



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, causing ingestion of the iodine 131. Ex 6

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 ACNM 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

Ex 4

Ex 6

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.

Ex. 6

3. The child and 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

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. [] is taking synthroid 37.5 mcg daily, and is growing normally. 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, [] synthroid dose was increased to 50 mcg daily. The child will be flown back to TAMC in two months for follow up laboratory studies.

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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 evidence of Tripler's spirit of cooperation and compliance can be seen in the radiation doseimetry studies performed on [redacted]. 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.

James Boyce
Notary Public, State of Hawaii

Mary E. Boyce
Typed or Printed Name

My Commission Expires: *16 February 1994*