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

J. Montgomery R
ref: RI

AUG - 3 1990

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

Gentlemen:

SUBJECT: NRC INSPECTION AND ENFORCEMENT CONFERENCE

This refers to the special safety inspection conducted at the Tripler Army Medical Center by Messrs. Frank Wenslawski and James Montgomery of this office on June 29 - July 2, 1990, of activities authorized by NRC License No. 53-00458-04 and to the discussion of our findings held by the inspectors with you and members of your staff at the conclusion of the inspection. Inspection Report No. 030-03537/90-01 is enclosed for your review.

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and the conditions of your license. The inspection consisted of selective examination of procedures and representative records, interviews with personnel, and observations by the inspectors.

During this inspection, one of your activities was found to be in apparent violation of NRC requirements. Due to the significance of the apparent violation we have scheduled an enforcement conference to be held between NRC management and your representatives at the Tripler Army Medical Center.

It was established that the enforcement conference would be held at the Tripler Army Medical Center at 9:00 AM, August 16, 1990. The following matters will be discussed:

1. The apparent violation identified during the inspection of June 29 - July 2, 1990.

2. NRC enforcement options.

3. NRC concerns.

The need for and nature of the enforcement actions relative to the apparent violation, as discussed in the enclosed inspection report, will be considered

B11

after the enforcement conference and will be the subject of separate correspondence.

If you have any questions prior to the conference, please contact Mr. Robert J. Pate at 415-943-3752.

Sincerely,

G. P. Yuhas for
Ross A. Scarano, Director
Division of Radiation Safety
and Safeguards

Enclosure:
Inspection Report No. 030-03537/90-01

U.S. NUCLEAR REGULATORY COMMISSION

REGION V

EA 90-132

Report No. 90-01

Docket No. 030-03537

License No. 53-00458-04

Licensee: Department of the Army
Commander, Tripler Army Medical Center
ATTN: HSHK-RP (Rad. Prot. Office)
Tripler AMC, Hawaii 96859

Inspection at: Tripler Army Medical Center
Honolulu, Hawaii

Inspectors: Robert J. Pate for — 8/2/90
F.A. Wenslawski, Deputy Director — Date Signed
Division of Radiation Safety and
Safeguards

James L. Montgomery — 8/2/90
James L. Montgomery, Senior — Date Signed
Materials Specialist

Approved by: G. P. Yuhas — 8/3/90
Ross A. Scarano, Director, — Date Signed
Division of Radiation Safety
and Safeguards

Inspection Summary:

Inspection on June 29 - July 2, 1990 (Report No. 030-03537/90-01)

Areas Inspected: This was a special announced reactive inspection of the licensee's activities related to a radiation exposure incident following a nuclear medicine procedure. The inspection included an examination of the licensee's organization; referral of the patient to the licensee; dose preparation and administration; radiation dosimetry; follow-up medical care; training and qualifications; quality assurance; dose calibrator checks; exit briefing.

Results: One apparent violation and no deviations were identified during the inspection. The apparent violation is summarized as follows:

Supervising authorized user instructions concerning breast feeding contained in a May 25, 1989 memorandum and the Patient Personal Data Record were not followed by a supervised individual resulting in a significant radiation exposure to a nursing infant (Section 11). This is an apparent violation of 10 CFR 35.25(a)(2).

DETAILS

1. Persons Contacted

Licensee

Major General Girard Seitter III, Commanding Officer,*
Colonel Charles Jones, Deputy Commander For Clinical Services *
Lt. Colonel John Zurcher, Executive Officer
Colonel Michael Bornemann, Director Dept. of Endocrinology
Colonel Mark Hansen, Chief of Radiology
Lt. Colonel Arthur Buckner, Acting Chief Nuclear Medicine
Lt. Colonel John Holland, Adult Endocrinologist
Lt. Colonel Richard Banks, Pediatric Endocrinologist
Major John Thomas, Radiopharmacist
Major Phillip Berry, Medical Physicist
Captain Lloyd Carrol, Radiation Protection Officer
George Vidis, Public Affairs Officer*
Andy Harrison, Chief Nuclear Medicine Technologist
Harry Teruya, Nuclear Medicine Technologist
Bryan Akau, Nuclear Medicine Technologist

Non-Licensee

Carol Marcus, Ph.D., M.D., NRC Medical Consultant (UCLA)*
Shirley Fry, M.D., NRC Medical Consultant (ORAU)
Bob Ricks, Ph.D., NRC Medical Consultant (ORAU)
Mike Stabin, NRC Medical Consultant (ORAU)
Sally Merchant, NRC Medical Specialist (NMSS)*
Marumina Sayon, Micronesia Liaison Officer

* Present at exit briefing

2. Background and Purpose of Inspection

On June 27, 1990, the Tripler Army Medical Center (TAMC) reported by telephone to the NRC Region V staff that an infant had been exposed to iodine 131 following a nuclear medicine diagnostic procedure administered to the infant's mother (referred to as the "patient" in the remainder of this report). TAMC estimated the total infant thyroid dose to be several thousand rads. On June 28, 1990, NRC inspectors were dispatched from Region V to TAMC. On July 1, 1990, an NRC medical consultant and a medical specialist from the NRC Office of Nuclear Materials Safety and Safeguards joined the Region V team in Honolulu.

