

July 3, 1997

Amira Gohara, M.D.
Vice President for Academic Affairs
Medical College of Ohio
3000 Arlington Avenue
P.O. Box 10008
Toledo, OH 43699-0008

SUBJECT: NOTICE OF VIOLATION DATED MAY 19, 1997

Dear Dr. Gohara:

This acknowledges receipt of Eddie Brentlinger's letter dated June 16, 1997, in response to our letter dated May 19, 1997, transmitting a Notice of Violation.

The Medical College's response to Violation No. 1 indicates disagreement with one of the two examples cited in the violation. Specifically, you contend that the licensed material stored in Laboratory No. 336 was adequately secured because a researcher working in an adjoining laboratory confronted the inspectors.

We acknowledge that a researcher working in an adjoining laboratory confronted one of our inspectors while he performed radiation surveys in Laboratory No. 337. However, both NRC inspectors initially searched Laboratory No. 337 and one of the inspectors subsequently searched Laboratory No. 336, before being confronted by the researcher. Several minutes elapsed before the researcher approached the inspectors from the adjoining laboratory, sufficient time for the licensed material stored within Laboratory No. 336 to be handled by unauthorized personnel. Consequently, both examples cited in Violation No. 1 are valid.

As described in the cover letter forwarding the Notice of Violation, the severity level of the laboratory security violation was reduced, in part, because our inspectors presence in the unattended laboratories was challenged by researchers several minutes later.

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A. Gohara

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We have reviewed your corrective actions for the five violations, which appear to be adequate, and have no further questions at this time. These corrective actions will be examined during a future inspection.

Sincerely,

TK
for Roy J. Caniano, Acting Director
Division of Nuclear Materials Safety

License No. 34-13011-04

Docket No. 030-09189

cc w/ltr dtd 6/16/97: E. Brentlinger, Director
Radiation Safety Office

bcc w/ltr dtd 6/16/97: PUBLIC

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419-381-4172

419-381-4301

3000 Arlington Avenue

Mailing Address: P.O. Box 10008

Toledo, Ohio 43699-0008



June 16, 1997

U. S. Nuclear Regulatory Commission
Regional Administrator, Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

Reply to Notice of Violation

Dear Sirs,

Enclosed is the Medical College of Ohio's response to the Notice of Violation we received May 21, 1997.

Violation 1

Security of Licensed Materials

The issue of what is seen as secured by the NRC and persons involved with using licensed material differs. Just as with the ALARA concept, what is reasonable? In reference to lab # 235 this violation occurred not because of deliberate disregard for the regulations but because leaving the lab for a few minutes did not seem an unreasonable security risk. Before the inspectors left the area they were confronted by a person from the lab. In reference to lab # 336 there was a person present in an adjacent lab that confronted one of the NRC inspectors. After finding out he was from the NRC she did not feel she needed to pursue the situation any further. The lab person told the inspector that if he had any questions she would be in the adjacent room. This did not seem to be a security risk to the lab worker. In neither case was licensed material being used at the time the inspectors visited the labs. All materials were in storage.

In the case of lab # 336 I do not feel this is a violation. The person in the adjacent lab was not in direct site of the licensed material but she was certainly aware that someone had entered the lab and confronted them (see attached statement). If she would not have been satisfied that the inspectors had reason to be in the lab she would have requested that they leave the area.

In the case of lab # 235 I do not contest this violation.

The corrective steps taken have been to reemphasize the importance of proper lab security with the department chairmen and all authorized users. Special emphasis will also be give to this issue in all radiation safety training sessions. Also Dr. Amira Gohara, Vice President for Academic Affairs, has directed the MCO Campus Police and Radiation Safety Office personnel to conduct random security checks of authorized labs. If any labs are found unsecured they are to be secured immediately and logged.

To avoid further violations labs that have repeat security violations will be referred to the Radiation Safety Committee for possible suspension of there privilege to use radioactive materials.

These steps have been implemented as of the date of this letter.

