

U. S. NUCLEAR REGULATORY COMMISSION
REGION V

Report No. 90-02

EA No. 90-132

License No. 53-00458-04

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

Conference at: Tripler Army Medical Center
Tripler AMC, Hawaii 96859

Conference Conducted: August 16, 1990

NRC Inspector:

J. L. Montgomery
J. L. Montgomery
Senior Materials Specialist

8/22/90
Date Signed

Approved by:

Robert J. Pate
Robert J. Pate, Chief
Nuclear Materials and Fuel
Fabrication Branch

8/23/90
Date Signed

Summary:

Enforcement Conference on August 16, 1990 (Report No. 90-02)

The following matters were discussed:

1. Description of inspection findings and apparent violation identified during the inspection of June 29 - July 2, 1990.
2. NRC Concerns
3. NRC Enforcement Policy and options

Results:

The licensee accepted full responsibility for the incident and did not dispute the 10 CFR 35.25(a)(2) citation. With the exception of to whom the RSO reported, the licensee had no disagreement with the facts presented in the inspection report. Corrective action has been implemented by the licensee to preclude a recurrence of this incident. Extensive follow-up medical care is planned for the patient and child.

ENFORCEMENT CONFERENCE

DETAILS

1. Enforcement Conference Attendees

B. Faulkenberry	Deputy Regional Administrator NRC Region V
F. Wenslawski	Deputy Director, Division of Radiation Safety and Safeguards NRC Region V
M. Blume	Regional Counsel NRC Region V
J. Montgomery	Senior Materials Specialist NRC Region V
Col. M. Hansen	Chief of Radiology, TAMC
Lt. B. Murphy	Health Physics Officer, TAMC
Ltc. R. Cherry	Radiation Protection Staff Officer Fort Sam Houston, Texas
G. Vidis	Public Affairs Officer, TAMC
Maj. D. Little	Center Judge Advocate, TAMC
Col. S. Hinton	Deputy Commander for Administration TAMC
Col. C. Jones	Deputy Commander for Clinical Services TAMC
Maj. Gen. G. Seitter, III	Commanding General
Cpt. R. Wright	Aide de Camp

2. Enforcement Conference

On August 16, 1990, an enforcement conference was held at the Tripler Army Medical Center (TAMC), Honolulu, Hawaii, with the individuals listed above participating. The enforcement conference was related to a June 29 - July 2, 1990 NRC inspection scheduled as a result of an inadvertent radiation exposure to an infant who had ingested breast milk from its mother who had received radioactive iodine 131 for a routine nuclear medicine diagnostic study.

Mr. Montgomery summarized the inspection findings and the one apparent violation as described in NRC Inspection Report number 030-03537/90-01, which the licensee had reviewed. The licensee asked that the NRC

inspection report be corrected to show that the Radiation Protection Office is under the Chief of Preventive Medicine Service and not the Chief of Radiology.

Mr. Wenslawski discussed the NRC concerns. The NRC staff considered the radiation exposure to be very serious and attributed the cause to inadequate procedures to preclude such an event. Adequate safeguards did not exist to prevent or mitigate an error by a single individual that resulted in this event. Mr. Wenslawski emphasized the need to anticipate personnel mistakes and design a program that will minimize any impact. It was noted that the licensee had reported two prior misadministrations (in 1987) that were attributed to personnel failure to follow procedures. It was suggested that the licensee consider whether management expectations are being adequately communicated to the working level and to assure itself that complacency was not a problem. Other NRC concerns expressed included the need for the licensee to evaluate staffing needs in the Nuclear Medicine Service and the relationship between TAMC and the Micronesian medical referral system.

