APPENDIX A

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Inspection Report: 030-01215/94-01

License: 04-00689-07

Licensee: Veterans Affairs Medical Center
5901 East Seventh Street
Long Beach, CA 90822

Facility Name: Veterans Affairs Medical Center

Inspection At: Long Beach, California

Inspection Conducted: August 10 through September 26, 1994

Inspectors: Mark R. Shaffer, Senior Radiation Specialist
Gregory P. Yuhas, Technical Assistant

Approved: Linda L Kasner 10/13/94
Linda L Kasner, Chief, Nuclear Materials Inspection Branch — Date

Inspection Summary

Areas Inspected: Special, announced inspection of licensed activities involving use of byproduct material for nuclear medicine procedures. The inspection was limited to a review of a medical misadministration which occurred at the licensee's facility on August 9, 1994, involving administration of the wrong radiopharmaceutical, strontium-89, to a patient scheduled to receive a diagnostic dose of thallium-201.

Results:

- The licensee estimated that the radiation dose resulting from the misadministration was approximately 250 centigray (rads) to the patient's bone surface. The licensee expected that the patient's white blood cell and platelet count would decrease by approximately 20-30 percent over a 12-week period.

- The direct cause of the misadministration was attributed to the failure of a technologist to read a syringe label immediately prior to administering the strontium-89 dose. The failure to read the syringe label or to verify the radiopharmaceutical dosage

prior to injecting a patient was identified as an apparent violation of the licensee's procedures.

- Some of the contributing factors identified during this inspection appear to indicate a deficiency in authorized users' direct supervision of daily activities involving the receipt and administration of radiopharmaceuticals. Although the authorized users had delegated specific tasks to supervised individuals to be performed in accordance with the authorized users' instructions and written procedures, other informal practices and procedures were in place which had not been reviewed or approved by the supervising authorized users. In addition, the authorized users had not identified the need to update departmental procedures to address the receipt and use of unit dose radiopharmaceuticals for therapeutic procedures. This appeared to indicate a lack of attention to detail in the oversight of daily activities delegated to individuals working under the supervision of authorized users.

Summary of Inspection Findings:

- Apparent violation 03001215/9401-01 was opened: Failure of a supervised individual to follow the written radiation safety procedures established by the licensee as required by 10 CFR 35.25(a)(2).

Attachments:

- Attachment 1 - Persons Contacted and Exit Meeting
- Attachment 2 - Medical Consultant's Report

DETAILS

1 PROGRAM OVERVIEW

The Veterans Affairs Medical Center, Long Beach, California (VAMC) is authorized under its NRC license to use byproduct material for diagnostic and therapeutic procedures as defined in 10 CFR 35.100-500, as well as research activities conducted under the specific approval of the radiation safety committee (RSC).

Routine diagnostic and therapeutic procedures involving use of radiopharmaceuticals had been performed under the direction and supervision of the Chief, Nuclear Medicine. The nuclear medicine service had been staffed by four authorized user physicians and nine staff technologists. The licensee had performed approximately 80 diagnostic procedures per month. The majority of the procedures involved administration of radiopharmaceuticals labeled with technetium-99m (Tc-99m) and cardiac imaging studies using thallium-201 (Tl-201), a radiopharmaceutical not regulated by the NRC. The licensee had prepared radiopharmaceuticals labeled with Tc-99m at its facility using a molybdenum-99/technetium-99m generator. All other radiopharmaceuticals were delivered in unit dose form from a local radiopharmacy.

Approximately 15 procedures were performed each year using millicurie quantities of sodium iodide iodine-131 for thyroid therapy and whole body scans to detect metastatic thyroid carcinoma. The licensee had also used strontium-89 (Sr-89) for palliative treatment of metastatic bone disease on one occasion prior to this misadministration.

2 BACKGROUND (87103)

On August 9, 1994, the licensee's radiation safety officer (RSO) notified the NRC Headquarters Duty Officer and the Walnut Creek Field Office of a misadministration that occurred earlier that morning at the licensee's facility. The RSO reported that a patient scheduled to receive a 5-millicurie (mCi) dose of Tl-201 for a myocardial perfusion study was mistakenly administered a 4-mCi dose of Sr-89.

The licensee's initial estimate of the potential radiation dose resulting from the misadministration was 250 centigray (rads) to the patient's bone surface. The RSO reported that no action had been taken to mitigate the potential radiation dose to the patient (i.e., administration of calcium as a blocking agent) because the patient had pre-existing cardiac problems which might have been exacerbated by administration of calcium. The RSO also reported that medical experts were being contacted to assist the licensee in an assessment of potential adverse health effects which might be suffered by the patient as a result of the misadministration.

In addition, the licensee stated that with exception of emergency procedures, VAMC had voluntarily suspended all nuclear medicine procedures involving intravenous administration of radiopharmaceuticals and had appointed an

internal investigation team to review the circumstances associated with the misadministration. On August 10, 1994, NRC issued a Confirmatory Action Letter (CAL) to confirm the licensee's actions as stated above.

3 SEQUENCE OF EVENTS (87103)

Based upon interviews with licensee personnel, re-enactments of the event by those technologists directly involved in handling the Sr-89, and a review of all related licensee records, the following sequence of events was established:

- On May 5, 1994, a consult sheet was prepared by a referring physician requesting that Patient A receive Sr-89 as a palliative treatment for the patient's metastatic bone disease.

- On July 22, 1994, a medical consultation sheet was signed by a staff cardiac surgeon requesting that Patient B be given a myocardial perfusion scan using Tl-201. A second consult sheet was then completed by a cardiac technologist to summarize the first consult sheet. The second consult sheet was initialed by a cardiac resident physician.

- Between 5:45 a.m. and 6:45 a.m. on August 9, 1994, Technologist A received an incoming shipment of radiopharmaceuticals from a local radiopharmacy. The shipment consisted of six unit doses contained in identical blue shields. Three of the blue shields contained a 3-mCi dose of Tl-201 in a 10 milliliter (ml) syringe, two shields contained a 5-mCi dose of Tl-201 in a 10 ml syringe, and the sixth shield contained a 4-mCi dose of Sr-89 in a 10 ml syringe.

  Each shield was affixed with an adhesive label which contained, in part, a description of the radiopharmaceutical, the dosage, and a physician's name. The label attached to the shield containing the Sr-89 dose also included a patient name. In addition to the adhesive labels applied to the blue shields, each syringe also had an adhesive label affixed near its upper flange which indicated the radiopharmaceutical name, dosage, and calibration time. The label affixed to the syringe containing Sr-89 also included a patient name.