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Violation 2

Evaluation of Solubility of Materials Disposed Via Sanitary Sewerage

The reason for this violation was a misunderstanding of what is a proper evaluation. 10 CFR 20.2003(a)(1) states that material discharged into the sanitary sewerage must be readily soluble (or is readily dispersible biological material). In 1994 it was confirmed that the Medical College of Ohio only engages in biomedical research and therefore only uses biological materials. A memo was sent to all authorized users emphasizing this requirement. We felt this satisfied the requirements. We were inspected in September of 1994 and in December 1995 and there was no question concerning this issue so we assumed there was no problem with the way in was handled.

At the Broad Scope licensees meeting held by the NRC in Chicago in March of 1997 it was then told to licensees that each chemical released had to be evaluated. This was the first time that the specifics of how this issue was going to be inspected was made known to the Medical College of Ohio.

The corrective steps that are being taken involve an inventory of all radiochemical disposed via sanitary sewerage since January 1994 to the present. This has been done. An attempt to evaluate each chemical form for solubility has been made. This evaluation was based on the reported solubility in water listed in the Material Safety Data Sheets for each radiochemical disposed via sanitary sewerage. For chemicals that do not provide solubility data on the MSDS an inquiry will be made to the manufacturer directly. Radiochemicals that do not require MSDS are looked up in the Merck Index for the solubility water. As of this date no chemicals have been shown to be insoluble in water.

Corrective steps to prevent further violation will be that a solubility evaluation will be required on all requests for authorization to use radioactive materials that include sanitary sewerage disposal.

Violation 3

Measurement of Ventilation Rates

The ventilation rates were performed by the Radiation Safety Office when the clearance times were calculated for the room used for Xenon-133 gas. The Radiation Safety Office was under the impression that the air quality persons were performing the routine airflows.

The corrective steps were to perform an airflow immediately after the inspection. The flow rate was found to be in compliance.

To prevent further violations of airflow's for this area, Nuclear Medicine is now included with the routine airflow checks in other areas. This will ensure that the airflow check of the Xenon-133 room will be done in the six month interval.

As of the date of this letter we are in compliance of this violation.

Violation 4

Testing of the Dose Calibrator

The dose calibrator used for checking Iodine-131 by the Radiation Therapy Department for thyroid oblations is under the control of the Nuclear Medicine Department. The routine thyroid oblation dose had been approximately 100 mCi. When Radiation Therapy used 200 mCi they did not inform the Nuclear Medicine Department to do a linearity over 200 mCi.

A linearity check at 205 mCi was performed immediately after the inspection and was found to be in compliance.

All future linearity checks of the dose calibrator used by Radiation Therapy for checking I-131 will be checked above 200 mCi's. The Radiation Therapy Department has been instructed to inform the Nuclear Medicine Department in advance if a dose will exceed 200 mCi.

As of the date of this letter we are in compliance of the violation.

Violation 5

Survey Program

Labs that use P-32 exclusively were surveyed for contamination with a pancake G M meter because it provided better coverage of the lab. The person performing the survey was not aware of the requirement to also perform wipe tests.

Persons performing laboratory contamination surveys during routine lab audits by the Radiation Safety Office are instructed to perform wipe surveys in all labs.

Lab surveys will be reviewed by the Radiation Safety Officer to ensure compliance.

As of the date of this letter we are in compliance with this violation.

If there are any questions regarding this response you can contact me at (419) 381-4301 or at the address above.



Eddie A. Brentlinger, Director / Radiation Safety Officer

enclosure

April 03, 1997

To: Radiation Safety

From: Michiyo Tomita, M.D.

Re: Encounter with the NRC

Michiyo Tomita

At approximately 1800 hours, on 27, March, 1997, I heard the sound of a Geiger Counter at the entrance of room 337 in the Block Health Sciences Building. At that time, I was working in room 338, which is contiguous with room 337. Wondering what was going on, I walked into room 337, and saw two men, one of whom was apparently probing the room with a pancake-type Geiger Counter. I said, "Oh, you are NRC people. I was in that room", pointing to room 338. One of the men asked, "Were you really in that room?". I told him, "Yes, I was there! That's my lab." They then left room 337, entered room 336, and I returned to my laboratory to continue my experiments.