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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

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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 The request for the scan was originally made in May 1989 by the patient's physician on Truk.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.

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

Mary E. Boyce

My Commission Expires: 6 February 1994

Care Plan of [ ] Ex 6 Exemption 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.

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 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.

7. The patient and [ ] mother can be reached at: Ex 6

Address:

[ ]

Exemption 6

Phone:

Exemption 6
Ex 6
Exemption 6