident and did not attempt to conceal it, seeking NRC guidance six days after discovery on whether it was reportable. Second, corrective actions were comprehensive and were implemented the day after Tripler's discovery of the incident. (The NRC's cover letter for the NOV noted that these factors weighed in favor of mitigation, and the staff noted in SECY-90-333 (at 3) that they would normally lead to full mitigation.) Third, in response to the NRC's explanation in its cover letter that the CP was proposed to "emphasize the importance of strict compliance" with NRC safety requirements and of management controls adequate to prevent similar violations, Tripler argues that no such emphasis is needed

> "because medical center decisions are by their very nature serious and often matters of life and death. Everything that effects patient care is important and is emphasized constantly. ... [But] human error can and does occur despite constant emphasis on patient care and safety. Could it have been prevented by more supervision? Since nothing of this kind had happened before during thousands of administrations, nor had there been any reported incidents from other hospitals or the NRC, our actions certainly met or exceeded the reasonably prudent person standard. ... The NRC's emphasis should ... not [be] on making [Tripler] an example by penalty. ... Other medical centers will change their procedures to comply with good patient care when they are given notice of a problem or incident. Their motive is better treatment and care, not the fact that another center was fined." Reply at 6-7.

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JAN 18 1991

required?

While the licensee's points have merit, we question whether it was reasonably prudent to permit reliance on informal, oral communications and to have no redundant checks before administering a radiopharmaceutical. Further, while a civil penalty may not be a panacea in terms of deterrence, we disagree with the licensee that it will have no deterrent effect. Moreover, the staff presented most of the licensee's arguments to the Commission in SECY-90-333 (including those for mitigation based on licensee identification and reporting and on corrective action), recommended a CP based in part on a significant injury having life-long effects on an individual, and the Commission did not object to that recommendation. Thus we cannot recommend mitigation or remission of the CP, and we have prepared the attached Order Imposing Civil Penalty. If it is decided to mitigate or remit the penalty, it may be appropriate to resubmit this matter to the Commission.

Regional Counsel has no legal objection to this package.

/s/ John B. Martin
John B. Martin
Regional Administrator

Attachments:
1. Draft Letter and Order Imposing
2. Licensee's Answer
3. Licensee's Reply

Docket No. 030-03537
License No. 53-00458-04
EA 90-132

Department of the Army
Commander, Tripler Army Medical Center
Tripler AMC, Hawaii 96859

Attention: Major General Girard Seitter III
Commanding Officer

Dear Sir:

SUBJECT: ORDER IMPOSING CIVIL PENALTY - $5,000

This refers to your letters dated December 7 and 21, 1990 in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by our letter dated October 22, 1990. Our letter and Notice describe one violation. You informed us of the event upon which the violation is based.

To emphasize the importance of strict compliance with NRC requirements to protect public health and safety, and to emphasize that you and other medical licensees must assure that management controls are adequate so that the necessary resources, oversight, and attention to detail prevent similar violations from occurring in the future, a civil penalty of $5,000 was proposed.

In your responses, you admitted the violation, but requested mitigation or remission of the civil penalty.

After consideration of your responses, we have concluded for the reasons given in the appendix attached to the enclosed Order Imposing Civil Monetary Penalty that mitigation or remission is unwarranted in this case. Accordingly, we hereby serve the enclosed Order on Tripler Army Medical Center imposing a civil monetary penalty in the amount of $5,000. We will review the effectiveness of your corrective actions during a future inspection.

PROPOSED ENFORCEMENT ACTION
NOT FOR PUBLIC RELEASE WITHOUT APPROVAL OF DIRECTOR, OE

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice", a copy of this letter and the enclosures will be placed in the NRC's Public Document Room.

Sincerely,

Hugh L. Thompson, Jr.
Deputy Executive Director for Nuclear
Materials Safety, Safeguards, and
Operations Support

Enclosures:
As stated

PROPOSED ENFORCEMENT ACTION
NOT FOR PUBLIC RELEASE WITHOUT APPROVAL OF DIRECTOR, OE

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UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	
Department of the Army	)	Docket No. 030-03537
Tripler Army Medical Center	)	License No. 53-00458-04
Tripler AMC, Hawaii	)	EA 90-132

ORDER IMPOSING CIVIL MONETARY PENALTY

I

The Department of the Army, Tripler Army Medical Center (Licensee) is the holder of Materials License No. 53-00458-04, issued by the Nuclear Regulatory Commission (NRC or Commission) on September 29, 1986. The license authorizes the medical and research use of radioactive materials in accordance with the conditions specified therein.

II

An inspection of the Licensee's activities was conducted from June 29 to July 2, 1990. The results of this inspection indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated October 22, 1990. The Notice states the nature of the violation, the provision of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violation. The Licensee responded to the Notice dated October 22, 1990. In its December 22, 1990 response, the Licensee admitted the violation, but argued that the $5,000 civil penalty proposed by the NRC should be mitigated or remitted.