- Technologist A performed the required package radiation surveys and completed the licensee's receipt log. Technologist A stated that she then arranged the six blue shields on a counter top with the three 3-mCi Tl-201 doses positioned together, followed by the two 5-mCi Tl-201 doses and the Sr-89 dose at the end of the line. The technologist then placed the duplicate labels provided by the radiopharmacy in the licensee's "Incoming Radiopharmaceuticals on Hand" log book. During this process Technologist A wrote, in bold black letters, a sequential VAMC tracking number, beginning with 5672, on each label in the log book. The Sr-89 label in the log book was marked as number 5677. The technologist then

wrote the sequential numbers, starting with 5672, on each blue shield beginning with the first 3-mCi Tl-201 dose and ending with 5677 on the last blue shield. At the time, Technologist A thought the last blue shield contained the 4-mCi Sr-89 dose.

- After numbering the six blue shields, Technologist A collected all six shields and placed them in the lead radiopharmaceutical storage cave located in the hot lab. Technologist A stated that she carefully read each label on the blue shields as she placed them in the cave. She remembered placing the three 3-mCi doses of Tl-201 in the center secondary shield and the Sr-89 dose in the far-right secondary shield. The two 5-mCi doses of Tl-201 were placed outside and to the left of the center secondary shield. Technologist A initially stated that she had read the label on the Sr-89 shield three times immediately prior to placing it in the far right secondary shield. In addition, since she was concerned that other technologists might confuse the 3- and 5-mCi Tl-201 doses, Technologist A wrote "5 mCi" on white adhesive labels and affixed a label to the top of each of the blue containers that she thought contained 5-mCi Tl-201 doses.

  Note: The patient's name did not appear on the labels affixed to the Tl-201 doses. The authorized user physicians had directed that 5-mCi doses of Tl-210 be used for large patients. Technologist A had scheduled two such patients and ordered the 5-mCi doses prior to August 9, 1994. Technologist A noted the need for the two 5-mCi doses on the patient schedule log and personally informed each of the other technologists that 5-mCi doses had been ordered to ensure that the correct dosages were selected. The technical staff stated that adding adhesive labels to the tops of the blue shields was an informal procedure routinely used to reduce the risk of selecting the wrong dosage for a particular patient.

- At approximately 7:00 a.m. Technologist B arrived, picked up the consult sheet for the first patient and entered the hot lab to retrieve a 3-mCi dose of Tl-201 from the radiopharmaceutical storage cave. Technologist B recalled that at that time there were three blue shields in the center secondary shield and two blue shields with white labels affixed to the tops located just to the right of the center shield. Technologist B did not recall what was stored in the far right secondary shield. Technologist B stated that she read the label and VAMC sequential number on the blue shield that she retrieved to confirm that it was a 3-mCi dose of Tl-201. Technologist B also noted that the dose she retrieved was labeled with the lowest batch number recorded in the log book for that morning.

  Technologist B then took the dose that she had selected to the dose preparation area, opened the shield and assayed the dose in the dose calibrator to confirm the activity. Technologist B placed the syringe in a syringe radiation shield and loaded it in a lead-lined rectangular

syringe carrier. The top of the syringe carrier was affixed with a white label to identify its content and taken to the patient injection area.

- Technologist C arrived in the department next and followed a similar process leading to the injection of a 3-mCi Tl-201 dose marked as "5673" to the second cardiac patient of the day. Technologist C recalled that there were two blue shields located in the center secondary shield and two blue shields with white labels on the tops located just to the left of the center secondary shield when she retrieved the dose for the second patient.

- Technologist C recalled that at approximately 8:20 a.m. she picked up the consult sheet for Patient B. (This was the second patient injection for Technologist C.) The consult sheet specified a 5-mCi dose of Tl-201 for a cardiac scan. Technologist C recalled that when she went to the radiopharmaceutical storage cave, one blue shield was located in the center secondary shield and two blue shields, each affixed with a white "5 mCi" label, were located just to the left of the center secondary shield.

  Technologist C stated that she selected a blue shield with a white label on top, read the pharmacy label, and took the blue shield to the dose preparation area. The technologist then opened the shield and read the label on the syringe, removed the syringe from the shield and put it in the dose calibrator, and noted that the calibrator read approximately 5-mCi. While Technologist C was in the process of placing the syringe in a syringe radiation shield she heard a page calling her to the treadmill room to assist with a cardiac study. At this same time the phone located next to the dose calibrator rang. Technologist C answered the phone and placed the caller on hold. Technologist C stated that she then decided to abort the injection and subsequently returned the syringe to its blue shield and replaced the shield in the same position in the cave from which it was taken. Technologist C then returned to the telephone call. After the telephone call, Technologist C was informed by another technologist that her presence was not immediately needed in the treadmill room and that she could continue with the injection she had just aborted.

- Technologist C later estimated that after an elapsed period of approximately 2 minutes, she resumed the 5-mCi Tl-201 injection she had earlier aborted. Technologist C returned to the cave and retrieved what she thought was the same blue shield with the white "5 mCi" label that she had assayed prior to the telephone call and took the blue shield to the dose preparation area. Technologist C stated that she had assumed she retrieved the dose which she had already assayed and therefore she did not read the radiopharmacy label nor the label on the syringe as she placed it in the syringe radiation shield. Nor did the technologist re-assay the dose prior to injection. Technologist C stated that she

placed the shielded syringe in the syringe carrier and labeled it as 5-mCi of Tl-201. Technologist C then carried the dose to the patient injection area and injected Patient B.

- Following the injection of Patient B, Technologist C stated that she returned the syringe carrier to the hot lab, deposited the empty syringe in the Tl-201 decay container, and removed the label from the syringe carrier. Technologist C stated that she then closed the blue shield that previously held the dose she had injected and placed it back on the shelf. Technologist C recalled that the white "5 mCi" label was still affixed to the top of the blue shield.

  Note: The syringe with the Sr-89 label was subsequently recovered from the Tl-201 decay container.

- At about 9:30 a.m. Technologist B attempted to perform the cardiac scan on Patient B. Technologist B was unable to visualize an image on the camera's persistence screen and tried re-positioning the patient with no success. Since Technologist B had earlier heard that the camera's photo-peak gain may have shifted, she attempted to locate another technologist who had adjusted that parameter earlier. Technologist B was subsequently instructed to re-peak the camera. Technologist B returned to the camera, removed the patient to the waiting room, and then returned to the hot lab and retrieved a 3-mCi Tl-201 dose to photo-peak the camera. Technologist B logged this dose into the "Dose Administered Log" as number 5674 and took the dose to the imaging area.