The purpose of the team inspection was to determine the current medical status and whereabouts of the patient and infant; assure patient and infant had received appropriate medical care; assure future medical care would be adequate; evaluate the cause of the incident; and determine the licensee's compliance with NRC requirements.

3. Licensee's Organization

The TAMC Commanding Officer (CO) is an Army Major General and a medical doctor. The Deputy Commander of Clinical Services was serving as the Acting CO at the time of the incident.

The Chief of Radiology commands diagnostic radiology, nuclear medicine and radiation therapy. He also supervises the Radiation Protection Officer (RPO) and assistant RPO. The Nuclear Medicine Department is run by an Acting Chief who is the only nuclear medicine physician currently at TAMC. A Chief Nuclear Medicine Technologist (NMT) supervises several technologists. The Chief NMT and all regular NMTs are civilians employed by TAMC. A radiopharmacist and medical physicist also serve under the Chief of Radiology. The Nuclear Medicine Department normally provides a service function to other medical departments by performing nuclear medicine procedures as requested by attending physicians. In the case of interest, a physician in the Department of Endocrinology referred the patient to nuclear medicine for the iodine 131 procedure.

Overseeing the entire radiation safety program at TAMC is the 14 member Radioisotope/Radiation Control Committee (R/RCC) which meets quarterly to oversee the radiation safety program and review and approve or disapprove the credentials of new users.

4. TAMC Provided Health Care For Micronesia

The patient is a 24 year old resident of the Truk Islands located in the Caroline Islands of the southwestern Pacific Ocean about 3000 miles southwest of Honolulu, Hawaii. Various agreements (not examined during this inspection) exist between the United States Government and the Federated States of Micronesia and other U.S. Trust Territories of the Pacific. Some provisions of the agreements specify health care arrangements whereby medical personnel located on some Micronesian islands, such as the patient's home island of Truk, can refer patients to the U.S. for specialized health care. TAMC is a primary medical care facility to which patients are sent.

Because of the great distances between U.S. Trust Territories and Hawaii and marginal or inadequate medical facilities on some islands, patients often arrive at TAMC with incomplete medical information concerning themselves.

Referrals to TAMC are usually arranged by the Liaison Office of the Federated States of Micronesia located in Honolulu. Initial medical information for the referral is usually transmitted by telephone. Subsequent medical information is typically brought by the patient on consultation forms known as "consult sheets". Some patients have been seen for several years but usually at lengthy intervals of several months to a year or more. As a result of the system of health care established for the Trust Territories, physicians at TAMC may not be completely aware of a patient's medical history.

No apparent violations or deviations were identified.

5. Events Leading To the Patient's Arrival at TAMC On June 17, 1990

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 were performed at TAMC. During her pregnancy in 1990, 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 called the Endocrinology Department to reverify 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.

No apparent violations or deviations were identified.

6. Preparation and Administration of Iodine 131 Dose

On June 19th the radiopharmacist, who normally prepares iodine 131 oral doses, was absent. The NMT had the responsibility for preparing and calibrating the dose, 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. The licensee's procedures require that all female patients age 12 and above fill out a pregnancy statement which is stamped on the Patient Personal Data Record 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 his or her name. A second stamp is contained on the form which contains a space for "physician", "scheduling", "radiopharmacy", and "technologist injecting". The person responsible for each area is suppose to initial the space when they have completed their work related to that patient.

The patient from Truk arrived at the Nuclear Medicine Department for her dosing at approximately 10:00 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 was unable to see 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 (i.e. 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 (if any) 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 Personal Data Record form. 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 which would show an elevated uptake of iodine 131. Upon learning of a lactating condition, the physician would conduct a medical evaluation and decide if and under what conditions (if any) the nuclear medicine study should proceed.

Due to his busy schedule, preparing two simultaneous doses and working without assistance from the radiopharmacist, the NMT forgot 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 by the inspector 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 through a straw to the patient. The patient was instructed to lean into the hood and drink the iodine 131 solution from the container which was flushed twice with a saline solution to insure essentially a 100% ingestion of the 4.89 millicurie dose.