General Seitter emphasized that he and his staff recognize the seriousness of the incident and the associated physiological and emotional effects. He acknowledged that TAMC is fully responsible for the error. He said he did not believe that inadequate staffing was a cause of the incident, and stated that he maintains an ongoing quality assurance program to evaluate TAMC's capability to handle the workload. General Seitter said he is also reevaluating the Pacific island referral system and is sensitive to potential problems that can be created by language, culture, geography and economics. The General also stated that the incident was reported to the NRC even though there was no clear NRC reporting requirement. He felt that TAMC should not be criticized for inadequate procedures when the NRC had no specific regulations or guidance concerning the matter.

Mr. Faulkenberry responded that the NRC staff cannot write a regulation or guide for every conceivable event. Licensees, especially broad scope licensees such as TAMC, are expected to foresee such events within their medical specialty areas and develop adequate procedures through their quality assurance and radiation safety programs.

Mr. Blume summarized the NRC enforcement policy as described in 10 CFR Part 2. He noted that the NRC conducts enforcement conferences whenever escalated enforcement action (e.g., a civil penalty or order) is being considered. He also described the five severity levels for violations, and the seven escalation and mitigation factors used to adjust civil penalty amounts. In response to Col. Hansen's inquiry, Mr. Faulkenberry replied that the TAMC incident was considered very significant, which was the main reason for holding the enforcement conference. However, to assist the NRC in assessing the significance of the event, the NRC staff requested a copy of the TAMC investigation report.

Col. Hansen described the corrective actions which had been implemented following the incident, including a new quality assurance procedure which uses a three-tier, redundant system whereby staff members verify pregnancy

and breast feeding status for all female patients between the ages of 12 and 60 years.

Col. Jones described the recent and future followup care for the mother and child. During a visit to TAMC during the week of July 23, 1990, the mother and child were determined to be normal, with some residual iodine 131 detectable. Within a few weeks, Dr. Banks of the TAMC Endocrinology Service will travel to the Truk Islands to evaluate the available medical care and speak with the mother's physician concerning the incident and the type of medical care that will be needed for the mother and child. Col. Jones described a long term care plan which will involve quarterly visits to TAMC by the mother and child for the next two years.

Mr. Blume noted the licensee's previous four diagnostic misadministrations were reported to the NRC since 1987. To further aid in assessing the licensee's past performance, Mr. Blume requested copies of the TAMC reports for the misadministrations, and descriptions of the actions implemented to prevent recurrence. The licensee agreed to provide these reports promptly.

Col. Hansen asked if the NRC considered incidents such as this to be reportable. Mr. Blume and Mr. Faulkenberry indicated this question had not yet received a legal interpretation by the NRC general counsel, but that an answer would be obtained and communicated to TAMC. It was emphasized that regardless of the legal reporting requirements, NRC has an interest in being informed of such significant events. Lt. Cherry acknowledged that the Army recognizes the need to report such events.

Maj. Little asked if the current 10 CFR Part 35 applied to TAMC. He referenced a TAMC letter to the NRC which stated TAMC preferred to remain under the "old" Part 35 until the time of license renewal. Mr. Faulkenberry stated that based on NRC Office of General Counsel (OGC) advice, the current or "new" Part 35 applied if there was no conflict with the licensee's procedures. Mr. Blume noted that the Statements of Consideration for Part 35 provided the basis for this OGC advice. Mr. Wenslawski provided a copy of the Statements of Consideration to Maj. Little.

3. Conclusions

The licensee assumed full responsibility for the incident and did not contest the violation of 10 CFR 35.25(a)(2). The licensee's Incident Investigation Report and Misadministration Reports will be evaluated by the NRC staff for applicability under the enforcement policy. Although not officially under NRC jurisdiction, it should be noted that the licensee's long term care plan appeared to be thorough and in the best interest of the mother, child and TAMC.