- Concurrent with the above noted activities, Technologists A and D prepared Patient A for administration of the Sr-89 dose. Technologist D went to the radiopharmaceutical storage cave to retrieve the Sr-89 dose and found only one blue shield in the storage cave, located in the far right secondary shield. Upon reading the radiopharmacy label, Technologist D discovered that the blue shield contained a 5-mCi Tl-201 dose marked as number 5677. The shield did not have a white "5 mCi" label affixed to its top.

  Technologist D searched the hot lab but was unable to locate the blue shield containing the Sr-89. Technologist A, who had returned to the hot lab, was also unable to locate the Sr-89 dose. During their search, Technologist A showed Technologist D the "Incoming Radiopharmaceutical On Hand" log to demonstrate that the Sr-89 dose had been received earlier that morning. During his review of the log book, Technologist D pointed out to Technologist A that her sequential numbering was in error. Technologist D noted that he was holding a shield labeled "5677" which according to the log book should have been the Sr-89 dose. Technologist A then modified the log book entries to correct the discrepancy. As Technologist A was marking over label number 5675 (which was a Tl-201 label) in the log book to correct it to number 5677, Technologist C entered the area and inquired about the Sr-89 dose.

- After re-peaking the camera, Technologist B was again unable to see an image from Patient B and she returned to the hot lab for assistance. At that point, Technologist D concluded that there must have been a misadministration and that perhaps Patient B had not received a dose of Tl-201 but had instead been administered the Sr-89 dose that could not be located. A discussion involving the three technologists occurred during the next few minutes concerning where the Sr-89 blue shield was located and the need to notify the Chief, Nuclear Medicine (CNM) and the RSO. At some point during the discussion the Sr-89 blue shield was located and according to Technologists A and D it did not have a white label on the top. Technologist A stated that someone handed her the Sr-9 blue shield but she was unable to recall who gave it to her.

- Between 9:30 and 10:00 a.m. Technologist A interrupted a meeting of the CNM and RSO to inform them of the apparent misadministration. The CNM immediately initiated an inquiry, notified the patient, and then briefed the licensee's Chief of Staff and the Acting Medical Center Director. The CNM and another nuclear medicine physician then met with Patient B and explained the misadministration and its potential consequences. A sample of the patient's blood was drawn for a baseline blood count and a meeting was arranged with the patient and his spouse for the next morning. The CNM notified the cardiac clinic that referred the patient and the Regional Veteran's Affairs Radiation Safety Program Manager and initiated contact with experts in Oakridge, Tennessee. Patient B subsequently notified the cardiac surgeon (referring physician) of the event shortly after his discussion with the CNM and RSO. The referring physician discussed the error with an authorized user physician on August 9, 1994.

- The Chief of Staff recommended closing the Nuclear Medicine service pending the completion of an administrative investigation. The Acting Director implemented the recommended action. The Chief of Staff issued a memorandum at 1:00 p.m. on August 9, 1994, directing that the Nuclear Medicine service stop administering radiopharmaceuticals to patients for the remainder of the week. In addition, the memorandum required that the staff prioritize the scheduled exams and schedule patients for procedures at another facility.

- At 1:20 p.m. the RSO notified the NRC headquarters operation officer of the misadministration. At 1:30 p.m. the NRC RIV Walnut Creek Field Office was informed by telephone of the misadministration.

- At 1:30 p.m. the Regional Radiation Safety Program Manager spoke with a nuclear medicine physician to discuss the need for a medical decision regarding the timeliness and appropriateness of intervention/mitigative actions to reduce the radiation dose to the patient.

- The Medical Center Director issued a memorandum initiating an administrative investigation on August 9, 1994. The Acting Chief,

Neurology Service was appointed to lead the investigation with assistance from the Chief, Endocrinology Section; the Acting Chief, Psychiatry Service; and the Assistant Chief, Human Resources Management.

- On August 10, 1994, NRC issued a Confirmatory Action Letter (CAL 4-94-09) to VAMC which confirmed actions taken by VAMC to temporarily suspend nuclear medicine procedures involving intravenous administration of radiopharmaceuticals labeled with byproduct material until:

  1) an Administrative Investigative Board appointed by VAMC conducted an investigation of the misadministration to determine the root cause(s);

  2) the Chief of Staff determined that safe clinical practices would be followed; and

  3) VAMC provided the NRC Region IV office with the results of its investigation and the Regional Administrator informed VAMC that the NRC had no objection to the licensee resuming full nuclear medicine services.

4 DIRECT CAUSE (87103)

The inspection revealed that the direct cause of the misadministration was the failure of a supervised individual to follow existing departmental procedures for dose preparation and patient administration.

10 CFR 35.25(a)(2) requires that supervised individuals follow (1) the instructions of the supervising authorized user and (2) the written radiation safety procedures and quality management procedures established by the licensee. In addition, the license must require that individuals using byproduct material under the supervision of an authorized user comply with NRC regulations and the conditions of the license with respect to the use of byproduct material.

The licensee's written procedure titled "INJECTION OF THE RADIOPHARMACEUTICALS," dated June 14, 1991, states, in part, that: (1) prior to injection it is absolutely mandatory to match the patient, the request form, and the prepared dose and (2) upon confirmation that the patient and consultation sheet match, the technologist then confirms that the scan ordered on the request form matches the prepared radiopharmaceutical by noting the name, date, radiopharmaceutical, and the color of the gummed label which has been affixed both to the lead carrier and the syringe within the carrier.

The licensee's written procedure titled "DISPENSING OF THE RADIOPHARMACEUTICAL," dated June 14, 1991, states, in part, that the syringe is assayed in the dose calibrator and then placed back into a syringe shield which will then in turn go into a lead box or carrier.

Technologist C acknowledged that she did not follow the above noted instructions the second time she removed the blue shield from the cave and injected Patient B Based on interviews with Technologist C regarding the steps taken prior to administering the radiopharmaceutical dose to Patient B, it appeared that the technologist failed to follow written departmental procedures established by the licensee in that she failed to read the label on the shield and syringe and failed to assay the dose prior to administration. Had the technologist completed either of the aforementioned actions, she would have recognized that the dose was not Tl-201 as she thought, and the misadministration would not have occurred. The failure of the technologist to follow the licensee's written radiatic safety procedures was identified as an apparent violation of 10 CFR 35.25(a)(2).

5 CONTRIBUTING CAUSE(S) (87103)

5.1 Mislabeling of Blue Shields

It appeared that during the receipt and check-in of radiopharmaceuticals, the technologist mistakenly labeled the blue shield containing Sr-89 with an incorrect batch number and also affixed a white label indicating that the shield contained a 5-mCi dose of Tl-201. Although the licensee's vendor had correctly labeled each shield and syringe received by the licensee on August 9 with the appropriate identifying data, the staff also used an informal labeling procedure to further distinguish the two 5-mCi Tl-201 doses from the remainder of the unit dose radiopharmaceuticals. As noted above, it was the latter informal process which appeared to have been in error in this particular instance.

