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NRCVeterans
Administration

September 5, 1985

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REGION V IAF

In Reply Refer To: 664/115
Your Reference
License 04-15030-01US Nuclear Regulatory Commission
Region V
1450 Maria lane, Suite 210
Walnut Creek, CA 94596

Gentlemen:

This is in reply to your letter of August 9, 1985 concerning the NRC inspection of the VA Medical Center, 3350 La Jolla Village Drive, San Diego, California, 92161. The inspection was conducted by Mr. J. Frank Pang on May 15-16 and July 1-3, 1985, and dealt with activities authorized by NRC License No. 04-15030-01.

We have examined the items of noncompliance detailed in Appendix A of your letter. We are including in this communication: (1) the corrective steps which have been taken; (2) the corrective steps which will be taken in the future; and (3) the date when full compliance will be achieved.

We will consider each item of noncompliance separately and in the same order as in Appendix A of your letter.

Item A(1). License condition 20 states that the licensee shall possess and use licensed material in accordance with statements, representation, and procedures contained in the application dated July 5, 1980; and letters dated March 26, 1975 and March 3, 1983.

Section 6.61 of the Radiation Safety Manual states, in part, that radioisotopes requiring labels must be stored in areas under the control of the Radiation Safety Officer (RSO) and secured against unauthorized removal.

Contrary to the above requirement, on three separate occasions, licensed material requiring labels was not under the control of the RSO and secured from unauthorized removal as evidenced by the following:

a. A shielded container containing Iridium-192 seeds totaling approximately 47 mCi, was left unattended in the patient's room overnight on April 24, 1985.

b. A ribbon/catheter containing 5 Iridium-192 seeds of approximately 0.76 mCi each, was found by the assistant RSO underneath the patient's bed on April 25, 1985.

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c. A ribbon containing 4 Iridium-192 seeds was confirmed to be lost on May 1, 1985.

This particular item of noncompliance resulted because of a breakdown in the procedure for handling therapeutic implants. The medical center has decided to discontinue all implants procedures in this hospital until such times as a complete and thorough revamping of the procedure for doing such therapy can be arrived at and approved by the radiation safety committee. When the revamp procedure is approved, it will be forwarded to the Nuclear Regulatory Commission for their concurrence. As of this date we will be in compliance in matters concerning implants since we have discontinued this procedure here at the medical center.

Item A(2). License condition 20 states that the licensee shall possess and use licensed material in accordance with statements, representations, and procedures contained in the application dated July 15, 1980; and letters dated March 26, 1975 and March 3, 1983. In the application dated July 25, 1980 the licensee committed to an ALARA program which requires that management and the Radiation Safety Officer independently conduct annual audits of the Radiation Safety Program.

Contrary to the above requirements, at the time of the inspection, the annual audit had not been conducted since 1980.

This item of noncompliance will be corrected by instituting an audit generally following the procedure laid out in Appendix E of the US Nuclear Regulatory Commission Pamphlet NUREG-0267 Revision 1, "Principals and Practices for Keeping Occupational Radiation Exposures at Medical Institutions As Low As Reasonably Achievable". Since our Radiation Safety Program is currently being heavily scrutinized and our manual changed to reflect the current condition of our Radiation Safety Program and since we have just undergone a rather thorough audit by the Nuclear Regulatory Commission, it was felt that the Radiation Safety Officer's audit should be conducted some time in the next three months with the audit by management being conducted within the next six months. This item of noncompliance has been thoroughly discussed in our radiation safety committee meeting and it is thoroughly understood that an annual audit by the Radiation Safety Officer as well as an annual audit by management should be conducted as soon as the program stabilizes. Our plan for a completely updated manual calls for a completion date of January 1, 1986.

A(3) License condition 20 states that the licensee shall possess and use licensed material in accordance with statements, representations, and procedures contained in the application dated July 25, 1980; and letters dated March 26, 1975 and March 3, 1983.

Section 3.4.5(a) of the Radiation Safety Manual states that smoking, eating, or drinking in radioisotope laboratories is prohibited.

Contrary to the above requirement, on July 1, 1985 the inspector observed individuals drinking or evidence of drinking in rooms 6022, 6058, 6069, 6122, 6124, 6197, and 6202. Food was observed in room 6122.

