

UNITED STATES NUCLEAR REGULATORY COMMISSION REGION V

1450 MARIA LANE WALNUT CREEK, CALIFORNIA 94596-5368

San Diego State University 5300 Campanile Drive San Diego, California 92182

Attention: Mr. William L. Erickson Vice President, Business and Simancial Affairs

Thank you for your letter dated October 15, 1992, informing us of your corrective actions in response to our Notice of Violation (Notice) dated September 11, 1992. You reply to violations A, B, and D appear satisfactory. Mr. Kent Prendergast of my staff discussed your reply to violation C, Failure to perform quarterly inventories, with Mr. R. Belanger, your RSO, on October 27, 1992. Based upon this conversation, it is our understanding that your physical inventories of NRC licensed materials will include either visually inspecting the sources or confirming their presence in their shielded container by appropriate measurements.

Your corrective actions will be verified during our next inspection.

Sincerely,

G. P. Luhaz

Gregory P. Yuhas Chief, Radioactive Materials Safety Branch

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bcc w/copy of itr dtd October 15, 1992: State of California Mr. Martin Mr. Faulkenberry Docket File Inspection File G. Cook

bcc w/o copy of itr dtd Uclober 15, 1992: M. Smith J. Zollicoffer

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VICE PRESIDENT FOR BUSINESS AND FINANCIAL AFFAIRS SAN DIEGO STATE UNIVERSITY SAN DIEGO CA 92182-0714

(619) 594-0017

October 15, 1992

Regional Administrator U.S. Nuclear Regulatory Commission Region V 1450 Maria Lane, Suite 210 Walnut Creek, CA 94596-5368.

Gentlemen,

Enclosed is San Diego State University's "Reply to a Notice of Violation". This reply 1 as been submitted in compliance with the provisions of 10 CFR 2.201. A copy of this reply has been sent to the U.S Nuclear Regulatory Commission, Document Control Desk, Washington, D.C. 20555.

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For San Diego State University

Vice President, Business and Financial Affairs

Enclosure:

Reply to Notice of Violation(s)

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Reply to Notice of Violation(s)

This letter is in reply to (1) the NRC's routine safety inspection conducted by Mr. Kent M. Prendergast on July 30, 1992, (3) the correspondence dated September 11, 1992 (signed b Mr. Gregory P. Yuhas, Chief, NMFFB) and (3) the Notice of Violation(s) (dated September 11, 1992) that accompanied Mr. Yuhas' letter.

General Response

San Diego State University is <u>committed</u> to the continued implementation of an effective Radiation Safety Program - one that is comprehensive in scope with regard to the radiological protection of its employees and the general public. Additionally, the University is <u>committed</u> to fulfilling <u>all</u> of the requirements contained in its SNM License, License Application, and in the body of the Code of Federal Regulations, Title 10, Chapter 1 that specifically apply to its Licensed operations. The University Administration, Radiation Safety Committee, and Radiation Safety Office spare no effort in acquiring these objectives.

The University pursues these goals on a three tiered basis. The primary tier involves "on-thespot" radioactive material use assistance, consultation, and support (e.g., spill response, shielding, isotope delivery, waste processing, etc.). The second tier is comprised of scheduled procedures which ultimately provide direct indication that operations are being conducted in a radiologically safe manner (e.g., survey/monitoring, instrument calibration, audit, etc.). The tertiary tier involves the preparation, review, and archive of documentation in support of the physical activities performed within the first two tiers (e.g., leak test records, survey records, uso proposals, Radiation Safety Committee meetings, etc.). Tier one is considered "reactive", that two is "proactive", and tier three is "post-active" (although a significant degree of RSC busitess is proactive). With reference to the NOV letter dated 9/11/92, violations B and D fall within the purview of the secondary tier. Violation: A and C lie within the scope of tier three.

There is "flow" and "feedback" within and between each tier. Ensuring that absolute program compliance is achieved depends on the human cooperation necessary for unimpeded flow and feedback. When the number of personnel and operational activities involved is large, there is un increased probability that errors will occur. This was demonstrated in the findings of the inspection conducted July 30, 1992. However, within the framework of the required NOV responses below, it will be shown that the combined conduct and efficacy of the University's Radiation Safety Program is significantly more solid than the violations may surgest.

SPECIFIC RESPONSES

Description of Violation (A)

License Condition 14.C. and your application dated October 17, 1989, required in part, that leak tests of sealed sources be performed at intervals not to exceed six months and that records of leak test results be maintained for inspection by the Commission.

Contrary to the above, there were no records maintained for sealed source numbers MRC 371 and MRC 93, containing 1 and 5 curies of Pu-Be respectively, between the period of July 1990 and July 1991.