Attachment 4 to
8/24/90 memo from
Martin

Encl. 4
LJ

BACKGROUND REFERENCE MATERIAL

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

53-00458-04

Docket or Reference number

030-03537

Amendment No. 58

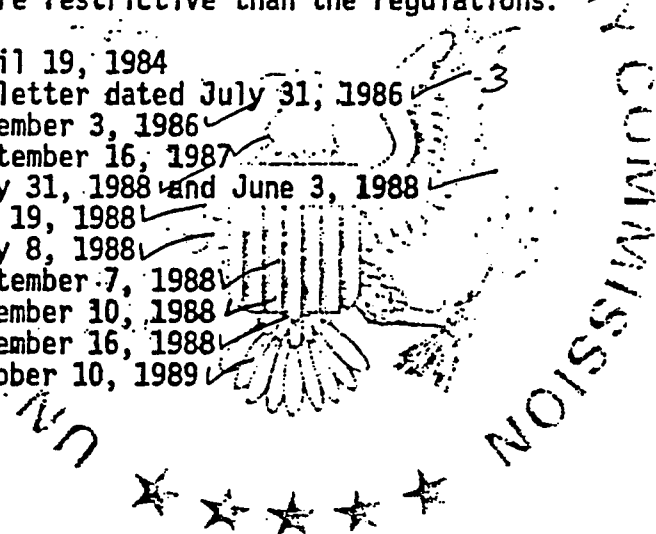
Department of the Army
Commander, Tripler Army Medical Center
ATTN: HSHK-RP (Rad. Prot. Office)
Tripler AMC, Hawaii 96859

In accordance with letter dated October 10, 1989, License No. 53-00458-04 is amended as follows:

Condition 26 is amended as follows:

26. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Letter dated April 19, 1984
- B. Application and letter dated July 31, 1986
- C. Letter dated December 3, 1986
- D. Letter dated September 16, 1987
- E. Letters dated May 31, 1988 and June 3, 1988
- F. Letter dated May 19, 1988
- G. Letter dated July 8, 1988
- H. Letter dated September 7, 1988
- I. Letter dated November 10, 1988
- J. Letter dated December 16, 1988
- K. Letter dated October 10, 1989



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date NOV 21 1989

By Beth A. Riedlinger
Beth A. Riedlinger
Health Physicist (Licensing)
Nuclear Materials Safety Section
Region V

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MATLSLICENSING PDR

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MATERIALS LICENSE

Amendment No. 57

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p>Licensee CORRECTED COPY</p> <p>1. Department of the Army</p> <p>2. Commander, Tripler Army Medical Center ATTN: HSHK-RP (Radiation Protection Office) Tripler AMC, Hawaii 96859</p>	<p>In accordance with letter dated December 16, 1988</p> <p>3. License number 53-00458-04 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date September 30, 1991</p> <hr/> <p>5. Docket or Reference No. 030-03537</p>
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6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material with atomic numbers 1 to 83 except as specified in Subitems 6.B. through 6.F. below	A. Any	A. 50 millicuries of each radionuclide with atomic numbers 1 to 83. Total possession limit for subitem A not to exceed 4 curies
B. Technetium 99m	B. Any	B. 6 curies
C. Molybdenum 99	C. Any	C. 6 curies
D. Iodine 131	D. Any	D. 2 curies
E. Iodine 125	E. Any	E. 500 millicuries
F. Xenon 133	F. Gas or gas in saline	F. 2 curies
G. Any byproduct material listed in Group VI of Schedule A, Section 35.100	G. Any sealed source listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35	G. 2.5 curies for all sources authorized in Subitem 6.G.

9. Authorized use

A. through F. Medical diagnosis and therapy. Research in laboratory animals. Research and development as defined in 10 CFR 30.4(q).