This item of noncompliance is being aggressively addressed as indicated in the two enclosed memorandums from the acting hospital director and an additional memorandum issued by the Radiation Safety Officer. These procedures for aggressively penalizing violators is currently in place and we are confident that they are strict enough to bring us into total compliance on this particular item in the very near future.

A(4). License condition 20 states that the licensee shall possess and use license material in accordance with statements, representations, and procedures contained in the application dated July 25, 1980; and letters dated March 26, 1975 and March 3, 1983.

Section 6.61.1 of Radiation Safety Manual states, in part, that radioactive waste requiring (a) "radioactive materials" label must be secured against unauthorized removal. Section 3.30.8 of the Radiation Safety Manual establishes 11,000 DPM as the criterion for determining whether an item is considered to be radioactively contaminated and thus requires disposal in a properly labeled and secured container.

Contrary to the above requirements, at the time of the inspection a contaminated gauze and bottle was found in a non-radioactive trash container in the Nuclear Medicine imaging room which was not labeled or secured against unauthorized removal. The contaminated gauze and bottle each measured approximately 150,000 DPM. This item of noncompliance has been thoroughly discussed in the department meetings of the Nuclear Medicine Service. A procedure has now been established for monitoring the non radioactive trash before it is removed from the Nuclear Medicine Service. This system is already in place and as of this date we should be in complete compliance.

A(5). License condition 20 states that the licensee shall possess and use license material in accordance with statements, representations, and procedures contained in the application dated July 25, 1980; and letters dated March 26, 1975 and March 3, 1983.

Section 6.51 of the Radiation Safety Manual states that when unsealed quantities of activity exceeds 100 times those listed in Appendix VI of the manual (extracted from 10 CFR 30.71, Schedule B) are used in a single procedure, a survey shall be made by the user and the results recorded.

Contrary to the above requirements the nuclear medicine laboratory containing unsealed quantities of activities greater than 100 times the quantity specified in 10 CFR 30.71, Schedule B, had not been surveyed on the following representative dates in 1985; April 22, 23, 26, and 29, May 6, 7, 14, and 20, and June 3, 7.

This particular item of noncompliance was also discussed thoroughly in the department meetings of the Nuclear Medicine Service. New forms have been adopted which will make it more readily apparent that surveys were not completed. In addition, a procedure for a monthly audit of the necessary surveys has been instituted. Since this new system has already been installed, we should have an immediate improvement in this particular item starting as of this date.

A(6). License Condition 20 states the licensee shall possess and use licensed material in accordance with the statements, representation, and procedures contained in the application dated July 25, 1980; and letters dated March 26, 1975 and March 3, 1983.

In a letter dated March 26, 1975, the licensee states that the janitors on the research floor (6th) of the hospital will be instructed in the proper use of a G.M. survey meter to check bagged non-radioactive waste before transferring it to the hospital's center disposal area.

Contrary to the above requirements, at the time of the inspection, the janitors on the 6th floor had not been instructed in the proper use of a G. M. survey meter to check bagged non-radioactive waste.

This item of noncompliance is to be addressed by a procedure which will involve a designee of the Radiation Safety Officer being appointed to monitor the bagged non-radioactive waste before it will leave the 6th floor. Alternate designees will also be appointed to help with these surveys. Contrary to our letter of March 26, 1975, all the janitors on 6th floor will not be instructed in the proper use of a G. M. survey meter. The monitoring of bagged non-radioactive waste will be performed by these designees of the Radiation Safety Officer. This system of monitoring is now being put in place. It should be fully functional by the end of September.

A(7). License condition 20 states that the licensee shall possess and use licensed material in accordance with the statements, representations, and procedures contained in the application dated July 25, 1980; and letters dated March 26, 1975 and March 3, 1983.

Section 6.62 of Radiation Safety Manual and 10 CFR20.401(C)(3) requires that records be maintained of all liquid radioactive waste disposed into the sanitary sewer.

Contrary to the above requirement, at the time of the inspection the radioimmunoassay laboratory had not maintained records of sanitary sewer disposal.

A system for maintaining records of disposed radioactive waste into the sanitary sewers has now been put in place in the radioimmunoassay laboratory. As of this time we are in complete compliance with this particular item of noncompliance.

B(1). 10 CFR20.207(A) requires that licensed material stored in a non-restricted area be secured from unauthorized removal from the place of storage.