III

After consideration of the Licensee's response and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that the violation occurred as stated, that the Licensee's arguments for mitigation or remission are not persuasive, and that the penalty proposed for the violation designated in the Notice should be imposed.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

The Licensee pay a civil penalty in the amount of $5,000 within 30 days of the date of this Order, by check, draft, or money order, payable to the Treasurer of the United States and mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555.

V

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Secretary, U.S. Nuclear Regulatory Commission and the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region V, 1450 Maria Lane, Suite 210, Walnut Creek, CA 94596.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event, the Licensee requests a hearing as provided above, the issue to be considered at such hearing shall be:

> Whether on the basis of the violations admitted by the Licensee, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, Jr.
Deputy Executive Director for Nuclear
Materials Safety, Safeguards, and
Operations Support

Dated at Rockville, Maryland
this __ day of February, 1991

APPENDIX

EVALUATIONS AND CONCLUSIONS

On October 22, 1990, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for a violation identified during an NRC inspection. The Department of the Army, Tripler Army Medical Center (Licensee or Tripler) responded to the Notice on December 7 and 21, 1990. Tripler admitted the violation but argued for mitigation or remission of the $5,000 civil penalty proposed by the NRC. The NRC's evaluation and conclusion regarding the licensee's request is as follows:

Restatement of Violation

A. 10 CFR 35.25(a)(2) provides, in part, that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user shall require the supervised individual to follow the instructions of the supervising authorized user.

The instructions of the supervising authorized user, entitled "Management of Pregnant Patients", dated May 25, 1989, require, in part, that all female patients between the ages of 12 and 60 fill out a pregnancy statement. The statement asks if the patient is pregnant or nursing (breast feeding). The instructions further require, with exceptions not applicable here, that no patient who indicates that she is pregnant or lactating be given a radioactive substance.

Contrary to the above, on June 19, 1990, a nuclear medicine technologist, an individual under the supervision of the licensee's authorized user, administered 4.89 millicuries of iodine-131 to a patient without having the patient complete the required "pregnancy statement", specifically, the portion that asks if the patient is nursing (breast feeding); and the patient was lactating at the time.

Summary of Licensee's Request for Mitigation or Remission

While admitting the violation in a December 7, 1990 Reply, in a December 21, 1990 Answer the Licensee requested mitigation or remission of the civil penalty. Tripler argues that several factors support its argument. First, Tripler identified the incident and did not attempt to conceal it, seeking NRC guidance six days later on whether it was reportable. Second, corrective actions were comprehensive and were implemented the day after Tripler's discovery of the incident. Third, in response to the NRC's explanation in its cover letter that the CP was proposed to "emphasize the importance of strict compliance with" NRC safety requirements and of management controls adequate to prevent similar violations, Tripler argues that no such emphasis is needed

> "because medical center decisions are by their very nature serious and often matters of life and death. Everything that effects patient care is important and is emphasized constantly. ... [But] human error can and does occur despite constant emphasis on patient care and safety. Could it have been prevented by more supervision?

> Since nothing of this kind had happened before during thousands of administrations, nor had there been any reported incidents from other hospitals or the NRC, our actions certainly met or exceeded the reasonably prudent persons standard. ... The NRC's emphasis should ... not [be] on making [Tripler] an example by penalty. ... Other medical centers will change their procedures to comply with good patient care when they are given notice of a problem or incident. Their motive is better treatment and care, not the fact that another center was fined." Reply at 6-7.

NRC Evaluation of Licensee's Request for Mitigation

Before issuing the proposed civil penalty, we considered most of the arguments now submitted by the Licensee. For example, we noted in our October 22, 1990 letter to the Licensee that a civil penalty was warranted despite its commendable identification and reporting of the event and its prompt, aggressive corrective actions. Further, while the Licensee's other points have merit, we question whether it was reasonably prudent to permit reliance on informal, oral communications and to have no redundant checks before administering a radiopharmaceutical. Moreover, while a civil penalty may not be a panacea in terms of deterrence, we disagree with the Licensee that a penalty will have no deterrent effect.

NRC Conclusion

The NRC has concluded that this violation occurred as stated, and that neither mitigation nor remission of the civil penalty is warranted. Consequently, the proposed civil penalty in the amount of $5,000 should be imposed.

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DEPARTMENT OF THE ARMY
HEADQUARTERS, TRIPLER ARMY MEDICAL CENTER
TRIPLER AMC, HAWAII 96859-5000

REPLY TO ATTENTION OF:

December 21, 1990

Office of the Center
Judge Advocate

Director
Office of Enforcement
U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C;. 20444

Dear Sir:

Enclosed is the Answer to Notice of Violation requesting mitigation or remission of the proposed penalty.

If there are any questions, please contact me at (808) 433-5311.

