U.S. NUCLEAR REGULATORY COMMISSION

REGION V

Report No. 90-04
EA No. 90-222

License No. 04-15030-01

Licensee: Veterans Administration Medical Center
3350 La Jolla Village Drive
San Diego, California 92161

Conference at: Veterans Administration Medical Center
San Diego, California

Conference Conducted: January 10, 1991

NRC Participants:

Frank Wenslawski
for Ross A. Scarano, Director
Division of Radiation Safety
and Safeguards — 2/8/91 Date Signed

Allen D. Johnson
Allen D. Johnson, Enforcement
Officer — 2/6/91 Date Signed

James L. Montgomery
James L. Montgomery, Senior
Materials Specialist — 2/6/91 Date Signed

Approved by:

Frank A. Wenslawski
for Ross A. Scarano, Director
Division of Radiation Safety
and Safeguards — 2/8/91 Date Signed

Summary:

Enforcement Conference on January 10, 1991 (Report No. 90-04)

The following matters were discussed:

1. Inspection findings and apparent violations identified during the inspection of November 2-4 and December 10-14, 1990.

2. NRC concerns.

3. NRC Enforcement Policy and options.

Results:

The licensee contested ten of the eleven apparent violations described in the inspection report. The licensee was allotted an additional thirty days beyond the Enforcement Conference date to provide additional documentation supporting their statements concerning the apparent violations.

ENFORCEMENT CONFERENCE

DETAILS

1. Enforcement Conference Attendees

R. Scarano	Director, Division of Radiation Safety and Safeguards, NRC RV
A. Johnson	Enforcement Coordinator, NRC RV
J. Montgomery	Senior Materials Specialist, NRC RV
T. Trujillo	Director, VAMC
G. Rossio	Associate Director, VAMC
R. Stevens	Administrative Assistant to the Director, VAMC
J. Verba, Ph.D.	Radiation Safety Officer, VAMC
S. Halpern, M.D.	Nuclear Medicine Service, VAMC
G. Greenspan, M.D.	Nuclear Medicine Service, VAMC
R. Engler, M.D.	Chief of Staff, Research, VAMC
J. Mathews	Radiation Safety Technician, VAMC

Participants by Conference Telephone:

R. Pate	Chief, Nuclear Materials and Fuel Fabrication Branch, NRC RV
D. Howe, Ph.D.	Office of Nuclear Materials Safety and Safeguards, NRC
S. Moore	Office of Nuclear Materials Safety and Safeguards, NRC
J. Delmedico	Office of Enforcement, NRC
V. Campbell	Region IV, NRC

2. Enforcement Conference

On January 10, 1991, an Enforcement Conference was held at the Veterans Administration Medical Center, San Diego, with the individuals listed above participating. The Enforcement Conference was related to the November 2-4 and December 10-14, 1990 special NRC inspection scheduled as a result of radiological incidents involving contamination, a medical diagnostic misadministration and reported excessive radiation exposure.

Following an introduction of the NRC and VAMC participants, Mr. Scarano began the conference by asking Mr. Trujillo if he had any comments on the NRC inspection report 90-03. Mr. Trujillo replied that he did have comments and began discussing the apparent violations as follows:

Syringe shield: Dr. Halpern stated that a violation of 10 CFR 35.60(c) had not occurred because the use of the shield was contraindicated for the patient due to difficulty in injecting into the back of the patient's hand.

Extremity badge: The licensee referenced section 8.21, item 4 in their Radiation Safety Manual and stated that procedures administered by nuclear

medicine physicians do not exceed the one rem hand dose limit listed in 8.21, item 4, and therefore no extremity badge was assigned.

Hand Overexposure: Despite the licensee's written report of an estimated 40 rem hand exposure to the physician involved with the misadministration, the licensee stated at the Enforcement Conference that they had reevaluated the dose estimates and found the dose to be 10 to 100 times less than the original 40 rem. Photocopy illustrations showing different syringe/hand positions were given to the NRC participants. Mr. Scarano agreed to allow the licensee an additional 30 days from the date of the Enforcement Conference to submit a reevaluation of the dose estimate.

Training: The licensee agreed that the training of the laboratory researcher most likely responsible for the P-32 spill and contamination was not adequate. However, the licensee maintained that the nuclear medicine assistant who selected the wrong container and syringe was in the process of being trained for his position at the time of the misadministration and did exactly as he was told, i.e. select "the long blue/grey pig". Since the assistant did as he was instructed, the licensee believes no training violation occurred.