This is a repeat Severity Level IV Violation. (Supplement IV)

Reason(s) for Violation

The violation occurred because of two (tier 3) errors in program continuity. These are addressed individually as follows:

- 1) The technician responsible for logging the leak test results (on the proper form) failed to accomplish two things; a) he failed to record the serial number of one of the herein referenced PuBe sources on the certificate he had prepared for that source, and (b) he failed (completely) to fill out a certificate for the other source in question. It is impossible to discern which failure applies to the sources individually. Collectively, we know that improper leak test documentation for two PuBe sources resulted during the January 1991 leak test performance period.
- 2) The Associate Radiation Safety Officer failed to properly reconcile the leak test result records with the list of eleven PuBe sources that are tested regularly. This allowed the technician's errors to go unnoticed.

The University contends that PuBe sources MRC 371 and MRC 93 were leak tested as required during the period in question. Evidence of this is shown in the January 1991 task/check list used by Radiation Safety Office employees. This database generated list is updated and printed out on a monthly basis, and informs the RSO/technicians of the chronological obligations that pertain to Licensed activities.

The check list is sorted by the type of table to be performed, with tasks/activities normally executed in a group fashion. When a task is completed in the field, a notation (date and initials of person performing the task) is made adjacent to the task entry. This prevents tasks from being executed redundantly, and serves as an indicator of performance. The "completed" check list is subsequently held as an internal record.

The January 1991 check list indicates (by virtue of check-off notation) that the eleven PuBe sources were tested for leakage. This document shows that the individual PuBe source leak test swabs were assigned numbers that referenced them to the vials that underwent liquid

scintillation analysis (see Attachment I). Included are sources MRC 371 and MRC 93. The printout of the liquid scintillation results in this case proved negative (see Attachment II).

In view of the above data, the University maintains that leak testing was performed as required in January 1991. The University concedes that a lapse in the <u>formal</u> record keeping process occurred.

Corrective Steps Taken and Results Achieved

A revised procedure to document leak testing was implemented in July 792 (just prior to the NRC's inspection). Prior to this revision, leak test results of individual PuBe sources were recorded on individual Leak Test Certificates. This method involved filling out numerous generic forms. It is evident that this repetitive process introduced or or in January 1991. The new procedure combines the leakage results of all tested PuBe sources, and records them on a single form (see Attachment III). Source serial numbers are pre-printed on the new form, thus precluding any data transfor errors in that area. Additionally, since all of the individual sources are accounted for on one form, any exclusion of information can be immediately recognized. The format has moved from generic to specific.

Corrective Steps Taken to Avoid Further Violations

The procedure used above (in conjunction with computerized record keeping) will preclude this type of violation, from occurring in the future. In addition, we have secured the services of a qualified individual (UCSD's Radiation Safety Officer) to perform a thorough audit of our radiation safety program. The audit will be performed during the last quarter of 1992.

Date When Full Compliance Will be Achieved

Compliance with License condition 14.C has been achieved as of July 21, 1992.

Description of Violation (B)

10 CFR 20.203(f) requires that, except as provided by 10 CFR 20.203(f)(3), each container of specified amounts of radioactive material bear a durable, clearly visible label identifying the radioactive contents.

Contrary to the above on July 30, 1992, a container of liquid plutonium 238 (1 μ Ci), and a box containing three uranium 235 fission chambers (0.11 μ Ci) did not bear any label identifying the radioactive contents and the containers were not exempted from such labeling.

This is a repeat Severity Level IV Violation. (Supplement IV).

Reason(s) for Violation

Two parties share in the failure to label containers. Primarily, there was a failure on the part of the individual investigators (who possessed the material) to properly label the containers in

question. The labeling requirement is expressed as a condition of the investigator's Radiation Use Authorization, and is reinforced through refresher training, audit, and memoranda (efforts of the Radiation Safety Office). Secondly, these errors occurred because the formal survey/audit procedures failed to identify that the labeling problems existed. This is the Radiation Safety Office's responsibility. It should be noted that the primary containers were properly labeled (i.e., the vial containing the Pu-238, and the individual fission chamber detectors).

Corregive Steps Taken and Results Achieved

Action was taken following the NRC inspection to properly label the containers mentioned in the violation above. Additionally, the Radiation Safety Office has directed its technical personnel to scrutinize laboratory operations more aggressively for labeling infractions. Finally, a memorandum will be sent to all investigators authorized to use radioactive materials detailing the Violation given above, and their responsibilities in precluding this type of occurrence

Corrective Steps Taken to Avoid Further Violations

The actions described above will eliminate this type of violation from occurring in the future. As mentioned above, we have also secured the services of a qualified individual (UCSD's Radiation Safety Officer) to perform a thorough audit of our radiation safety program. The audit will be performed during the last quarter of 1992.

Date When Full Compliance Will be Achieved

Compliance with 10 CFR 20.203(f) has been achieved as of July 31, 1992.