Sincerely,

David A. Little
Major, U.S. Army
Center Judge Advocate

Enclosure

Copy furnished:

Mr. John B. Martin
Regional Administrator
U.S. Nuclear Regulatory Commission
Region V
1450 Maria Lane, Suite 210
Walnut Creek, California 94596-5368

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Answer to Notice of Violation and Imposition of Fine

(10 CFR 2.205)

To Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555

Reference USNRC By-product Material License Number 53-00458-04 (Human Use), Docket Number 030-03537, issued to the Department of the Army, Tripler Army Medical Center (TAMC), Honolulu, Hawaii, 96859-5000, expiration date of September 30, 1991, and NRC Inspection Report No. 030-03537/90-01.

Licensee, Tripler Army Medical Center has been cited under the provisions of 10 CFR Subsection 35.25, Supervision. Licensee is being penalized for the negligent act of one of its employees, and does not contest the validity of that provision of the law, but does contest the severity of the proposed penalty of $5,000.00 and requests mitigation or remission of the penalty for the reasons set out below:

Facts

On June 19, 1990, a nuclear medicine technologist, an individual under the supervision of the licensee's authorized user, administered 4.89 millicuries of iodine 131 to a patient from the Pacific Island of Truk without having the patient complete the required "pregnancy statement", specifically, the portion that asks if the patient is nursing; and the patient was lactating at the time. Shortly thereafter, the patient breast fed her three week old child, Pearl Lynn Phillip, causing ingestion of the iodine 131.

From 1983 to 1989, the patient underwent surgery and nuclear medicine diagnosis and therapy treatments for thyroid cancer. The therapy treatments (two) and diagnostic scans (four) were performed at Tripler Army Medical Center (TAMC). In June 1990, the patient was referred to TAMC for a routine metastatic survey (whole body scan) by her physician on the island of Truk to detect any remaining thyroid tissue which might be related to the original cancer. The Chief of Endocrinology was not informed that the patient delivered a baby girl on June 1, 1990 and might be nursing. He requested the Nuclear Medicine Department to perform a routine scan, but was unable to see her before her June 19th arrival at TAMC.

On June 19, the radiopharmacist who normally prepares iodine 131 oral doses, was performing in vitro isotope labeling of a blood specimen and delegated the task to the Nuclear Medicine Technologist. The Nuclear Medicine Technologist (NMT) had the responsibility for preparing, and administering the dose to the patient in accordance with the procedure prepared by the Acting

Chief of Nuclear Medicine (ACNM). TAMC's procedures require that all female patients age 12 and above fill out a pregnancy statement which is stamped on the patient consult form. The statement asks if the patient is pregnant or breast feeding with the appropriate "yes" or "no" answer to be circled. Also on the statement is printed "last MP" (menstrual period) where a date is to be written. Finally, the statement stamp contains a space where the patient is to sign her name. A second stamp on the form contains a space for "physician", "scheduling", "radiopharmacy", and "technologist injecting". The person responsible for each area is required to initial the space when they have completed their work related to that patient.

The patient arrived at the Nuclear Medicine Department for her dosing at approximately 9:00 AM on June 19, 1990. When she arrived the NMT asked the ACNM if the routine pregnancy and TSH tests were done. The ACNM replied that the tests were normal and instructed the NMT to dose the patient. The ACNM reviewed her multiple prior nuclear medicine studies and therapies, but did not speak to the patient at that time.

The NMT neglected to have the patient answer the pregnancy, breast feeding and menstrual period questions and did not initial the "radiopharmacy" and "technologist injecting" spaces on the patient personal data record form. A review of previous forms indicated that the information was normally obtained from patients. The NMT stated he was aware of the requirement to confirm breast feeding status and had been instructed in the past to do so as part of his training. He said he simply forgot to ask the remaining questions once the ACMN informed him the patient was not pregnant. At approximately 10:00 AM, June 19, 1990, the dose was administered orally to the patient.

After dosing, the patient left TAMC with instructions to return in two days for a scan. Apparently concerned about nursing her infant, she did not breast feed until 9:00 PM on the evening of June 19, 1990. At approximately 10:00 AM on June 21, 1990, she returned to TAMC for her whole body scan. During the scan, the NMT and ACNM noticed high uptake of iodine 131 in her breasts. The patient revealed she had given birth on June 1, 1990, on Truk, and had been nursing, supplementing with formula up to the morning of June 21, 1990. The mother was instructed by the ACNM to cease all breast feeding and to bring the infant to the hospital as soon as possible. The TAMC Radiation Protection Officer and patient's referring clinic, Endocrine Clinic were notified immediately.

At 1:00 PM on June 21, 1990, the patient and infant returned to TAMC. The infant was examined by an endocrinologist and the ACNM who stated that the infant appeared normal and weighed eight

pounds. A prescription was prepared to start the infant on synthroid, an artificial thyroid hormone. The infant received whole body and thyroid scans. Additional patient imaging was performed on July 25, 1990.