G. Any procedure listed in Group VI of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

53-00458-04

Docket or Reference number

030-03537

Amendment No. 57

CONDITIONS

10. Licensed material shall be used only at Jarrett White Road, Tripler Army Medical Center, Hawaii.
11. A. Licensed material shall be used by, or under the supervision of, individuals designated by the Radioisotope/Radiation Control Committee, Russell W. Jenna, Jr, M.D., Chairman.
- B. The use of licensed material in or on humans shall be by a physician as defined in 10 CFR 35.3(b).
- C. Physicians designated to use licensed material in or on humans shall meet the training criteria established in Appendix A of Regulatory Guide 10.8 (Revision 1), dated October 1980, and as revised December 2, 1982 (47 FR 54376).
12. The Radiation Protection Officer for the activities authorized by this license is CPT Loyd D. Carroll.
13. A. (1) Each sealed source acquired from another person and containing licensed material, other than hydrogen 3, with a half-life greater than thirty days and in any form other than gas shall be tested for contamination and/or leakage before use. In the absence of a certificate from a transferor indicating that a test has been made within six months before the transfer, a sealed source received from another person shall not be put into use until tested.
- (2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting materials or 10 microcuries or less of alpha emitting material.
- (3) Except for alpha sources, the periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage before any use or transfer to another person unless they have been leak tested within six months before the date of use or transfer.
- B. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to use or transfer as a sealed source. If the inspection or test reveals any construction defects or 0.005 microcurie or greater of contamination, the source shall not be used or transferred as a sealed source until it has been repaired, decontaminated and retested.
- C. Each sealed source containing licensed material, other than hydrogen 3, with a half-life greater than 30 days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed 6 months except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed 3 months.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

53-00458-04

Docket or Reference number

030-03537

Amendment No. 57

CONDITIONS

(continued)

D. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently or semipermanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

E. If the test required by Subsection A. or C. of this condition reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U. S. Nuclear Regulatory Commission, Region V; Nuclear Materials Safety and Safeguards Branch; 1450 Maria Lane, Suite 210; Walnut Creek, California 94596, describing the equipment involved, the test results, and the corrective action taken.

14. Sealed sources containing licensed material shall not be opened.
15. This license does not authorize medical research studies in humans.
16. Radioactive gases as free gas or in solution, to be administered to humans, shall be procured from a supplier who distributes the product indicated for human use in accordance with the Federal Food, Drug, and Cosmetic Act.
17. Patients containing iodine 131 for the treatment of thyroid carcinoma (or patients containing therapeutic quantities of gold 198) shall remain hospitalized until the residual activity is 30 millicuries or less.
18. Pursuant to Title 10, Chapter 1, Code of Federal Regulations, Part 40, 'Domestic Licensing of Source Material', the licensee is authorized to possess, use, transfer, and import up to 999 kilograms of depleted uranium contained as shielding material in the molybdenum-99/technetium-99m generators authorized by this license".
19. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:
 - A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of ten (10) half-lives.
 - B. Prior to disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License number

53-00458-04

Docket or Reference number

030-03537

Amendment No. 57

CONDITIONS

continued)

- C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.
- D. Radioactive wastes containing microcurie amounts of iodine-125 may be disposed to the ordinary trash after being held for decay for a minimum of five (5) half-lives. Prior to disposal, these wastes must be monitored in accordance with the procedures described in the licensee's application dated July 31, 1986. The survey conducted prior to disposal must confirm that the radioactivity of the wastes cannot be distinguished from background.
20. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in 10 CFR 20.203(a)(1), the licensee is hereby authorized to label detector cells and cell baths, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols without a color requirement.
21. Detector cells containing licensed material shall not be opened or the sources removed from the detector cell by the licensee.
22. A. Detector cells containing titanium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 225 degrees Centigrade.
- B. Detector cells containing scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 325 degrees Centigrade.
23. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material".
24. The licensee shall conduct a physical inventory every six (6) months to account for all sources and/or devices received and possessed under Items 6.A. through 6.F. of the license. Records of the inventories shall be maintained for two (2) years from the date of each inventory.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License number

53-00458-04

Docket or Reference number

030-03537

Amendment No. 57

CONDITIONS

(continued)