A review by the inspectors of the Patient Personal Data Record for this case, showed that the pregnancy and breast feeding questions were circled "no" and "yes" respectfully. 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 her on June 21st.

Conclusions regarding the NMT's conformance with instructions are provided in paragraph 11 of this report.

7. Initial Scan Following Dose Administration

After dosing, the patient left TAMC with instructions to return in two days for a scan. Apparently concerned that nursing her infant may be

wrong, 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 with a Pho-Con LFOV camera using a high energy collimator. Upon completion of the scan the ACNM noticed an extremely 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 the infant 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.

No apparent violations or deviations were identified.

8. Short Term Follow-Up Care

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 remove some of the residual iodine 131 and thereby reduce further radiation exposure. The milk [several milliliters (ml)] was saved 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. The patient also received another whole body scan for the purpose of obtaining additional data on breast tissue uptake of iodine 131. However, the patient's quantitative whole body scan results were inadvertently erased from the imaging computer storage disk and could not be retrieved.

According to the ACNM, 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 to Atlanta, Georgia, 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.

According to the ACNM, early in the morning on June 25th, the patient and infant arrived at the TAMC Pediatric Clinic. The infant weighed in at 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 good English and had been on synthroid herself since her thyroid was ablated. It was also learned by the inspectors in talking with the Micronesia Liaison Officer that the patient had completed some education involving nursing or other paramedical work which possibly enhanced her awareness of her infant's medical condition and the need for synthroid.

On June 26th 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 June 27th at 2:00 PM Pacific Standard Time, the TAMC RPO called NRC Region V and reported the incident.

Based on interviews with TAMC medical personnel, including physicians, and an evaluation of all relevant documentation by the NRC inspection team and medical consultant, it is concluded that the licensee provided appropriate care to the patient and infant between the time the incident was discovered on June 21st and the patient and infant departure from Honolulu on June 27th.

No apparent violations or deviations were identified.

9. Radiation Dosimetry

Milk samples were collected from the patient on June 21st and June 25th by the TAMC Nuclear Medicine Department. The radiopharmacist and RPO initially counted the samples using different instruments at different times and made predecay calculations to determine the iodine 131 activity at the time the infant resumed breast feeding. These initial counting results were used by the RPO to estimate a thyroid dose to the infant which was reported to the NRC Region V staff on June 27th as 7872 rads. A review of the initial milk analysis data by the NRC inspectors, medical consultant and RPO revealed possible errors in aliquot preparation, counting, calibration and predecay calculations. Therefore, on July 2nd, the NRC inspectors and medical consultant asked the RPO to recount the samples using the licensee's Packard Auto-Gamma 5530 well counter which was calibrated with a barium 133 rod source. The counting efficiency was determined to be 32.5% for the preset iodine 131 counting window of 260-470 keV. The June 21st sample contained 0.41 microcuries per ml, and the June 25th sample contained 0.0097 microcuries per ml. These counting results are decay corrected to the time of milk collection (i.e. 1:30 PM on June 21st and 11:00 AM on June 25th).

On June 21st, the Nuclear Medicine Department also performed a thyroid bioassay on the infant using a sodium iodide scintillation uptake probe. The probe measured over one million counts per minute from the infant's thyroid. This number was reported to the NRC Region V staff on June 27th

For the breast dose to the mother, ORAU assumed a linear filling of the breasts to 100 ml every three hours, except after 1:30 PM on June 21st when it was assumed the breasts filled at the same rate to 400 ml and remained at that level indefinitely.

The ORAU doses in rads are as follows:

Infant:	
- Thyroid	30,000
- Stomach Wall	44
- Small Intestine Wall	26
- Thymus Gland	22
- Urinary Bladder Wall	12
- Liver	8.2
- Lungs	5.7
- Heart Wall	5.7
- Bone Surfaces	4.5
- Red Marrow	4.0
- Ovaries	3.3
- Total Body	17
Patient:	
-Breasts	8.9

No apparent violations or deviations were identified.

10. Long Term Follow-up Care

At the time of the inspection, the consult sheet prepared by the PE served as the licensee's official plan for long term care of the mother and child. In discussions with the inspectors, the licensee had agreed to develop more specific plans to provide further assurance that the infant would receive appropriate medical attention. In a July 19, 1990 telephone conversation, the RPO informed the NRC Region V inspector that arrangements had been made for the patient and infant to return to TAMC from Truk during the week of July 23, 1990. The patient and infant were scheduled to see the PE for additional medical evaluation and to arrange for appropriate long term medical care.

No apparent violations or deviations were identified.