The fact that the technical staff had adopted such an informal practice appeared to indicate that the technologists may not have always carefully verified the radiopharmacy's label in the past because they deemed it necessary to implement an informal method for labeling the shields to supplement the labels applied by the radiopharmacy. This practice placed the staff at risk of relying solely on the informal labels to identify certain doses.

It must be noted that at the conclusion of the inspection, Technologist A approached the inspectors and stated that although she had previously been certain that she had placed the Sr-89 blue shield in the far right secondary shield, upon further reflection she had concluded that it was possible that she may have made an error. The technologist stated that she may not have placed the Sr-89 container in the far right secondary shield and may have instead placed it in a different location and affixed a white "5 mCi" label on the Sr-89 container.

The informal practice of labeling certain doses with white adhesive labels and the technologist's reliance upon this method, combined with the apparent error in this particular instance, was identified as a contributing factor to the misadministration.

5.2 Similarity of Syringe Containers

As noted in Section 1, the licensee had received some radiopharmaceuticals in unit dose form from a local radiopharmacy. Radiopharmaceuticals received in unit dose form included both diagnostic and therapeutic doses, although the therapeutic doses were primarily limited to those which are administered orally rather than intravenously. The majority of the diagnostic unit dose radiopharmaceuticals received by VAMC had consisted of Tl-201 and a limited number of Tc-99m labeled radiopharmaceuticals.

Albeit the licensee had administered Sr-89 on one occasion prior to August 9, 1994, the licensee's use of therapeutic radiopharmaceuticals had been primarily limited to administration of millicurie quantities of sodium iodide iodine-131 (I-131) for thyroid treatments. Because sodium iodide I-131 is administered orally, in either capsule form or solution, it had been received in shielded containers which were markedly different from the blue shields used for diagnostic unit dose radiopharmaceuticals.

VAMC had routinely received therapeutic doses of sodium iodide I-131 as a solution contained in a glass vial housed in a white lead container. Both the color and size of the container made it readily distinguishable from other unit doses received by the licensee. However, Sr-89, a therapeutic radiopharmaceutical which is administered intravenously, was received in a blue shield that was identical in size and color to the shields containing Tl-201, a diagnostic radiopharmaceutical. The use of shielded containers that were identical in size and color for both Tl-201 and Sr-89 was identified as a contributing factor in that there was no readily apparent means to distinguish between the Tl-201 doses and the Sr-89 dose.

The inspectors noted that VAMC had received a limited number of Tc-99m labeled radiopharmaceuticals, in unit dose form, on a routine basis. The Tc-99m labeled unit dose radiopharmaceuticals were packaged in shielded containers that differed both in size and color (white) from the shielded containers used for Tl-201 and Sr-89 doses. Thus, the Tc-99m labeled radiopharmaceuticals were readily distinguishable from Tl-201 or other radiopharmaceuticals packaged in the blue shields, thereby reducing the risk of errors involving the selection of the wrong dose.

Based on interviews with VAMC staff members, it appeared that VAMC had not given consideration to the similarity in packaging between some diagnostic unit doses and therapeutic unit doses of Sr-89. This appeared to be due, in part, to the fact that VAMC had not had much experience in using Sr-89 which is unique in that it is one of few therapeutic radiopharmaceuticals that is dispensed as a unit dose for intravenous administration. Other therapeutic radiopharmaceuticals used in nuclear medicine are generally packaged much differently because they are either administered orally, rather than by syringe, or they are not routinely dispensed as a unit dose and are instead received in a vial.

5.3 Storage of Radiopharmaceuticals

Through interviews of licensee personnel, the inspectors determined that all doses of sodium iodide I-131 had been stored in the licensee's fume hood, an area separate from the lead cave where other radiopharmaceuticals were routinely stored prior to administration. However, based on interviews of the staff, it appeared that the practice of separating sodium iodide I-131 from diagnostic radiopharmaceuticals was established due to the volatility of radioiodine rather than with the intent to separate therapeutic radiopharmaceuticals from diagnostic unit doses in order to prevent an inadvertent misadministration. A review of the licensee's written procedures disclosed that no procedural requirement had been established relative to segregating therapeutic radiopharmaceuticals from diagnostic radiopharmaceuticals.

The inspectors noted that the licensee's practice of storing Sr-89 doses along with diagnostic radiopharmaceutical doses in the same radiopharmaceutical storage cave appeared to have contributed to the potential for inadvertent selection of the wrong radiopharmaceutical dose.

5.4 Human Factors

Interviews with Technologist C disclosed that mental stress may also have contributed to the error. It was noted that the technologist involved in the misadministration had received some troubling personal information the evening prior to the misadministration which may have contributed to the technologist's less than adequate attention to detail on the morning of the misadministration. In addition, the pages and telephone calls which the technologist received during the dose preparation phase caused her to divert attention from the dose verification process and appeared to have contributed to the technologist's retrieval of the wrong radiopharmaceutical dose.

5.5 Reliance on Informal In-house Procedures

As noted in Section 3 of this report, in addition to the licensee's established written procedures, the technical staff had developed some informal procedures for receipt and storage of unit dose radiopharmaceuticals. The informal procedures were neither documented nor approved by the licensee's authorized users. The procedures included the use of additional labels (white stickers denoting "5 mCi") on blue shields containing certain Tl-201 doses and the implementation of an in-house batch numbering system for unit doses received from the radiopharmacy. The staff's reliance on informal practices, apparently aimed at augmenting the technologist's ability to identify specific radiopharmaceutical doses, may have resulted in a reduced emphasis on verifying the radiopharmaceutical label on the syringe with the patient consult sheet to ensure that the correct radiopharmaceutical was administered.

5.6 Incomplete/Insufficient Written Procedures

The inspectors' review of the licensee's procedures for radiopharmaceutical administration revealed them to be deficient regarding the receipt of unit doses. The licensee's procedure titled "Guidelines For Radiopharmaceutical Administration," dated June 1991, appear to refer only to radiopharmaceuticals prepared in-house rather than those received in unit dose form from a radiopharmacy. In addition, the procedure did not specify how unit doses of therapeutic agents (i.e., Sr-89) were to be received and logged.

5.7 Oversight of Daily Activities

Some of the contributing factors identified during the inspection appeared to indicate a deficiency in the authorized users' direct supervision of daily activities involving receipt and administration of radiopharmaceuticals.