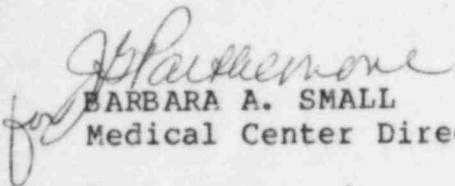
Contrary to the above requirements during a walk through inspection conducted on July 1, 1985, rooms 6122 and 6158 each contained licensed material and were found unlocked and unattended during the lunch hour.

Similar to Item A(3), this particular item of noncompliance is being aggressively addressed as indicated by the two memorandums enclosed

from the acting hospital director to investigators on the 6th floor along with a similar memorandum from the Radiation Safety Office. We feel that this aggressive treatment of these particular items should bring us into compliance within a very, very short time.

We have tried to take corrective steps on all the detailed items pointed out in Appendix A and, in addition, have accepted all the comments of the inspector in the constructive spirit that they were made, and we hope our action, as outlined above will adequately resolve the deficiencies noted. We feel that we are promptly implementing all the programs outlined above, and plan on reviewing the procedures and the results of their implementation in the near future to determine their effectiveness.

Sincerely yours,


BARBARA A. SMALL
Medical Center Director

Enclosures: 4

cc: Director, Nuclear Medicine Service (115)
VACO
Regional Director, Western Region (10BA6)
VACO

I have read the enclosed memorandum of September 6, and have discussed it with all of my laboratory employees.

Principal Investigator

Please sign this sheet and return it to the Radiation Safety Office.



**Veterans
Administration**

Date: September 6, 1985
00:JP-sbw/X3911

Memorandum

To: All Supervisors with Responsibility for
Supervising Radioactive Material

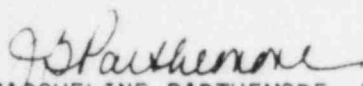
Subj:

1. The utilization of radioactive material is an integral part of the mission of this Medical Center, both from the point of view of our ongoing patient care responsibilities and in the area of medical research.
2. We are presently faced with a problem of considerable moment: the possibility that our Medical Center may no longer enjoy the privilege of utilizing radioactive material.
3. I have addressed this memorandum to a relatively small and senior group of individuals who are intimately aware of both the value of radioactive material and its potential for harm. You are similarly aware of the fact that radioactive material is carefully controlled by the Nuclear Regulatory Commission, an independent agency of the Federal government which is primarily responsible for the safe use and frequent monitoring of radioactive materials in this and other government facilities. This Medical Center is licensed by the Nuclear Regulatory Commission to possess and utilize radioactive material. The Commission uses a relatively involved series of procedures to measure our ability to safely handle this material. Briefly, irregularities, shortcomings and failures on our part to follow the rules of the Nuclear Regulatory Commission are cumulative in the sense that for each class of penalty, punishments progress from basically administrative to mandatory fines and loss of license. Since shortly after our activation we have been guilty of violations, which, if considered alone, would be relatively minor. But under the cumulative penalty system of the NRC, over the past decade we have reached the point at which any further violation, however, trivial, will lead to serious consequences, i.e., fines of up to \$20,000 and/or loss of license and therefore shutdown of all activities utilizing radioactive materials.
4. In accordance with the foregoing, I must solicit, and in fact insist on, your cooperation in ensuring that appropriate local and NRC regulations are henceforth scrupulously followed. Our most recent violation pertains to the failure of several laboratories and work locations to maintain total security of radioactive materials, and also to scrupulously exclude food and drink from areas in which radioactive materials are used. Radioactive material, in any form, must be secured against unauthorized removal. Food and drink should never be found in controlled radioactive material areas. To accomplish this,

2.

I must direct that each supervisor receiving this memorandum immediately take steps to meet with his/her staff and personally review the gravity of the situation with them. Secondly, and most importantly, each supervisor will establish failsafe procedures which address radiation safety issues for their work areas. Management is presently pursuing avenues of disciplinary and/or adverse action which can be taken against employees and their supervisors who fail to follow required precautionary procedures.

5. I would appreciate your rapid and full compliance with the foregoing instructions. In this connection, I have attached copies of a memorandum you should distribute to each employee with access to your rooms containing nuclear material. It also emphasizes the importance of this matter. Any questions concerning the above may be discussed with Dr. John Verba, Radiation Safety Officer.