On the morning of June 22, 1990, the patient picked up from the TAMC pharmacy, a 30-day supply of synthroid and began administering doses to the infant as directed by her TAMC physician. A blood sample was taken from the infant at the Pediatric Clinic. The ACNM was present with the patient and infant at the pharmacy and Pediatric Clinic and explained to the patient and to a relative of the patient how to crush the synthroid tablets and mix with the infant's formula.

Early in the morning of June 25, 1990, the patient and infant arrived at the TAMC Pediatric Clinic. The infant weighed 8.27 pounds. At approximately 10:00 AM the infant was seen by the Pediatric Endocrinologist (PE). The ACNM and PE verified that the patient was not breast feeding the infant and that formula feedings with the synthroid were normal. The PE prepared a hand written consult sheet for the mother to deliver to her physician on Truk who, according to the consult sheet, she was to see in six weeks. The PE's consult sheet also specified laboratory tests, diagnostic scans and follow-up visits to TAMC for the child.

Following the pediatric consultation, on June 25, the patient visited the ACNM who gave her the consult sheet described above and the results of the scans of herself and her infant. She also picked up an additional 60-day supply of synthroid for her infant from the pharmacy. On June 27, 1990, the mother and infant left Honolulu for Truk.

Care Plan of Pearl Lynn Phillip

1. Mother and child returned to Hawaii on 23 July 1990. the baby was completely examined, and blood sent for appropriate studies. The baby then underwent a repeat scan of the thyroid, and the mother a repeat scan of her breasts, to measure residual iodine 131 activity. Following completion of studies, they returned home.

2. Colonel Richard A. Banks, MD, Chief, Pediatric Endocrine Service, traveled to Truk in early September 1990, in order to evaluate the child, to document facilities available for testing and to educate the local physicians on the need for close follow up.

3. The child and her mother will be brought back to Tripler Army Medical Center every three months for routine follow up

examinations. Cost of the travel and medical care will be paid by Tripler.

4. When the child is two years old, thyroid hormone replacement will be discontinued, and the child will have a thyroid scan six weeks later. If there is obvious thyroid tissue present at that visit, serious consideration will be given to ablation of the remaining thyroid tissue.

5. The child and mother will then be followed on a yearly basis unless indications for more frequent monitoring are found.

6. Thyroid hormone replacement will be continued indefinitely, unless a contraindication arises.

Current Condition of Pearl Lynn Phillip

Pearl Lynn Phillip was seen by Colonel Richard A. Banks, Chief Pediatric Endocrinology Service between 20 and 23 November in follow up for her accidental exposure to iodine 131. She is taking synthroid 37.5 mcg daily, and is growing normally. Her development is appropriate for a child of six months. Thyroid function tests done on 19 November showed a TSH of 59.87 uU/ml and a free T4 of 0.74 (Normal range 0.90 to 2.2). This is the first biochemical manifestation of her thyroid status, indicating that a state of hypothyroidism does exist. Due to these values, her synthroid dose was increased to 50 mcg daily. The child will be flown back to TAMC in two months for follow up laboratory studies.

Request for Mitigation or Remission

Section V B of 10 CFR Part 2, Appendix C (1990) enumerates several factors the NRC may consider in adjusting base civil penalty values. Licensee relies on the following to support its request to mitigate or remit the penalty.

1. Identification and Reporting. The incident occurred on June 19, 1990 and was identified on June 21, 1990, Thursday afternoon. It was reported to the NRC Regional Office in Walnut Creek, California on the following Wednesday, June 27 at 11:00 AM local time. There was no attempt to hide the incident. The Radiation Protection Officer was unsure whether or not the event was reportable since there was little guidance. He called the NRC to seek guidance and at that point it became a reportable event. Immediate action was taken to correct the problem when discovered on June 21, 1990.

2. Corrective Action to Prevent Recurrence. New policies and procedures were established for the Nuclear Medicine Service on June 22, 1990. From that day forward, all female patients between the ages of twelve and sixty years of age will sign a statement that they are not pregnant or breast feeding. The statement will be presented to the patient for completion by the receptionist at the time of check-in. After completing the statement the patient will return the form to the receptionist for verification. The technologist administering the radiopharmaceutical will review the information sheet and then verbally question the patient regarding pregnancy and breast feeding. The technologist will also verify that the receptionist has signed the sheet. The technologist will then sign the information sheet. The staff physician will review the information sheet for completeness and verify the signatures of the receptionist and technologist by signing the information sheet.

In addition:

a. Two nuclear medicine personnel must screen female patients for pregnancy or nursing.

b. Additional "Pregnancy and Breast Feeding" warning signs have been placed in the reception/waiting area and dose room.

c. A class was presented to all service personnel on June 22, 1990, with a sign in log completed by attendees.

d. Review of 25 female patient folders per month for completeness of patient questionnaire, and technician review will be performed as a quality assurance indicator.