Although an authorized user may delegate specific tasks to supervised individuals, such as package receipt, quality control, radiopharmaceutical administration, performance of clinical procedures, and radioactive waste disposal, the authorized user must provide adequate supervision to ensure that supervised individuals comply with NRC regulations and the conditions of the license with respect to the use of byproduct material. The inspectors noted that the CNM and other authorized users were apparently unaware of the informal practices/procedures instituted by the staff technologists (supervised individuals). In addition, the CNM had not identified the need to update departmental procedures to address the receipt and use of unit dose radiopharmaceuticals used for therapy.

The findings noted above appeared to indicate a lack of attention to detail in the authorized users' oversight of daily activities delegated to supervised individuals and was identified as a contributing factor to this misadministration.

6 CONSEQUENCES (87103)

6.1 Licensees Assessment of Dose Consequences

The licensee's estimate of the potential radiation dose resulting from the misadministration was approximately 250 centigray to the bone surface. In addition, the licensee expected that the patient's white blood cell and platelet count would decrease by approximately 20-30 percent over a 12-week period, although the white blood cell and platelet counts were expected to return to normal levels within 12 weeks following the misadministration.

6.2 NRC Medical Physician Consultant's Review

On August 10, 1994, NRC contracted a medical physician consultant to: (1) perform an assessment of any probable deterministic effects of the radiation exposure of the patient; (2) evaluate the radiation dose received by the patient as a result of the administration of Sr-89; (3) assess the

licensee's decision regarding the administration of chelating agents (such as calcium) or other pharmacologic agents that could potentially mitigate the radiation dose received by the patient; and (4) evaluate the licensee's notification to the exposed patient and referring physician.

The consultant interviewed licensee staff members and the patient's primary physician during the initial onsite portion of the inspection. The consultant continued his review of information provided by the licensee following the initial segment of the inspection and planned to continue to follow clinical evaluations scheduled for the patient through the 4-8 week period following the misadministration.

The consultant's review disclosed that the patient's medical management following the misadministration was reasonable given the patient's medical history. The consultant's assessment of the probable deterministic effects of the radiation exposure indicated that the probability of serious bone marrow suppression following administration of 4-mCi of Sr-89 to an individual who did not have metastatic bone disease was low. The consultant estimated the radiation dose received by the patient to be approximately 250 centigray to the bone surface, 150 centigray to active bone marrow and 15 centigray to the kidneys.

A report of the consultant's initial review and recommendations concerning the misadministration is enclosed as Attachment 2 to this report.

7 LICENSEE CORRECTIVE ACTIONS (87103)

7.1 Response to CAL

By letter dated August 19, 1994, the licensee responded to the CAL issued by NRC on August 10, 1994. The licensee's response indicated that the Administrative Investigative Board (AIB) appointed by the medical center director had concluded its investigation of the misadministration and that the licensee's Chief of Staff had determined that safe clinical practices would be followed. A report prepared by the AIB was reviewed by the inspectors and other NRC Region IV staff members during NRC's inspection and review of the licensee's response.

During a preliminary exit briefing conducted at the licensee's facility on August 19, 1994, the licensee was informed by NRC representatives that based on NRC's review of VAMC's written response to the CAL and discussions held with licensee representatives, the NRC had determined that VAMC had satisfactorily completed the actions identified in the CAL. NRC representatives informed VAMC that NRC had no objection to VAMC resuming nuclear medicine procedures involving intravenous administration of radiopharmaceuticals. NRC confirmed the above in writing by letter dated August 25, 1994.

7.2 VAMC Investigative Report

The purpose of the licensee's AIB was to ascertain the facts surrounding the incident and to determine its direct, contributing, and root cause(s). In addition, the board was charged with recommending appropriate corrective actions to prevent a recurrence.

The AIB determined the direct cause of the misadministration to be the technologist's failure to read the label on the syringe and failure to assay the dose prior to injecting the radiopharmaceutical. The AIB noted that the contributing factors appeared to stem from a systematic problem with the licensee's procedures and recommended that the systematic problem be addressed through the licensee's corrective actions rather than focusing the corrective actions solely on the technologist's error. The AIB noted that it was unable to identify specific contributing factors because some evidence was no longer available (the shield labels applied by VAMC staff) and some aspects of various accounts of the activities which took place on August 9 were in conflict. The AIB did, however, make several recommendations to licensee management. The AIB's recommendations are summarized below:

- Consider eliminating the use of in-house batch numbers on incoming radiopharmaceutical doses.
- Eliminate the use of additional white labels on the top of certain dose shields since the practice introduces an extra step which could be a potential source of error.
- Designate areas for storage of radiopharmaceutical doses that will provide for segregation of doses by isotope.
- Consider introducing a requirement for independent verification of radiopharmaceutical doses prior to injection.
- Develop strict procedural rules for handling and identifying radiopharmaceuticals from the time of receipt to administration to patients.

The licensee subsequently implemented corrective actions aimed at addressing the recommendation made by the AIB. With regard to the systematic problem identified by the AIB, the licensee planned to develop procedural rules for the handling and identification of all radiopharmaceuticals from the time of receipt through the time of administration to a patient. The licensee noted that the procedures would be written and distributed to all appropriate staff and frequent in-service training sessions would be conducted to ensure compliance.

2 EXIT MEETINGS

A preliminary site exit briefing was conducted on August 19, 1994, with those individuals identified in Section 1. A final exit briefing was conducted telephonically between the licensee's representatives identified in Section 1 and Ms. Linda L. Kasner and Mark R. Shaffer of the NRC Region IV office on September 26, 1994, to review the specific findings as presented in this report.

ATTACHMENT 1

1 PERSONS CONTACTED

1.1 Licensee Personnel

A. Achen, V.A. District Counsel
J. Allen, Nuclear Medicine technologist
* B. Fallen, AA/Chief of Staff
* D. Ganoe, Chief, Engineering Service
D. Gilltrap, Nuclear Medicine Technologist
I. Gordon, M.D., Surgery
H. Greenbaum, M.D., Associate Chief, Neurology Service
*+M. Hartford, Acting Medical Center Director
J. Hicky, Lead Nuclear Medicine Technologist
A. Kabok, M.D., Nuclear Medicine Physician
S. Lai, Ph.D., Radiopharmacist
S. Lally, Supervisor Nuclear Medicine Technologist
E. Leidholdt, Jr., Ph.D., Radiation Safety Program Manager
*+K. Lyons, M.D., Chief, Nuclear Medicine Service
*+S. Mills, Radiation Safety Officer
* N. Milne, M.D., Assist. Chief, Nuclear Medicine Service
+E. Mindes, M.D., Assist. Chief of Staff
* J. Moravec, Ph.D., Medical Center Director
M. Nilsen, Nuclear Medicine Technologist
* L. Price, Acting Assistant Medical Center Director
* R. Rogers, Assist. Chief, Engineering Service
S. Rubin, M.D., Cardiology
T. Sandoval, Nuclear Medicine Technologist
J. Segal, M.D., General Medicine
R. Simmons, Public Affairs Officer
C. Talkinton, Medical Clerk, Nuclear Medicine
* P. Taraszkiewicz, Secretary to Chief of Staff
* C. Thielman, Health Physicist
*+H. Wepsic, M.D., Chief of Staff

1.2 NRC Personnel

*+L. Kasner, Chief, Nuclear Materials Inspection Branch
Z. Petrovich, M.D., NRC Medical Physician Consultant
*+M. Shaffer, Senior Radiation Specialist
* G. Yuhas, Technical Assistant

*Indicates those individuals present during the pre-exit meeting held on August 19, 1994.