- 25. The licensee may use the Calicheck device for doing linearity tests of its dose calibrator provided it follows the procedures in the Calcorp, Inc. Manual dated March 2, 1982.
- 26. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.
 - A. Letter dated April 19, 1984
 - B. Application and letter dated July 31, 1986
 - C. Letter dated December 3, 1986
 - D. Letter dated September 16, 1987
 - E. Letters dated May 31, 1988 and June 3, 1988
 - F. Letter dated May 19, 1988
 - G. Letter dated July 8, 1988
 - H. Letter dated September 7, 1988
 - I. Letter dated November 10, 1988
 - J. Letter dated December 16, 1988

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date January 19, 1989

By

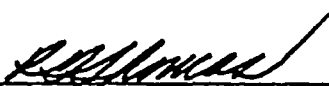

R.D. Thomas, Chief
Nuclear Materials Safety Section
Region V

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5 SEPT 89

STANDARD OF PROCEDURES

Described below is the normal method of performing a Nuclear Medicine procedure.

1. Nuclear Medicine receives a properly filled out consult. Consult is stamped with date of receipt and quality assurance checklist (initials of physician, receptionist, pharmacy, and technologist)
2. Nuclear Medicine physician determines feasibility, dose and type of test needed. He will initial the consult upon verification of the request and the prescription will be filled.
3. Nuclear Medicine personnel schedules date and time of study and initials the consult. The patient is notified.
4. Receptionist prepares forms and Nuclear Medicine Master folder according to Army Digital Filing System regulations.

Patient arrives.
6. Patient forms are transferred to Radiopharmacy
7. Radiopharmacy technician reads consult and interprets requisition for appropriateness and enters conformation into the computer database. The technician then prepares the requested dose and initials the consult.
8. Imaging Technician receives dose.
9. Technician verifies 1.) that the dose and consult agree, 2.) the patient is not pregnant, 3.) that what is being requested is being done, 4.) the identification of the patient and 5.) that suitable time has been allotted for all phases of the exam. 6) the Technician initials the consult.
10. Technician explains test to patient.
11. Test is performed according to protocol.
12. All forms, films, printouts, etc., will be checked and corrected as necessary by the technician.
13. If available, a Nuclear Medicine physician will check all results before release of patient.

4. Patient is released.
15. Films are given to Nuclear Medicine physicians for reading.
16. Report is dictated and Preliminary Findings Report is logged.

- . Report is typed.
- 18. Report is verified and signed by an authorized physician.
- 19. Report is distributed to requesting physician and to patients' record.
- 20. Report is filed in the patients Nuclear Medicine Record.

23 May 1989

Orientation of Newly Assigned Personnel

All newly assigned personnel will complete the Department of Radiology orientation. After completion, the Nuclear Medicine Orientation will be provided to all newly assigned personnel.

RESPONSIBILITIES:

Physicians will be given their orientation by the Chief, Nuclear Medicine Service. Pharmacists will be oriented by the Chief of Pharmacy Service. All other personnel will be introduced into the Service by the Supervisor of Nuclear Medicine.

The above responsible officials will insure that at a minimum the orientation includes:

- a.) Introduction to the staff
- b.) Reading and signing the SOP manuals.
- c.) A thorough explanation of individual duties and responsibilities.

All female patients age of the age 12 and above are required to fill out the pregnancy statement on the study requisition form.

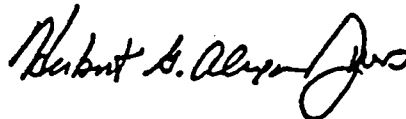
No patient who indicates that she is pregnant or lactating will be given a radioactive substance except under the following conditions:

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.

Following any procedure performed on a pregnant patient, the Radiation Physicist, Department of Radiology will calculate the dose to the fetus. A copy of this report will be included in the report of the procedure performed. This report will become a permanent part of the patient's record. This report will be prepared for patients who indicate on the form that they are not pregnant and are later determined to be pregnant.