The promptness and extent of this corrective action should be considered. The new policies were implemented the day after discovery of the misadministration, and they will prevent recurrence. This prompt corrective action was recognized in the October 22, 1990 letter of Mr. John B. Martin, the Regional Administrator for Region V, NRC, where he states, "The staff recognizes that you took prompt corrective action including modifying your quality assurance procedures to provide for a redundant system to verify pregnancy and nursing status and posting new signs in patient waiting areas to make clear that pregnant or nursing patients notify the receptionist. In addition, you established a plan for follow up medical care for the infant."

He further states, "The NRC recognizes your identification and reporting of the event, and your prompt, aggressive corrective actions."

Again, there has been no attempt to conceal this incident, no failure to cooperate with the NRC and no denial of responsibility. Most importantly, Tripler Army Medical Center identified the patient and child and immediately took action to prevent any further harm to the child or other patients.

3. Duration. The misadministration of June 19, 1990 was a one-time incident that was discovered on June 21, 1990. The patient was immediately cautioned to stop breast feeding and to bring the child in for examination and treatment. The child was examined on that same day and a course of treatment using synthroid was begun the next day.

4. Importance of Strict Compliance. Mr. Martin's letter of October 22, 1990 lauds licensee for its prompt corrective action, but goes on to say that a civil penalty of $5000.00 will be imposed to "emphasize the importance of strict compliance with NRC requirements to protect the public health and safety." Tripler Army Medical Center is a federal government institution that treats over one million patients a year. The leadership of the medical center is committed to excellent patient care and the daily operation of the center is governed by federal, state and local rules, regulations and guidelines. The importance of strict compliance is not lost on TAMC's staff because medical center decisions are by their very nature serious and often matters of life and death. Everything that effects patient care is important and is emphasized constantly. Nevertheless, an incident of a serious nature did occur. TAMC strives to build into its medical care system enough redundancy to prevent human error. In this case the patient consult request had the questions on it, the Nuclear Medicine Technologist knew the importance of having them answered and had been trained to ask them. Unfortunately he forgot. Human error can and does occur despite constant emphasis on patient care and safety. Could it have been prevented by more supervision? Since nothing of this kind had happened before during thousands of administrations, nor had there been any reported incidents from other hospitals or the NRC, our actions and procedures certainly met or exceeded the reasonable prudent person standard. The new system has more redundancy and should prevent any inadvertent exposure through breast milk.

Mr. Martin also says, "a civil penalty is warranted to emphasize that you and other medical licensees must assure that management controls are adequate...to prevent similar violations." The lesson has already been learned, and corrective action was taken long before the NRC was even involved. Our cooperation, attitude, and procedure changes show that there is and was an emphasis on safety and patient care. The NRC's emphasis should be on what was done to correct and treat, not on making TAMC an example by penalty. TAMC should be an example of

a medical center that reported and rectified the situation. Other medical centers will change their procedures to comply with good patient care when they are given notice of a problem or incident. Their motive is better treatment and care, not the fact that another center was fined.

5. Other Factors. Further eivdence of Tripler's spirit of cooperation and compliance can be seen in the radiation dosemitry studies performed on Pearl Lynn Phillip. The Nuclear Medicine Service did extensive studies of the child in June and July 1990. These studies calculated the radiation dose in rads for the child's total body and for internal areas including bones, glands and organs. Tripler's efforts and results garnered praise from Doctor Carol Marcus, the Medical Consultant to the NRC. Doctor Marcus felt these studies showed Tripler's dedication to the future treatment of the child by compiling every available piece of data. Apart from their diagnostic and treatment purpose there was an alternate benefit. They assisted researchers at Oak Ridge Associated Universities (ORAU) Oak Ridge, Tennessee, in their studies of nuclear medicine and radiation. For the first time ORAU was able to use and compare accurate biological data with their computer models. Using Tripler data ORAU calculated the dose in rads to eleven areas of the child's body. These studies are a valuable diagnostic and treatment tool which will aid future research and patient care.

6. Financial Impact. Finally, the financial impact should be considered. The civil penalty is not an insignificant sum, especially in these days of tightened federal funding. Also to date TAMC has spent more than $5000.00 on treatment and transportation of the patient and her child, to include sending the chief of pediatric endocrinology to the Island of Truk. The future care will cost thousands more. These amounts do not include the man hours spent by TAMC staff in implementing new procedures, investigation of the incident and all the various conferences and meetings required to rectify the problem, educate the staff and comply with NRC orders. Hundreds of man hours and thousands of dollars have already been spent and more will be spent in the future to properly care for this child. No further penalty should be imposed.