#Indicates those individuals contacted by telephone only.

ATTACHMENT 2

MEDICAL CONSULTANT REPORT

Medical Consultant Name: Zbigniew Petrovich, M.D.

Signature: [redacted]

Report Date: September 12, 1994

Licensee Name: The Veterans Affairs Medical Center
5901 E. Seventh Street
Long Beach, California 90822
License No: 04-00689-07

Patient's Identification No: N/A

Incident Date: August 9, 1994

Referring Physician Name: [redacted] M.D. and [redacted] M.D. - both from The Veterans Affairs Medical Center, Long Beach, California.

Individuals Contacted During Investigation: Interviews were conducted during a site visit on August 11, 1994 with the following individuals:

[redacted] M.D., Chief of Staff,
[redacted] M.D., Cardiology,
[redacted] M.D., General Medicine,
[redacted] M.D., Surgery,
[redacted] M.D., Nuclear Medicine,
[redacted], Assistant Chief of Staff,
[redacted] C.O.S. Secretary,
[redacted] NRC-RIV, Arlington, Texas,
[redacted], NRC-WCFO,
Chief Technologist of Nuclear Medicine Service - the person who administered the radionuclide,
The Medical Center Radiation Safety Officer.

Records Reviewed: All of the provided patient's medical records were reviewed by this medical consultant. The patient's medical history is a long and very complex one.

Present problem: The patient is a 69 year old male veteran. In July and August of 1994 he was diagnosed as having an aneurysm of the abdominal aorta. To correct this abnormality the patient was being considered for surgical treatment. As a part of presurgical work-up he was scheduled to have a myocardial perfusion study requiring the use of Thallium-201.

Relevant and important past medical history: The patient has had over 20 years history of adult onset diabetes mellitus, obesity, hypertension and a severe coronary artery disease. In 1974 he had a myocardial infarction. This according to the medical records occurred again in 1976 and 1977. He required a coronary artery by-pass procedure which was performed on

Dec. 10, 1975. An additional CAB was performed in April 1976. Early in 1994 the patient developed intermittent claudication and during the process of vascular work-up was diagnosed as having a significant aneurysm of the abdominal aorta. This abnormality was felt to be of sufficient severity to consider surgical treatment. As a part of the presurgical work-up the patient needed a Thallium-201 study in order to assess myocardial perfusion. On August 9, 1994 this patient received 4mCi of Strontium-89 instead of the ordered 4mCi of Thallium-201.

The patients has also had a long history of important emotional disorders including: intermittent periods of agitations followed by periods of depressions, suicidal threats, multiple personal problems, alcoholism, insomnia and frequent unexplained headaches. He was diagnosed as organic brain syndrome and was chronically receiving multiple psychiatric medications.

Comments: The patients available medical records were frequently inaccurate as to the dates of major events such as: an important surgical procedure or a serious illness like a myocardial infarction. Additionally, an important event such as a misadministration of a radionuclide was not recorded on the patients main chart. These problems do not meet an acceptable standards for medical records.

Estimated Dose To Individual Or Target Organ: This question is difficult to answer based on the available relevant medical literature. Strontium-89 is preferentially taken up by bone with increased osteoblastic activity such as is the case in patients with metastatic bone disease. Strontium-89 is not administered in patients who show no evidence of metastatic bone disease therefore there are few published human data on this subject. One can however discuss this issue and present the best estimated doses to important target organs.

Strontium-89 chloride (Mesastron) is an important radionuclide used primarily to treat patients with adenocarcinoma of the prostate who have symptomatic multiple bone metastases (1-3) Strontium-89 is a calcium analog. This radionuclide is a betta emitter with maximum energy of 1.4 MeV, physical half-life of 50.5 days and specific activity of 5 GBq/g (4).

There is also a clinically insignificant gamma emission of 910 KeV. Following intravenous administration the radionuclide is preferentially taken up by areas of increased osteoblastic activity which are present at and near metastatic foci in bones (4). Whole body retention in two patients with osteogenic sarcoma were reported: at 20% 3 months following the administration of Strontium-90 in the first patient and 84% at 12 days in the second patient (4). Strontium renal plasma clearance rates were: 7.61 day (-1) for the first patient and 1.51 day (-1) for the second patient. In the 5 healthy patients the renal plasma clearance rate ranged from 8.1 to 15.4 days (-1), (5) and an accepted mean for normal patients of 8.31 day (-1), (6).

From the above it is apparent that in this patient who does not have metastatic adenocarcinoma of the prostate, Strontium-89 whole body clearance should be relatively fast. For clinical purposes it is estimated to be 3 to 4 weeks. Based on the available data the following dose of radiation is estimated to be received by the patient:

Bone Surface 250cGy
Active Bone Marrow 150cGy
Kidneys 15cGy

Description of the incident: At 0930hr. on August 9, 1994 a 69 year old male patient was scheduled to undergo a myocardial perfusion study using a Thallium-201 test. He was to receive a dose of 4mCi of this radionuclide. A nuclear medicine technician identified the lead container with the prepared Thallium-201 dose, removed the inner container with the radionuclide, identified the number on the vial and placed into a Capintec counter. The counter showed the radionuclide to be the correct one and of the stated activity. At this time the technician received a call "Gene we are ready for you" from the treadmill room where the patient

was waiting for his test. A moment later another phone call was received by the technician. At this point she took the vial with radionuclide, place it into its proper lead container and put it back in the original position in the "hot" laboratory. Following the completion of the above telephone conversation the technician removed the vial containing the radionuclide but failed to identify it by reading its label, its ID number and failing to place it again into the Capintec counter. Immediately after she injected the patient with the radionuclide. Shortly after the injection of the radionuclide no expected images could be obtained at which point a concern was raised about a possibility of a misadministration. [redacted] Chief of Nuclear Medicine Service and the medical center Radiation Safety Officer were notified. About 1330hr. NRC was notified of this misadministration of a radionuclide.