HERBERT G. ALEXANDER
MAJ, MC
Chief, Nuclear Medicine

15.
155- 4171
0/21/90

NUCLEAR MEDICINE FEMALE PATIENT
INFORMATION SHEET

AGE 12 AND UP

1. You will receive a dose of radioactive material administered in a prescribed method depending upon the study that your physician has requested.

2. Your signature signifies your understanding of the dose and indicate that you understand the following questions and have answered them as accurately as possible.

a. Are you pregnant?

b. List all medications you are taking (include birth control pill and over the counter vitamin medication).

c. Are you nursing (breast feeding) any of your children?

d. List all x-ray procedures you have had within two (2) years.

Initials _____
NURSE _____
PHYSICIAN _____
PHARMACEUTIC _____
PHYSICIAN INJECTING _____

Signature _____

Print Name _____

Date _____

Ref: KY 5 L
Attachment 5 to Shylao memo fm
MOTON Encl. 5

TRIFLER ARMY MEDICAL CENTER
INSPECTION HISTORY

September 22, 1989	Diagnostic misadministration: wrong radiopharmaceutical given to patient because technologist withdrew the dose from the wrong stock vial.
June 5-6, 1989	Routine inspection with one violation. Two nurses attending a brachytherapy patient were not given radiation safety training.
September 16, 1987	Routine inspection with three violations. Dose calibrator accuracy test records not properly maintained. Linearity test not conducted. Radioactive waste stored in unlocked and unattended room.
July 17, 1987	Diagnostic misadministration: wrong radiopharmaceutical given to patient because technologist failed to verify patient identification in accordance with procedures.
April 28, 1987	Diagnostic misadministration: wrong radiopharmaceutical given to patient because technologist withdrew the dose from the wrong stock vial.
March 18, 1987	Diagnostic misadministration: wrong radiopharmaceutical given to patient because technologist failed to verify patient identification in accordance with procedures.

Ref: EW 6 k
Encl. 6

TRIPLER ARMY MEDICAL CENTER .
APPENDIX

Attachment 6 to
R2460 memo from Matten

Documentation Quality Control Checklist

Where Located*

<u>Information</u>	<u>Where Located*</u>					
	Insp Rept	Conf Rept	Draft Nov	Draft Ltr	Cover Memo	Other
B.1. What was the requirement and, if the requirement was conditional, how were the conditions satisfied which made the requirement applicable?				X	X	
B.2. How the requirement was violated?	X					
B.3. When the requirement was violated and what was the duration of the violation?	X					
B.4. Who caused the violation?	X					
B.5. How and by whom (be specific) was the violation discovered?	X					
B.6. Was the violation required to be reported and, if so, what was the applicable reporting requirement?	X				X	
B.7. Was the violation reported and, is so, when and by whom was it reported?	X					
B.8. If the violation was reported, but the report was late, why was the report late?	X					N/A
B.9. Was the report complete and accurate?	X					
B.10. Were there multiple examples of the violation?	X				X	

*Place an "X" in the appropriate column(s) or N/A if the issue is applicable to the case. When an issue is N/A'd, the supporting documentation will support the conclusion that the issue is not applicable.

Where Located*

<u>Information</u>	Insp Rept	Conf Rept	Draft Nov	Draft Ltr	Cover Memo	Other
B.11. What was the apparent root cause and contributing casual factors for the violation?	X					
B.12. Describe any facts and circumstances that address the aspects of negligence, careless disregard, willfulness and management involvement.						N/A
B.13. Was there economic or other personal or corporate gain associated with the violation?						N/A
B.14. What were the opportunities and when did they exist for licensee staff and management to be aware of the violation?	X					
B.15. What were the circumstances surrounding the violation, such as system configuration and operational conditions for reactor cases, which effect the significance of the violation?	X					
B.16. Is the violation indicative of programmatic problems or is it an isolated case?	X					
B.17. What short term corrective and remedial action was taken and when was it taken?	X					
B.18. Did NRC have to intervene to accomplish satisfactory short term correction and remedial action?	X					
B.19. Were there previous similar NRC inspection or licensee audit findings and, if so, should the corrective actions from those findings have prevented this violation?		X		X	X	