Conclusion

The solution to any medical misadministration is to treat the patient to prevent further harm, to analyze the problem and to take immediate corrective steps to rectify the situation to prevent harm to others. Tripler Army Medical Center discovered the problem, began a long-term treatment program for the child, investigated and implemented new policies and procedures in nuclear medicine. This incident was the first of its kind. It was caused by human error, an error made despite emphasis on safety, patient care and training in the use of the patient questionnaire. As long as there are humans involved in medical care, mistakes can be made, but Tripler has devised a system for nuclear medicine that will prevent this type of mistake in the future. Tripler should be rewarded not penalized for its cooperation, corrective measures, and rapid treatment of the child. The penalty should be reduced or eliminated.

AFFIDAVIT OF MAJOR GENERAL GIRARD SEITTER, III

STATE OF HAWAII)
) SS.
COUNTY OF HONOLULU)

MAJOR GENERAL GIRARD SEITTER, III, being first duly sworn on oath deposes and says:

1. That he is the affiant herein;

2. That he is a member of the United States Army, currently residing in the City and County of Honolulu, State of Hawaii;

3. That he has read the said Answer to Notice of Violation and knows the contents thereof;

4. That the said Answer to Notice of Violation is true to the best of his knowledge and belief.

Further affiant sayeth not.

Girard Seitter III
MAJOR GENERAL GIRARD SEITTER, III

Subscribed and sworn to before me this 21st day of December 1990.

Notary Public, State of Hawaii

Mary E. Bouce
Typed or Printed Name

My Commission Expires: 6 February 1994

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DEPARTMENT OF THE ARMY
HEADQUARTERS, TRIPLER ARMY MEDICAL CENTER
TRIPLER AMC, HAWAII 96859-5000

REPLY TO ATTENTION OF.

December 7, 1990

Office of the Center
Judge Advocate

Director
Office of Enforcement
U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

Dear Sir:

Enclosed is the Reply to the Notice of Violation. Licensee also will submit the Answer to Notice of Violation in about two weeks requesting mitigation or remission of the proposed penalty.

If there are any questions, please contact me at (808) 433-5311.

Sincerely,

David A. Little
Center Judge Advocate

Enclosures

Copy furnished:

Mr. John B. Martin
Regional Administrator
U.S. Nuclear Regulatory Commission
Region V
1460 Maria Lane, Suite 210
Walnut Creek, California 94596-5368

Reply to a Notice of Violation

To Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555

Reference USNRC By-product Material License Number 53-00458-04 (Human Use), Docket Number 030-03537, issued to the Department of the Army, Tripler Army Medical Center (TAMC), Honolulu, Hawaii, 96859-5000, expiration date of September 30, 1991, and NRC Inspection Report No. 030-03537/90-01.

Comes now Major General Girard Seitter, III, after being duly sworn upon oath makes the following statement:

1. Violation: On June 19, 1990, a nuclear medicine technologist, an individual under the supervision of the licensee's authorized user, administered 4.89 millicuries of iodine 131 to a patient without having the patient complete the required "pregnancy statement", specifically, the portion that asks if the patient is nursing (breast feeding); and the patient was lactating at the time. Shortly thereafter, the patient breast fed her three week old child, causing ingestion of the iodine 131 by the child.

Admit.

2. Reasons for Violation: From 1983 to 1989, the patient underwent surgery and nuclear medicine diagnosis and therapy treatments for thyroid cancer. The therapy treatments (two) and diagnostic scans (four) were performed at TAMC. During her pregnancy in 1989, the patient was referred to TAMC for a routine metastatic survey (whole body scan) by her physician on Truk. The purpose of the scan was to detect any remaining thyroid tissue which may be related to the original cancer. The request for the scan was originally made in May 1989 by the patient's physician on Truk. In May of 1990, the physician talked to the Endocrinology Service to re-verify the scheduling of the scan. The telephone call was initially screened by the secretary to the Chief of Endocrinology. The secretary noted the patient was pregnant and suggested the test be scheduled after delivery of the baby. Rescheduling to mid-June was accomplished. The Chief of Endocrinology was not informed that the patient delivered a baby on June 1st and might be nursing. The Chief of Endocrinology requested the Nuclear Medicine Department to perform a routine scan. He did not have the opportunity to see the patient before her June 19th arrival at TAMC for the administration of the iodine 131.

On June 19th the radiopharmacist, who normally prepares iodine 131 oral doses, was performing in vitro isotope labeling of a blood specimen and delegated the task to the Nuclear Medicine Technologist. The Nuclear Medicine Technologist (NMT) had the

responsibility for preparing, and administering the dose to the patient in accordance with a written prescription for the procedure prepared by the Acting Chief of Nuclear Medicine (ACNM) The NMT also had the same responsibilities for a second patient scheduled to receive a similar dose for a whole body scan. The NMT prepared two oral doses of approximately five millicuries each from a stock solution of sodium iodide (I-131) manufactured by Squibb Diagnostics and stored in the nuclear medicine hot lab hood. The doses were calibrated in the dose calibrator and then placed in the hood and readied for oral ingestion. TAMC's procedures required that all female patients age 12 and above fill out a pregnancy statement which is stamped on the patient consult form. The statement asks if the patient is pregnant or breast feeding with the appropriate "yes" or "no" answer to be circled. Also on the statement is printed "last MP" (menstrual period) where a date is to be written. Finally, the statement stamp contains a space where the patient is to sign her name. A second stamp on the form contains a space for "physician", "scheduling", "radiopharmacy", and "technologist injecting". The person responsible for each area is required to initial the space when they have completed their work related to that patient.