Comments: The entry into the log book recording receival of radionuclides was incorrect. The number in the log book was 5675 which was the same as on the lead pig was incorrect. The correct number for the Strontium-89 should have been 5677 rather than 5675. This error in numbers was corrected after the misadministration. This error should be discovered by a properly trained technician responsible for administration of the radionuclide. A contributing factor to this misadministration was the procedure permitting a side by side storage of various radionuclides for therapeutic and diagnostic applications. The technician in question stated that she never handled Strontium-89 before August 9, 1994.

Assessment of probable deterministic effects of the radiation exposure on the individual:

The following problems present themself as a result of this misadministration:

1. The patient in the judgment of his physicians and surgeons required a surgical procedure to correct the problem with aneurysm of the abdominal aorta. This procedure as a result of the misadministration needs to be delayed. The impact of this delay cannot be determined by this medical consultant.

2. This patients being a diabetic has a potential for development of serious infection as a consequence of a probable decrease in the white cell count. The reported probability of a serious bone marrow suppression following the administration of 4 mCi of Strontium-89 is however low (1,7,8). The blood count nadir usually occurs at 10 to 12 weeks after Strontium-89 injection. Due to a lack of metastatic disease in this patient and expected more rapid clearance of the administered radionuclide this nadir is expected between 3 and 6 weeks.

3. Realistically, no other important medical problems are likely to occur in this patient as a result of the reported misadministration.

4. Based on all of the available data on this patient it is very likely that the most serious effects of the reported misadministration will be psychological both on the patient himself and his wife.

Describe the current medical condition of the exposed individual: There are no important changes in the patient medical condition as a result of the reported misadministration.

The patient should be included in the DOE Long-Term Medical Study Program.

1. Based on your review of the incident, do you agree with the licensee's written report that was submitted to NRC pursuant to 10 CFR 35.33 in the following areas:

   a. Why the event occurred - Yes
   b. Effect on the patient - No

c. Licensee's immediate actions upon discovery - Yes
d. Improvements needed to prevent recurrence - Yes

2. In areas where you do not agree with the licensee's evaluation (report submitted under 10 CFR 35.33), provide the basis for your opinion:

The licensee does not seem concerned about the psychological effect of this misadministration on the patient.

3. Did the licensee notify the referring physician of the misadministration? - Yes

Did the licensee notify the patient's or the patient's responsible relative or guardian? - Yes

If the patient or responsible relative or guardian was not notified of the incident, did the licensee provide a reason for not providing notification consistent with 10CFR 35.33? - N/A

4. Provide an opinion of the licensee's plan for patient follow-up, if available.

The follow-up plan as provided in a letter of August 23, 1994 is satisfactory except for a lack of need for psychological counseling for the patient and his spouse.

REFERENCES

1. Porter A.T., McEwan A.J.B., Powe J.E. et al.: Results of a randomized phase III trial to evaluate the efficacy of Strontium-89 Adjuvant to local field external beam irradiation in the management of endocrine resistant metastatic prostatic cancer. It J Radiat Oncol Biol Phys 25:805-813, 1993.

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4. Blake G.M., Zivanovic M.A., McEwan A.J. et al.: Strontium-89 therapy: strontium kinetics and dosimetry in two patients treated for metastatic osteosarcoma. Br J Radiol 60:253-259, 1987.

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6. Harrison G.E., Sutton A.: Ratio of fecal to urinary clearance of strontium in man. In "Strontium metabolism, Lenihan J.M.A., Loutit J.F., Martin J.H., Eds., Academic Press, London, 1976, pp. 161-166.

7. Blake G.M., Zivanovic M.A., Blaquiere R.M. et al.: Strontium-89 therapy: Measurement of absorbed dose to skeletal metastases. J Nucl Med 29:549-557, 1988.

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APPENDIX B

ENFORCEMENT CONFERENCE WITH VETERANS AFFAIRS MEDICAL CENTER
LONG BEACH, CALIFORNIA
OCTOBER 24, 1994

NRC REGION IV, WALNUT CREEK, CALIFORNIA

1. OPENING REMARKS & INTRODUCTIONS - CHIEF, NUCLEAR MATERIALS INSPECTION BRANCH
2. LICENSEE INTRODUCTIONS - LICENSEE
3. ENFORCEMENT PROCESS - ENFORCEMENT OFFICER
4. APPARENT VIOLATIONS & REGULATORY CONCERNS - CHIEF, NUCLEAR MATERIALS INSPECTION BRANCH
5. LICENSEE PRESENTATION
6. BREAK (10-MINUTE NRC CAUCUS IF NECESSARY)
7. RESUMPTION OF DISCUSSION
8. CLOSING REMARKS - LICENSEE
9. CLOSING REMARKS - CHIEF, NUCLEAR MATERIALS INSPECTION BRANCH

Two-Year Trial Program for Conducting Open Enforcement Conferences; Policy Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Policy statement.

SUMMARY: The Nuclear Regulatory Commission (NRC) is issuing this policy statement on the implementation of a two-year trial program to allow selected enforcement conferences to be open to attendance by all members of the general public. This policy statement describes the two-year trial program and informs the public of how to get information on upcoming open enforcement conferences.

DATES: This trial program is effective on July 10, 1992, while comments on the program are being received. Submit comments on or before the completion of the trial program scheduled for July 11, 1992. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Send comments to: The Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555. ATTN: Docketing and Service Branch.

Hand deliver comments to: One White Flint North, 11555 Rockville Pike, Rockville, MD between 7:45 a.m. to 4:15 p.m., Federal workdays.

Copies of comments may be examined at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC

FOR FURTHER INFORMATION CONTACT: James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555 (301–504–2741).

SUPPLEMENTARY INFORMATION:

Background

The NRC's current policy on enforcement conferences is addressed in Section V of the latest revision to the "General Statement of Policy and Procedure for Enforcement Actions," (Enforcement Policy) 10 CFR part 2, appendix C that was published on February 18, 1992 (57 FR 5791). The Enforcement Policy states that, "enforcement conferences will not normally be open to the public." However, the Commission has decided to implement a trial program to determine whether to maintain the current policy with regard to enforcement conferences or to adopt a new policy that would allow most enforcement conferences to be open to attendance by all members of the public.

Policy Statement

Position

The NRC is implementing a two-year trial program to allow public observation of selected enforcement conferences. The NRC will monitor the program and determine whether to establish a permanent policy for conducting open enforcement conferences based on an assessment of the following criteria:

(1) Whether the fact that the conference was open impacted the NRC's ability to conduct a meaningful conference and/or implement the NRC's enforcement program;

(2) Whether the open conference impacted the licensee's participation in the conference;

(3) Whether the NRC expended a significant amount of resources in making the conference public; and

(4) The extent of public interest in opening the enforcement conference.