Where Located*

<u>Information</u>	<u>Where Located*</u>					
	Insp Rept	Conf Rept	Draft Nov	Draft Ltr	Cover Memo	Other
C.1. List the enforcement conference attendees from the NRC and licensee.		X				
C.2. Describe additions or corrections to the factual information in the inspection report.		X				
C.3. If the licensee takes issue with the violations, describe the licensee position.		X				
C.4. Describe any additional information which effects the regulatory or safety significance of each violation.	X					
C.5. Describe any additional information on correction and remedial actions the licensee has implemented has committed to implement.	X					
D.1. A concise, clear statement of the requirement appropriately referenced, paraphrased or quoted.	X		X			
D.2. A brief statement of the circumstances of the violation including the dates of the violation and the facts necessary to demonstrate that one or more elements of the requirements were not met.	X		X			
D.3. The severity level proposed for the violation.			X	X	X	
D.4. The civil penalty proposed for the violation.			X	X	X	
E.1. When, where, and by whom an inspection was conducted.	X					

Where Located*

<u>Information</u>	Insp Rept	Conf Rept	Draft Nov	Draft Ltr	Cover Memo	Other
E.2. When and where an enforcement conference was conducted and who were the lead NRC and licensee representatives.		X				
E.3. When reports of the inspection and enforcement conference results were provided to the licensee.	X	X				
E.4. A description of the violations, including who identified the violations, and the apparent root cause of the violations, and any other major attributes of the violations necessary to support the safety and regulatory significance of the violations.	X					
E.5. A statement of the results which we expect to achieve through issuance of the proposed enforcement action focusing on correction of the underlying problems disclosed by the violation.					X	
E.6. A description of the proposed enforcement sanctions including severity level and civil penalty valve.			X	X	X	
E.7. An analysis of any factors which caused the severity level to be different from the normal severity level for the type of involved violations, for example, programmatic aspects, or willfulness.				X	X	
E.8. An analysis of any factors which caused the civil penalty valve to be different than the base valve for that severity level violation.				X	X	

Where Located*

<u>Information</u>	Insp Rept	Conf Rept	Draft Nov	Draft Ltr	Cover Memo	Other
F.1. The Enforcement Action (EA) number.	X	X	X	X	X	
F.2. The referenced inspection report numbers.	X	X	X	X	X	
F.3. A summary of the nature of the violation(s).	X		X			
F.4. A summary of the root cause(s)/problem area(s) represented by the violation(s).	X					
F.5. A description of the regulatory and Technical Safety significance of the violation(s)/problem area(s), including considerations such as operational configuration, supervision/management involvement and willfulness.	X					
F.6. A description of the purpose of the enforcement action and the message we intend to send to the licensee and industry.					X	
F.7. A description of the rationale for the recommended severity level and grouping of the violations including reference to the relevant sections of the Enforcement Policy and OE guidance and prior EA's.				X	X	
F.8. A description of the rationale for the recommended civil penalty addressing all five Enforcement Policy escalation and mitigation factors as well as duration, willfulness, ability to pay, and prior EA's which are similar.				X	X	

Where Located*

Information

- F.9 An analysis of the licensee's position on any aspect of the violations or application of the Enforcement Policy to those violations which is in substantial disagreement with the regional proposal.

- F.10 The Regional Counsel's view of the legal aspects and _____ risk associated with the proposed action and the advisability of OGC review of the proposed action.

- F.11 Any other regulatory framework factors that need to be considered in review of the case; such as, pending licensing issuance or renewal action, and commission meetings.

Insp Rept	Conf Rept	Draft Nov	Draft Ltr	Cover Memo	Other
	X				
				X	
				X	