DEPARTMENT OF VETERANS AFFAIRS
Clement J. Zablocki Medical Center
Milwaukee WI 53295-1000

November 4, 1996

In Reply Refer To: 695/00C-S

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

SUBJECT: REPLY TO A NOTICE OF VIOLATION (DOCKET NO. 030-03427)

This reply refers to the "Notice of Violation" issued on October 18,1996 and includes our response regarding each of the violations noted.

1. 10 CFR 20.1801: Security of licensed material stored in unrestricted areas.
a. Reason for violation: The non-medical authorized user was unaware of this regulation.
b. Corrective steps that have been taken: The non-medical authorized user of the laboratory in violation of this regulation was notified on August 28, 1996 of his responsibility to comply with this and all NRC regulations and license conditions. He immediately notified his laboratory personnel of this regulation. Weekly unannounced security audits of this laboratory have found no subsequent violations since your inspection. On September 6, 1996 a memo regarding the security of licensed material was sent to all non-medical authorized users. A copy of this memo is appended as attachment 1. Also, weekly unannounced security audits of all laboratories using licensed material have been conducted. During these audits two other violations were found on September 27, 1996. The authorized users were notified and prompt action was taken by both authorized users and they are now in compliance.
c. Corrective steps that will be taken to avoid further violations: We will continue our weekly unannounced security audits that we implemented after your inspection. The RSC will review the records of these audits quarterly and decide if further action against an authorized user needs to be taken. They will also decide if the frequency of the audits need to be changed. This review will continue on an ongoing basis. We are also going to emphasize the importance of security of licensed material during our initial and annual radiation safety training.
d. Date when full compliance will be achieved: We are currently in full compliance and will continue to monitor compliance.

2. 10 CFR 20.1501: Improper Surveys.
I. Survey of room 70-D-100.
a. Reason for violation: The surveys for this room were not completed for low energy beta emitters.
b. Corrective steps that have been taken: During your inspection a proper survey of the room was conducted and no contamination above our action levels were found. We have re-evaluated our removable contamination survey procedure for all laboratories that require surveys and have made the necessary changes to comply with this regulation.
c. Corrective steps that will be taken to avoid further violations: When the type of licensed

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material used in a laboratory changes an evaluation of the removable contamination survey required will be completed and the necessary changes made.
d. Date when full compliance will be achieved: We are currently in full compliance.

II. Survey of sewer effluent.
a. Reason for violation: The 1994 change in regulation adding the requirement that sewer effluents be either water soluble or dispersible biological material was overlooked.
b. Corrective steps that have been taken: The corrective steps taken are documented in our letter dated September 4, 1996.
c. Corrective steps that will be taken to avoid further violations: New forms to help track the contents of radioactive liquid waste containers have been ordered. These forms will keep track of the chemical forms of the radioisotopes and any other material added to the containers. When these forms are received, all personnel will be trained on the proper procedures for using the new forms to track the contents of liquid radioactive waste.
d. Date when full compliance will be achieved: We are currently in full compliance.

3. Condition 18 of our license.
a. Reason for violation: When our facility changed from multi-dose vials to unit dose vials of ^{133}Xenon this test was no longer completed.
b. Corrective steps that have been taken: As stated in our letter dated September 4, 1996 we have completed this test on August 28, 1996 and September 4, 1996. We have also performed the test on October 10, 1996. The trap effluent monitor is functioning properly.
c. Corrective steps that will be taken to avoid further violations: The RSC will review the records of this test quarterly.
d. Date when full compliance will be achieved: We are currently in full compliance.

4. 10 CFR 35.59(g): Quarterly inventory of sealed sources.
a. Reason for violation: The sealed sources found to be in violation were in storage and the exception for leak testing sealed sources in storage (10 CFR 35.59(f)(4)) was assumed to exempt the quarterly inventory of these sources.
b. Corrective steps that have been taken: These sealed sources were inventoried during your inspection on August 28, 1996 and were added to the list of sealed sources that require a quarterly inventory.
c. Corrective steps that will be taken to avoid further violations: The RSC will review the records of these inventories annually.
d. Date when full compliance will be achieved: We are currently in full compliance.

5. 10 CFR 35.315(a)(7): Removable contamination survey after inpatient radiopharmaceutical therapy.
a. Reason for violation: The previous forms used to document surveys during and after inpatient radiopharmaceutical therapies did not include an entry for the required removable contamination survey. This caused the person performing the final survey of the room to omit this section of

the survey.
b. Corrective steps that have been taken: The corrective actions taken are documented in our letter dated September 4, 1996.
c. Corrective steps that will be taken to avoid further violations: The packet of forms used during and after an inpatient radiopharmaceutical therapy have been updated to include a section for the required removable contamination survey prior to the release of the therapy room for general use. Prior to the release of the room the RSO or his designee will review the packet of forms to insure that all required surveys have been completed. The RSC will audit all radiopharmaceutical therapy forms annually.
d. Date when full compliance will be achieved: We are currently in full compliance.

6. 10 CFR 35.60(c): Use of syringe shields during the preparation of radiopharmaceutical kits.
a. Reason for violation: The Nuclear Medicine technologist preparing the kit did not have knowledge that there was a 10 cc syringe shield for his use.
b. Corrective steps that have been taken: The corrective actions taken are documented in our letter dated September 4, 1996.
c. Corrective steps that will be taken to avoid further violations: We will continue to audit the use of syringe shields monthly and the RSC will review the records of the audits quarterly until our next inspection.
d. Date when full compliance will be achieved: We are currently in full compliance.

With regard to our self-assessment program we are planning the following actions to identify any problem associated with our radiation safety program that we will implement by January 1, 1997. Using 10 CFR 20, 10 CFR 35, Regulatory Guide 10.8 Revision 2, and our license application we are developing an audit list to be completed quarterly for the review of our radiation safety program. These audit forms will identify any weaknesses in our program that need to be addressed. If weaknesses are found we will promptly implement and document corrective actions taken. The results of these audits will be reviewed by the RSC quarterly. The audit lists will be updated at least annually or more often if changes in the regulations and/or our license conditions are implemented.

If you have any question regarding this reply please call Mr. Daniel J. Miron at (414) 384-2000 extension 2631.

R. E. Struble, FACHE
Medical Center Director

Enclosure

cc: Regional Administrator, Region III, 801 Warrenville Road, Lisle Illinois 60532-4351

Attachment 1

Department of Veterans Affairs

Memorandum

Date:

September 6, 1996

From:

Radiation Safety Officer (115)

Subj:

Radioactive Material Security

To:

All Radioisotope Authorized Users

1. The Nuclear Regulatory Commission (NRC) regulations for security are:

   "§20.1801 Security of stored material. The licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

   §20.1802 Control of Material not in storage. The licensee shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage."

2. Please inform all radiation workers that work under your supervision that everyone is responsible for assuring that laboratories that contain radioactive material are secured when unattended, or that the radioactive material is secured within the laboratory. The NRC's definition of secured is that the door to the laboratory is closed and locked or that the radioactive material is secured in a locked container and the key/combination is controlled by the authorized user or radiation worker.

3. An apparent violation of this regulation was identified during the NRC's inspection from August 26 thru August 28, 1996. Please be advised that I will conduct weekly walk through security inspections. An authorized user will be notified of any security violations when they are found.

4. If you have any questions regarding this information, please call me at extension 2631.

Daniel J Miron

Daniel Miron

cc: B. David Collier M.D., Chair, Radiation Safety Committee (115)
Phil Cook, Director of Research Operations (151)