I. Criteria For Selecting Open Enforcement Conferences

Enforcement conferences will not be open to the public if the enforcement action being contemplated—

(1) Would be taken against an individual, or if the action, though not taken against an individual, turns on whether an individual has committed wrongdoing;

(2) Involves significant personnel failures where the NRC has requested that the individual(s) involved be present at the conference;

(3) Is based on the findings of an NRC Office of Investigations (OI) report; or

(4) Involves safeguards information, Privacy Act information, or other information which could be considered proprietary.

Enforcement conferences involving medical misadministrations or overexposures will be open assuming the conference can be conducted without disclosing the exposed individual's name. In addition, enforcement conferences will not be open to the public if the conference will be conducted by telephone or the conference will be conducted at a relatively small licensee's facility. Finally, with the approval of the Executive Director for Operations, enforcement conferences will not be open to the public in special cases where good cause has been shown after balancing the benefit of public observation against the potential impact on the agency's enforcement action in a particular case.

The NRC will strive to conduct open enforcement conferences during the two-year trial program in accordance with the following three goals:

(1) Approximately 25 percent of all eligible enforcement conferences conducted by the NRC will be open for public observation;

(2) At least one open enforcement conference will be conducted in each of the regional offices; and

(3) Open enforcement conferences will be conducted with a variety of the types of licensees.

To avoid potential bias in the selection process and to attempt to meet the three goals stated above, every fourth eligible enforcement conference involving one of three categories of licensees will normally be open to the public during the trial program. However, in cases where there is an ongoing adjudicatory proceeding with one or more intervenors, enforcement conferences involving issues related to the subject matter of the ongoing adjudication may also be opened. For the purposes of this trial program, the three categories of licensees will be commercial operating reactors, hospitals, and other licensees, which will consist of the remaining types of licensees.

II. Announcing Open Enforcement Conferences

As soon as it is determined that an enforcement conference will be open to public observation, the NRC will orally notify the licensee that the enforcement conference will be open to public observation as part of the agency's trial program and send the licensee a copy of this Federal Register notice that outlines the program. Licensees will be asked to estimate the number of participants it will bring to the enforcement conference so that the NRC can schedule an appropriately sized conference room. The NRC will also notify appropriate State liaison officers that an enforcement conference has been scheduled and that it is open to public observation.

The NRC intends to announce open enforcement conferences to the public normally at least 10 working days in advance of the enforcement conference through the following mechanisms:

(1) Notices posted in the Public Document Room;

(2) Toll-free telephone messages; and

(3) Toll-free electronic bulletin board messages.

Pending establishment of the toll-free message systems, the public may call (301) 492-4732 to obtain a recording of upcoming open enforcement conferences. The NRC will issue another Federal Register notice after the toll-free message systems are established.

To assist the NRC in making appropriate arrangements to support public observation of enforcement conferences, individuals interested in attending a particular enforcement conference should notify the individual identified in the meeting notice announcing the open enforcement conference no later than five business days prior to the enforcement conference.

III. Conduct of Open Enforcement Conferences

In accordance with current practice, enforcement conferences will continue to normally be held at the NRC regional offices. Members of the public will be allowed access to the NRC regional offices to attend open enforcement conferences in accordance with the "Standard Operating Procedures For Providing Security Support For NRC Hearings And Meetings" published November 1, 1991 (56 FR 56251). These procedures provide that visitors may be subject to personnel screening, that signs, banners, posters, etc., not larger than 18" be permitted, and that disruptive persons may be removed.

Each regional office will continue to conduct the enforcement conference proceedings in accordance with regional practice. The enforcement conference will continue to be a meeting between the NRC and the licensee. While the enforcement conference is open for public observation, it is not open for public participation.

Persons attending open enforcement conferences are reminded that (1) the apparent violations discussed at open enforcement conferences are subject to further review and may be subject to change prior to any resulting enforcement action and (2) the statements of views or expressions of opinion made by NRC employees at open enforcement conferences or the lack thereof, are not intended to represent final determinations or beliefs.

In addition to providing comments on the agency's trial program in accordance with the guidance in this notice, persons attending open enforcement conferences will be provided an opportunity to submit written comments anonymously to the regional office. These comments will subsequently be forwarded to the Director of the Office of Enforcement for review and consideration.

Dated at Rockville, MD, this 7th day of July 1992.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 92-16233 Filed 7-9-92; 8:45 a.m.]

BILLING CODE 7590-01-M

Two-Year Trial Program for Conducting Open Enforcement Conferences; Continuation of Trial Program

AGENCY: Nuclear Regulatory Commission.

ACTION: Supplement to Policy Statement; Continuation of Trial Program.

SUMMARY: The Nuclear Regulatory Commission (NRC) is issuing a supplement to its two-year trial program for conducting open enforcement conferences. The purpose of this supplement is to inform the public of the NRC's continuation of the trail program until the commission acts upon the NRC staff's recommendations regarding open enforcement conferences.

FOR FURTHER INFORMATION CONTACT: James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555 (301-504-2741).

SUPPLEMENTARY INFORMATION: The Commission published a policy statement on the implementation of a two-year trial program to allow selected enforcement conferences to be open to public observation on July 10, 1992 (57 FR 30762). The purpose of the trial program was to determine whether to maintain the current policy stated in Section V of the "General Statement of Policy and Procedure for Enforcement Action," (Enforcement Policy) 10 CFR Part 2, Appendix C that, "enforcement conferences will not normally be open to the public," or to adopt a new policy that would allow most enforcement conferences to be open to attendance by all members of the public. Comments were required to be provided to the Commission on or before the completion date of the trial program. A correction to the original notice was issued on July 17, 1992 (57 FR 31754) to correctly identify the scheduled completion of the trial program as July 11, 1994.

On May 13, 1994, the Executive Director for Operations directed a reexamination of the NRC enforcement program by a Review Team of senior NRC staff. As part of this comprehensive review of the Enforcement Policy, the NRC intends to consider the issue of whether the Commission should establish open enforcement conferences as the normal practice. In the interim, the NRC is continuing the open enforcement conference trial program pending the outcome of the Enforcement Policy Review. The Review Team intends to complete its review of the Enforcement Policy in early 1995.

As part of its review of the Enforcement Policy, the NRC intends to issue a Federal Register notice soliciting public comments to assist the Review Team. The notice will include soliciting comments on the issue of open enforcement conferences.

Dated at Rockville, MD, this 13th day of July 1994.

For the Nuclear Regulatory Commission.

James Lieberman,

Director, Office of Enforcement.

[FR Doc. 94-17500 Filed 7-18-94; 8:45 am]