JACQUELINE PARTHEMORE, M.D.
Acting Medical Center Director



Veterans
Administration

Memorandum

To: All Investigators/Technicians
Using Radioactive Material
Subj: Enforcement of NRC Regulations

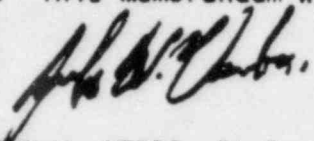
Date: August 30, 1985
151:JWV-sbw/x3911

1. In an effort to enforce NRC regulations, random walk-through inspections of Research laboratories will be instituted. Rooms marked with radioactive material signs, found open and unattended at night, will be cited. During the day, if you are storing no radioactivity (i.e., trash, liquid waste, inventory), or if you have all your radioactive materials locked in a refrigerator, freezer or cabinet, and are not in the process of doing an open procedure, you may post a notice on your outer door stating that the lab is either free from radioactivity or that all radioactivity is secured against unauthorized removal during the daytime normal working hours only. Please sign and date this notice. A wipe test must be done prior to posting this notice. You will be required to show wipe test records. With such posting, doors may be left open and the room unattended. Without such a posting, rooms must be occupied when the door is open. This will apply only during the day. Random inspections will be made and violators cited. For the first violation, the lab will be closed and secured for one day. The second violation in a calendar quarter will result in a two-day closure. The third violation will result in a four-day closure. The fourth will result in an eight-day closure, etc.
2. Floors may be cordoned off with tape to designate controlled and non-controlled areas within your lab space. Notify Radiation Safety once your floors have been marked, so they can be checked. Specify which side of the line is controlled and which is non-controlled. Food or drink should never be found in controlled areas. Finding food or drink in controlled areas will constitute lab closure. Closure will increase in duration in the same manner as unattended lab closures.
3. Non-radioactive trash must be monitored before being removed from your lab area. Building Management will do the monitoring on the sixth floor. Labs using open radioactivity on other floors will be required to monitor their own trash. See Radiation Safety if you have any questions.
4. A log must be kept of all radioactivity that is poured down the drain. This log should include an estimate of the amount poured down the drain and a wipe test of the drain trap. This applies to wash water. Please continue to bring all other liquid waste to the centralized storage area - Room 6056. Radiation Safety will be glad to help you set up your log book.

page 2

5. Radiation Safety will begin auditing each laboratory's radiation safety compliance program. You are advised to review your records and procedures. Irregularities could constitute lab closure. See Radiation Safety personnel if you have any specific questions.

7. This memorandum will go into effect on September 6, 1985.



JOHN W. VERBA, Ph.D.
Radiation Safety Officer



Veterans
Administration

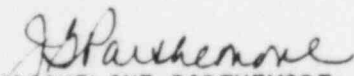
Date: September 6, 1985
00:JP-sbw/X3911

Memorandum

To: Employees working in laboratories or
spaces where nuclear material is
Subj: stored or utilized

1. I have recently directed a memorandum to your supervisor regarding serious deficiencies in our nuclear radiation control program at this Medical Center. I have asked your supervisor to discuss this problem with you and to explain fully the impact on this Medical Center of any future dereliction in our responsibility toward safeguarding of nuclear material. I have also directed your supervisor to establish specific procedures to be followed in insuring that nuclear material is always secure.

2. This is a matter of great concern to this Medical Center. We must insist on your full cooperation with all current regulations of the Nuclear Regulatory Commission and of this Medical Center. New procedures will be established in the days to come by your supervisor, to prevent future deficiencies. Please make certain that you are fully aware of these. Management is presently pursuing avenues of disciplinary and/or adverse action which can be taken against employees and their supervisors who fail to follow required precautionary procedures. With the Radiation Safety Committee, I plan to monitor the implementation of this program personally.


JACQUELINE PARTHEMORE, M.D.
Acting Medical Center Director

APPENDIX A

NOTICE OF VIOLATION

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

Docket No. 030-08456
License No. 04-15030-01
EA 85-82

During an NRC inspection conducted on May 15-16 and July 1-3, 1985, violations of NRC requirements were identified. The violations include: (1) the loss of radioactive materials; (2) failure to survey areas in which radioactive materials are located or handled; (3) failure to conduct annual audits; (4) failure to maintain adequate records; (5) inadequate training; and (6) several examples of failing to comply with the requirements of the Radiation Safety Manual. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1985), the violations are listed below:

- A. License Condition 20 states that the licensee shall possess and use licensed material in accordance with statements, representations, and procedures contained in the application dated July 25, 1980; and letters dated March 26, 1975 and March 3, 1983.
1. Section 6.61 of the Radiation Safety Manual states, in part, that radioisotopes requiring labels must be stored in areas under control of the Radiation Safety Officer (RSO) and secured against unauthorized removal.