11. Training and Qualifications

The TAMC Radioisotope/Radiation Control Committee (R/RCC) is authorized by license condition 11 to designate users of licensed radioactive material. On July 31, 1989 the R/RCC reviewed and approved the ACNM as an authorized user based on his training and experience. The ACNM approval and his training and experience were in compliance with 10 CFR 35.22 and 35.910 through 35.934.

The NMT who administered the iodine 131 dose to the patient is a Certified Nuclear Medicine Technologist with more than twenty years of experience. He has worked as an NMT at TAMC since February 13, 1984. When he started work in 1984 he stated he was not given any formal

training but was given a "Nuclear Medicine Protocol Procedures" manual and told to read it. He was asked to sign a statement saying he had read the material but could not locate the statement. He said he had been instructed to always ask female patients over twelve years of age if they were pregnant or breast feeding. A nuclear medicine staff memorandum dated May 25, 1989 entitled "The Management of Pregnant Patients" stated in part:

No patient who indicates that she is pregnant or lactating will be given a radioactive substance except under the following conditions:

1.) The study (e.g. lung scan, renal scan) is considered necessary for proper patient management and is approved by a Staff physician listed on the Tripler radioisotope license to authorize administration of a radiopharmaceutical.

AND

2.) The patient has been counseled and an informed consent form has been filled out by the patient or a family member if the patient is unable to fill out the consent form.

This memorandum was signed by the former Chief of Nuclear Medicine. The NMT stated he had read the memorandum prior to June 19, 1990.

10 CFR 35.25(a)(2) requires a supervised individual to follow the instructions of the supervising authorized user. The instructions contained in the May 25, 1989 memorandum and the patient personal data record containing the pregnancy and initial stamps were not followed by the NMT relative to breast feeding inquiries.

One apparent violation and no deviations were identified.

12. Quality Assurance

Internal audits of consult sheets, prescriptions and other medical record forms are conducted by physicians in the Department of Radiology on a semi-annual basis. The ACNM stated that the physicians also discuss and review cases and patient records approximately once a week. The audits did not include a review of the Patient Personal Data Records and the radiation protection portions pertaining to pregnancy and breast feeding. A random sampling by the inspector of a few patient records in 1989 and 1990 indicated the stamps were being properly filled out and initialed.

The R/RCC conducts quarterly meetings and reviews occupational radiation dose summaries, radiation incidents and the RPO's annual report on the status of the radiation safety program. The RPO also performs periodic audits of health physics records and conducts laboratory surveys. The RPO's audits do not include patient medical records or forms.

The licensee also maintains a written Quality Assurance Plan for Nuclear Medicine patient care which is based on the Joint Commission On Accreditation of Healthcare Organizations. The plan does not specifically address any radiation protection subjects or the use of patient forms for patients who may be pregnant or nursing.

No apparent violations or deviations were identified.

13. Dose Calibrator Checks

The inspector reviewed the licensee's checks of the Capintec Model CRC-12 dose calibrator operation to ensure that the assay of the 4.89 millicurie iodine 131 dose was correct. The daily constancy check had been performed at the beginning of the work day on June 19th in accordance with 10 CFR 35.50. Annual accuracy and quarterly linearity tests had also been performed as required by 10 CFR 35.50. The NMT demonstrated the procedure he followed on June 19th in preparing and assaying the 4.89 millicurie iodine 131 dose. All checks and uses of the dose calibrator were adequate and indicate the 4.89 millicurie dosage was accurate.

No apparent violations or deviations were identified.

14. Exit Briefing

The inspectors, NRC staff and NRC medical consultant held an exit briefing with the Commanding Officer and his staff. The excellent assistance and cooperation from many licensee personnel was acknowledged. The ORAU dose assessment results were summarized. The NRC medical consultant expressed her concerns for ensuring adequate long term health care for the patient and infant including care related to possible psychological effects of the ordeal on the patient.

The inspectors summarized the possible violations of NRC requirements. It was emphasized that the inspectors considered the incident and overexposure to the infant, a member of the general public. The possible violations discussed were unrestricted area exposure [10 CFR 20.105(b)(1) & (2)]; inadequate surveys and evaluation [20.201]; and failure to report an overexposure in a timely manner [20.403]. The licensee was urged to review and assess the NRC requirements in these regulatory areas. The licensee was informed that if the violations are sustained by NRC management, an enforcement conference would probably be scheduled.

The Commanding Officer replied that he was personally committed to insure that the infant and patient received proper long term medical care and that his staff were developing a comprehensive plan to accomplish this. He believed the incident was a medical problem involving the mother and infant as a "patient unit" where the infant would not be considered "a member of the general public". Therefore, he maintained the incident was not reportable under NRC regulations. He also stated that similar incidents had probably occurred in the past at other medical institutions but were never reported. He was opposed to TAMC being singled out for possible enforcement action.