The patient from Truk arrived at the Nuclear Medicine Department without her infant for her dosing at approximately 9:00 AM on June 19th. When she arrived the NMT asked the ACNM if the routine pregnancy and TSH tests were done. The ACNM replied that the tests were normal and instructed the NMT to dose the patient. The ACNM reviewed her multiple prior nuclear medicine studies and therapies, but did not speak to the patient at that time.

The ACNM stated that a "normal" pregnancy test result was defined as negative (e.g. not pregnant). The routine pregnancy test consists of a blood sample from the patient which is analyzed for a hormone produced during pregnancy, human chorionic gonadotropin. The purpose of the test is to alert the physician to the radiation exposure potential to an embryo or fetus. The physician would then conduct a medical evaluation and decide if and under what conditions the nuclear medicine study should proceed.

The NRC medical consultant indicated that the routine pregnancy test would not detect a lactating patient. If the patient's medical record does not indicate a recent pregnancy and birth, knowledge of a lactating patient at TAMC can only be derived through the patient's personal history. The purpose of inquiring about lactation would be to alert the physician to the radiation exposure potential to the nursing infant and patient's lactating breast tissue. Upon learning of a lactating condition, the physician would conduct a medical evaluation and decide if and under what conditions the nuclear medicine study should proceed. The NMT neglected to have the patient answer the pregnancy,

breast feeding and menstrual period questions and did not initial the "radiopharmacy" and "technologist injecting" spaces on the patient personal data record form. A review of previous forms indicated that the information was normally obtained from patients. The NMT stated he was aware of the requirement to confirm breast feeding status and had been instructed in the past to do so as part of his training. He said he simply forgot to ask the remaining questions once the ACNM informed him the patient was not pregnant. At approximately 10:00 AM, June 19th, the dose was administered orally to the patient.

A review of the patient consult request for this case, showed that the pregnancy and breast feeding questions were circled "no" and "yes" respectively. During an interview with the inspectors, the NMT, who dosed the patient, stated he did not circle any answers. During a subsequent interview with the ACNM, the inspectors were informed that another NMT had circled the answers when he asked the patient if she was pregnant or breast feeding during the scan performed on June 21st.

3. Corrective steps: After dosing, the patient left TAMC with instructions to return in two days for a scan. Apparently concerned about nursing her infant, she did not breast feed until 9:00 PM on the evening of June 19th. At approximately 10:00 AM on June 21st, she returned to TAMC for her whole body scan. At about 11:00 AM the scan was begun. During the scan, the NMT and ACNM noticed high uptake of iodine 131 in the patient's breasts. Upon questioning, the patient revealed she had given birth on June 1, 1990, on Truk, and had been nursing, supplementing with formula up to the morning of June 21st. She indicated the infant was in the care of a relative in Honolulu. The mother was instructed by the ACNM to cease all breast feeding and to bring the infant to the hospital as soon as possible. The TAMC Radiation Protection Officer and patient's referring clinic, Endocrine Clinic were notified immediately.

At 1:00 PM on June 21st, the patient and infant returned to TAMC. The infant was examined by an endocrinologist and the ACNM who stated that the infant appeared normal and weighed eight pounds. A prescription was prepared to start the infant on synthroid, an artificial thyroid hormone. The patient's breasts were pumped to obtain a specimen of radioactive breast milk for analysis. A second milk sample was collected from the patient on June 25th and also saved for analysis. The infant received whole body and thyroid scans. Additional patient imaging was performed on July 25, 1990.

On the morning of June 22nd, the patient picked up from the TAMC pharmacy, a 30-day supply of synthroid and began administering doses (37.5 micrograms per day) to the infant as directed by her TAMC physician. A blood sample was then taken from the infant at the TAMC Pediatric Clinic. The ACNM was present with the patient and infant at the pharmacy and Pediatric Clinic and explained to

the patient and to a relative of the patient how to crush the synthroid tablets and mix into the infant's formula. The patient was also reminded of the need for her infant to be seen by the TAMC pediatric endocrinologist (PE). Upon his return from a business trip, the PE was contacted by the ACNM and an appointment for the patient and infant was made for 9:00 AM, June 25th.

On Sunday, June 24th, the ACNM contacted the patient at a local residence and verified that she and the infant were normal. The mother indicated she had no problems in giving the infant the synthroid in the formula as directed. She was instructed to express breast milk manually to reduce unnecessary radiation exposure to breast tissue.