Contrary to the above requirement, on three separate occasions, licensed material requiring labels was not under the control of the RSO and secured from unauthorized removal as evidenced by the following:

- a. A shielded container containing iridium-192 sources totaling approximately 47 millicuries was left unattended in the patient's room overnight on April 24, 1985.
- b. A ribbon/catheter containing five iridium-192 seeds of approximately 0.76 millicuries each was found by the Assistant RSO underneath the patient's bed on April 25, 1985.
- c. A ribbon containing four iridium-192 seeds was confirmed to be lost on May 1, 1985.
2. In the application dated July 25, 1980 the licensee committed to an ALARA program which requires that management and the Radiation Safety Officer independently conduct annual audits of the radiation safety program.

Contrary to the above requirement, at the time of the inspection, the annual audits had not been conducted since 1980.

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3. Section 3.40.5(a) of the Radiation Safety Manual states that smoking, eating, or drinking in radioisotope laboratories is prohibited.

Contrary to the above requirement, on July 1, 1985, the inspector observed individuals drinking or evidence of drinking in Rooms 6022, 6058, 6069, 6122, 6124, 6197, and 6202. Food was also observed in Room 6122.

4. Section 6.61.1 of the Radiation Safety Manual states, in part, that radioactive waste requiring a "Radioactive Materials" label must be secured against unauthorized removal. Section 3.30.8 of the Radiation Safety Manual establishes 11,000 dpm as the criterion for determining whether an item is considered to be radioactively contaminated and thus requires disposal in a properly labeled and secured container.

Contrary to the above requirements, at the time of the inspection, a contaminated gauze and bottle were found in the non-radioactive trash container in the Nuclear Medicine imaging room which was not labelled or secured against unauthorized removal. The contaminated gauze and bottle each measured approximately 150,000 dpm.

5. Section 6.51 of the Radiation Safety Manual states that when unsealed quantities of activity exceeding 100 times those listed in Appendix VI of the manual (extracted from 10 CFR 30.71, Schedule B) are used in a single procedure, a survey shall be made by the user and the results recorded.

Contrary to the above requirement, the Nuclear Medicine Laboratory, containing unsealed quantities of activity greater than 100 times the quantities specified in 10 CFR 30.71, Schedule B, had not been surveyed on the following representative dates in 1985: April 22, 23, 26 and 29, May 6, 7, 14 and 20, and June 3, 7.

This a repeat violation.

6. In the letter dated March 26, 1975, the licensee stated that the janitors on the research floor (6th) of the hospital will be instructed in the proper use of a G.M. survey meter to check bagged non-radioactive waste before transferring it to the hospital's central disposal area.

Contrary to the above requirement, at the time of the inspection, the janitors on the sixth floor had not been instructed in the proper use of a G. M. survey meter to check bagged non-radioactive waste.

7. Section 6.62 of the Radiation Safety Manual and 10 CFR 20.401(c)(3) requires that records be maintained of all liquid radioactive waste disposed of into the sanitary sewer.

Contrary to the above requirement, at the time of the inspection, the Radioimmunoassay Laboratory had not maintained records of sanitary sewer disposals.

- B. 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured from unauthorized removal from the place of storage.

Contrary to the above requirement, during the walkthrough inspection conducted on July 1, 1985, Rooms 6122 and 6158, each containing licensed material, were found unlocked and unattended during the lunch hour.

This a repeat violation.

Collectively, the above violations constitute a Severity Level III problem (Supplements IV and VI).

Pursuant to the provisions of 10 CFR 2.201, the Veterans Administration Medical Center, San Diego is hereby required to submit to this Office within 30 days of the date of this Notice, a written statement or explanation including for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, (3) the corrective steps which have been taken and the results achieved, (4) corrective steps which will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, the Director, Office of Inspection and Enforcement, may issue an order to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown.

AUG 09 1985

Dated