Although the licensee agreed that some training was inadequate, it objected to being cited for a training violation. The licensee stated that after the incidents occurred, investigating committees appointed by management identified training and other violations and efforts were made to correct problems. The licensee maintained that since it had identified the violation, there should be no citation.

Principle Investigator Responsibility: As with the training above, the licensee objected to this violation because after the P-32 incident a special meeting was held between the Chief of Staff and all Principle Investigators where responsibility problems were identified and corrective actions implemented.

Unauthorized Individual in Restricted Area: The attendees agreed that the licensee had erroneously identified this as a violation. Since the individual was under the constant supervision of an authorized user, this was not a violation of the licensee's Radiation Safety Manual and will not be cited.

Missing and Inadequate Surveys: The licensee produced a copy of their December 5, 1990 memorandum which they said identified the same survey violations as the NRC inspection report. The licensee requested that this violation be dropped since they identified it prior to the December 10-14, 1990 NRC inspection. Mr. Scarano stated that his staff would review the memorandum and make a determination on the validity of this violation.

Incorrect Radiation Survey Units: The licensee agreed that some survey records contained the incorrect units of counts per minute (CPM) instead of disintegrations per minute or mr/hr. Despite their efforts to instruct personnel on the proper units to be recorded, the licensee felt that there would always be an occasional error.

Inadequate Dose Calibrator Constancy Check: It was agreed that since the cause of this violation was due to a misunderstanding from a previous NRC inspection, no citation would be made.

Inadequate Dose Calibrator Linearity Test: The licensee acknowledged that technically this was a violation of 10 CFR 35.50(b)(3). However, they stated that they probably do not administer doses below 700 microcuries and believed the requirement to test down to 10 microcuries was unnecessary.

Inadequate Molybdenum 99 Breakthrough Testing: The licensee did not object to this violation but stated that the testing method had been discussed at a pre-license renewal meeting with the NRC Region V staff and no objections were raised. The NRC staff does not recall any previous discussions with the licensee on this subject.

This concluded the licensee's reply to each apparent violation contained in the NRC inspection report. Mr. Scarano asked why the NRC should not cite the training violation since it was repetitive. The licensee replied that improvements were continuing to be made in their radiation safety program and that the previous training violation was not exactly the same as the current one.

Mr. Scarano asked how often the laboratories received radiation safety audits and the licensee replied that the audits were not often enough and that improvements were needed.

3. NRC Concerns

Mr. Scarano stated that his staff would evaluate any new information that the licensee could send within the next 30 days. Despite disagreements on certain violations, Mr. Scarano noted some basic deficiencies with the VAMC/SD radiation safety program. The licensee's written policies and procedures appear to be good but the program implementation was not. Specifically, the licensee has failed to aggressively audit its licensed activities to identify problems before they occur. Also, principle investigators function with little oversight from the Radiation Safety Office or VAMC management.

Mr. Johnson asked if the licensee planned to increase their surveillance of radioactive material users. The licensee replied that this was being considered. Periodic independent outside audits by other VAMC radiation safety personnel were planned and the licensee stated that recruiting for a new radiation safety officer had begun. However, the licensee stated that while corrective actions were under way or being contemplated, they were not prepared to give the NRC a comprehensive list at this time.

Dr. Halpern asked how the NRC defined "adequate training". Mr. Scarano replied that when the technical assistant was asked to retrieve "the long blue/grey pig", an evaluation should have been made to determine if this instruction was adequate to ensure an accurate selection of the proper container. During the NRC inspection the technical assistant stated he did not understand the notations contained on labels used in nuclear medicine procedures. Dr. Halpern indicated he had given the technical assistant some undocumented training on reading labels. Mr. Scarano

stated that it is important for someone to evaluate training content of training given by principle investigators to ensure it is effective for the specific radioisotope work being conducted.

Mr. Delmedico asked for a description of the P-32 researcher's training and experience with radioactive material. The Radiation Safety Officer briefly provided this information. Dr. Engler stated that the researcher was not technically qualified to do the procedure with P-32, and added that there are many procedural steps with each type of radioisotope experiment, making it impossible for the radiation safety staff to monitor all work. For this reason the VAMC/SD management developed the policy long ago to assign the safety responsibility to the principle investigators.

4. NRC Enforcement Policy

Mr. Johnson summarized the NRC Enforcement Policy contained in 10 CFR Part 2. He described the enforcement options which may be applied, including civil penalties, orders, and license modification or revocation. Mr. Johnson indicated that the licensee's comments would be considered and that the licensee would be informed of NRC conclusions concerning the apparent violations in future correspondence.

5. Conclusions

The licensee agreed to provide additional information within 30 days relative to their disagreements with the apparent violations contained in the NRC inspection report.