Early in the morning of June 25th, the patient and infant arrived at the TAMC Pediatric Clinic. The infant weighed 8.27 pounds. At approximately 10:00 AM the infant was seen by the PE. The ACNM and PE verified that the patient was not breast feeding the infant and that formula feedings with the synthroid were normal. The PE prepared a hand written consult sheet for the mother to deliver to her physician on Truk who, according to the consult sheet, she was to see in six weeks. The PE's consult sheet also specified laboratory tests, diagnostic scans and follow-up visits to TAMC for the child.

The PE again explained to the patient the importance of keeping the child on synthroid as directed. The PE, ACNM and other TAMC personnel who spoke with the patient all believe she comprehended the physicians instructions because she spoke English very well and had been on synthroid herself since her thyroid was ablated. It was also learned in talking with the Micronesia Liaison Officer that the patient had completed some education involving nursing or other paramedical work which enhanced her awareness of her infant's medical condition and the need for synthroid.

Following the pediatric consultation, on June 25th, the patient visited the ACNM who gave her the consult sheet described above and the results of the scans of herself and her infant. She also picked up an additional 60-day supply of synthroid for her infant from the TAMC pharmacy. On June 27th, the mother and infant left Honolulu for Truk. On that same day at 2:00 PM Pacific Standard Time, the TAMC Radiation Protection Officer (RPO) called NRC Region V and reported the incident. Having previously queried persons outside of TAMC and being told the incident was not a reportable violation under NRC regulation, the RPO notified NRC Region V and was again told the incident was not reportable.

Tripler Army Medical Center has established a comprehensive follow-up care plan for the child. It is enclosed at Tab A. The child was last seen at TAMC on November 20, 1990 and is healthy and growing at a normal rate.

4. Corrective Steps to Avoid Further Violations: New policies and procedures were established for the Department of Radiology on June 22nd, 1990. From that day forward, all female patients between the ages of twelve and sixty years of age will sign a statement that they are not pregnant or breast feeding. The statement will be presented to the patient for completion by the receptionist at the time of check-in. After completing the statement the patient will return the form to the receptionist for verification. The technologist administering the radiopharmaceutical will review the information sheet and then verbally question the patient regarding pregnancy and breast feeding. The technologist will also verify that the receptionist has signed the sheet. The technologist will then sign the information sheet. The staff physician will review the information sheet for completeness and verify the signatures of the receptionist and technologist by signing the information sheet.

In addition:

a. Two nuclear medicine personnel must screen female patients for pregnancy or nursing.

b. Additional "Pregnancy and Breast Feeding" warning signs have been placed in the reception/waiting area and dose room.

c. A class was presented to all service personnel on 22 June 1990 with a sign in log completed by attendees.

d. Review of 25 female patient folders per month for completeness of patient questionnaire, and technician review will be performed as a Quality Assurance indicator.

5. Date of Full Compliance: The violation was an isolated incident that was discovered by Tripler Army Medical Center personnel two days after the iodine was administered. Corrective steps to treat the child and avoid future occurrences were taken immediately.

Care Plan

1. Mother and child returned to Hawaii on 23 July 1990. The baby was completely examined, and blood sent for appropriate studies. The baby then underwent a repeat scan of the thyroid, and the mother a repeat scan of her breasts, to measure residual iodine 131 activity. Following completion of studies, they returned home.

2. _ Chief, Pediatric Endocrine Service, traveled to Truk in early September 1990, in order to evaluate the child, to document facilities available for testing and to educate the local physicians on the need for close follow up.

3. The child and her mother will be brought back to Tripler Army Medical Center every three months for routine follow up examinations. Cost of the travel will be paid by Tripler.

4. At two years of age, thyroid hormone replacement will be discontinued, and the child will have a thyroid scan six weeks later. If there is obvious thyroid tissue present at that visit, serious consideration will be given to ablation of the remaining thyroid tissue.

5. The child and mother will then be followed on a yearly basis unless indications for more frequent monitoring are found.

6. Thyroid hormone replacement will be continued indefinitely, unless a contraindication arises in the future.

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AFFIDAVIT OF MAJOR GENERAL GIRARD SEITTER, III

STATE OF HAWAII)
) SS.
COUNTY OF HONOLULU)

MAJOR GENERAL GIRARD SEITTER, III, being first duly sworn, on oath deposes and says:

1. That he is the affiant herein;

2. That he is a member of the United States Army, currently residing in the City and County of Honolulu, State of Hawaii;

3. That he has read the said Reply to a Notice of Violation and knows the contents thereof;

4. That the said Reply to a Notice of Violation is true to the best of his knowledge and belief.

Further affiant sayeth not.

Girard Seitter III

MAJOR GENERAL GIRARD SEITTER, III

Subscribed and sworn to before me this 6th day of December 1990.

Mary E. Boyce

My Commission Expires: 6 February 1994