Description of Violation (C)

License Condition No. 18 and your application dated October 17, 1989, requires in part, that inventories of radioactive materials be performed by the RSO and users at least quarterly.

Contrary to the above, no inventory was performed during the first, second, and fourth, quarters of 1991 and 1992.

This is a Severity Level IV Violation. (Supplement IV)

Reason(s) for Violation

Firstly, the University would like to point out an inaccuracy in the Vi lation description. It states that no inventory was performed during the fourth quarter of 1992. Given the date of the inspection (July 30, 1992), it would appear this assessment is somewhat premature. Secondly, the wording of Violation C implies that an absolute neglect of the inventory requirement occurred. The University contends that this implication cannot be further from the truth. If ality, quarterly inventories for users have been performed without fail (as can

be shown by computerized "hard-copy" inventory records). The dispute in this matter would appear to focus on the manner in which the inventories are performed, and the record keeping processes involved.

On a quarterly basis, the Radiation Safety Office distributes (computer database generated) authorized-user-specific inventories of radioactive materials. These inventories include those additions of radioactive materials that the user has acquired (if any) since the prior quarterly inventory. The authorized user is responsible for reconciling usage and additions. The user retains one copy of the reconciled inventory, and forwards another copy to the Radiation Safety Office. The Radiation Safety Office then makes adjustments to the computerized database using on the information provided by the authorized user. The Radiation Safety Office has in its possession the "hard-copy" inventory records received from the authorized users of Special Nuclear Materials for the periods in question.

The Radiation Safety Office has not in the past issued internally a "hard-copy" inventory. Adjustments to the RSO inventory (which includes SNM) have been made through receipt, transfer, and waste records. These adjustments are made in the database, and are considered an "electronic record". The computer database represents, in fact, the most accurate compilation of radioactive material inventory information that the University has.

The University is of the opinion, however, that the NRC may perceive a failure on the University's part with regard to the requirement given in 10 CFR 70.51(f)(2)(ii). The University submits that this requirement is fulfilled by the performance of monthly surveys in those areas where SNM are stored. Through the process of survey, any "irregularities" or compromise to tamper-safing devices use. to secure the storage areas would be discovered It should be stressed that these surveys are performed on a monthly (not quarte should again be noted that the SNM in question is stored securely, and only on source is used on an average of twice a year for instructional purposes.

Corrective Steps Taken and Results Achieved

However, if the LRC's interpretation of this requirement and the manner in which the University addresses it are in conflict, the University requests specific guidance with which to preclude miscarriage of those obligations.

Corrective Steps Taken to Avoid Further Violations

As mentioned above, the University wishes to defer any action until a) the NRC acknowledges that the University is in technical compliance with inventory requirements, or b) the University receives explicit instructions from the NRC in accomplishing that objective (to the satisfaction of the Commission).

Date When Full Compliance Will be Achieved

The University will take <u>any action necessary</u> to achieve compliance upon receiving a reply from the NRC on this matter.

Description of Violation (D)

License Condition No. 18, and your application dated October 17, 1989, requires in part, that the Radiation Safety Committee meet at least quarterly.

Contrary to the above, a Radiation Safety Committee meeting was not held during the third quarter of 1991, between the period of April 5, 1991, and October 8, 1991.

This is a Severity Level IV Violation (Supplement IV)

Reason(s) for Violation

The reason for this Violation stems from the occasional difficulties that arose in organizing a quorum of the Radiation Safety Committee. Meetings were held (more or less) at member convenience, which led to considerable scheduling problems.

Corrective Steps Taken and Results Achieved

The difficulties mentioned above were discussed during a November 1991 meeting between the RSO and the Chairman of the Radiation Safety Committee. During the discussion it was decided that Radiation Safety Committee meeting dates for the following year (1992) would be selected in December (1991), and that these dates would reflect the quarterly requirement. This (in theory) would enable members to clear their calendars well in advance of the proposed dates, and keep the University in License compliance. The dates chosen for 1992 were February 21st, May 1st, September 11^{sb}, and December 4^{sb}. The September 11^{sb} meeting was postponed and held on September 25^{sb} (in anticipation of NRC inspection results).

It was also decided that a review and re-structuring of the Radiation Safety Committee Charter and Bylaws should be undertaken. Newly written into the bylaws were rules regarding RSC membership term limits, and sanctions regarding attendance. The reorganized RSC Bylaws and Charter were adopted during the December 13, 1991 Radiation Safety Committee meeting.

Corrective Steps Taken to Avoid Further Violations

The Radiation Safety Officer, in cooperation with the Chairman of the Radiation Safety Committee, will continue to schedule Radiation Safety Committee meetings a year in advance. This strategy appears to have eliminated the scheduling compromises of the past.

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Date When Full Compliance Will be Achieved

Compliance with License Condition 18 and the University's License Application has been achieved as of February 21, 1992.