

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Environmental Health and Safety
Office of Vice President for
Finance and Operations

410 Church Street S.E.
Minneapolis, MN 55455
612-626-6002

January 21, 1997

US Nuclear Regulatory Commission
Region III Office
801 Warrenville Rd.
Lisle, Illinois 60532-4351
Attn.: Cynthia D Pederson

30-00842

Dear Ms. Pederson:

In response your December 20, 1996 letter to Nils Hasselmo, President of the University of Minnesota from Cynthia D. Pederson, Director, Division of Nuclear Materials Safety, concerning the NRC inspection conducted on November 18 - 21, 1996 at the University of Minnesota, I am submitting the following reply to the items of violation noted in the enclosed Notice of Violation.

Reply to Notice of Violation

A. NRC License No. 22-00187-46

1. The first violation related to the requirement to secure licensed materials in an unrestricted area from unauthorized removal or access by maintaining constant surveillance of the material or otherwise securing the material.

a. The reason for this violation was the failure on November 20, 1996 to maintain constant surveillance of radioactive materials packages receipts while they were stored in a posted but unlocked storage closet.

b. Immediate steps taken to correct this violation included the relocation of the packages to a posted and locked area as soon as the inspector noted the lack of surveillance of the closet. In addition, until a lock could be placed on the closet door, the receptionist who signs for the packages was instructed to notify Radiation Protection Division (RPD) staff upon receipt of subsequent packages and to maintain surveillance of the closet until RPD removed the packages.

c. To avoid further violations, the Radiation Protection Officer requested that a lock accessible only by RPD staff be placed on the closet door to secure the packages in the future and prevent unauthorized access to the storage area.

d. Full compliance was achieved on January 7, 1997, the date that the lock was installed and the access code assigned to RPD.

2. The second violation related to the requirement for a written directive to be both signed and dated by an authorized physician prior to administration of brachytherapy treatment.

a. The reason for the violation was the failure of the physician who signed the written directives to also date their signature. This date was listed elsewhere in the treatment file on the QMP checklist but was not on the written directive as required.

b. To correct this oversight, all staff were instructed concerning the potential violation immediately following the inspection, and have been dating their signature on the written directive since the inspection.

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c. To avoid further violations, the written directive form is being revised and reprinted to incorporate a date line in conjunction with the physician's signature on the written directive.

d. Full compliance will be achieved as of the end of January 1997, with the implementation of the revised written directive form.

3. & 4. Both of these items related to the December 6, 1996 inspection of facilities authorized for University of Minnesota use at 3M Center, St. Paul, Minnesota, and the two violations concerned survey requirements at this location.

a. The cause of the violations was the failure to perform a weekly exposure rate survey of radioactive materials storage and waste storage areas, and a weekly removable contamination survey of materials use and storage areas within Rms. SC344 & SC348. These areas had been surveyed with a portable gamma scintillation instrument after each use of materials in the rooms, but separate exposure rate and removable contamination surveys had not been performed.

b. Upon notification of these violations by Region III NRC, we spoke with representative of 3M Health Physics Services, and agreed upon corrective measures to be taken to assure compliance with 10CFR35 exposure rate and removable contamination survey requirements. Attached is a letter from 3M dated December 11, 1996 that summarizes these actions, which have been in effect since December 12, 1996.

c. To avoid further violations, 3M staff will notify the University Radiation Protection Division (RPD) on the day of each transfer of radioactive materials to the U of M license, and will send a report of all dates of use and corresponding surveys to the RPD on a quarterly schedule. Daily exposure rate surveys will be conducted of all preparation and use areas when radioactive materials are in use. A minimum of weekly removable contamination surveys of all preparation, use and storage areas, and weekly exposure rate surveys of materials and waste storage areas will be conducted if radioactive materials are present.

d. Full compliance was achieved for these items on December 12, 1996.

B. NRC License No. 22-00187-49

The inspection of activities conducted under this NRC license resulted in one item of violation concerning the use of the waste compactor installed at the Integrated Waste Management Facility (IWMF). The Notice of Violation stated that on several occasions radioactive waste had been compacted at the facility, and that the NRC license amendment that authorizes use of the IWMF for radioactive waste handling and storage does not currently authorize the use of the compactor for radioactive waste compaction. This statement requires clarification in that although the compactor had been used, it had not been used for compaction of radioactive waste except for a few occasions. In those few instances where radioactive waste was present, it involved short half-life decay stored waste that had been decay stored for over ten half-lives. Except for these instances, all waste compacted at the IWMF was non-radioactive waste (radioactive materials labels/wording removed from decayed wastes that was surveyed and documented to be at background level).

a. The cause of the violation was the compaction on a few occasions of decay stored radioactive waste that had low level residual activity after the waste had been decay stored for greater than 10 half-lives.

b. Upon notification of a potential violation by NRC inspectors, RPD staff put an immediate hold on all compaction of radioactive waste at the IWMF.

c. To avoid further violations, this cessation of compaction of radioactive waste will remain in effect until such time as an NRC license amendment is approved to allow this compaction at the

IWMF. An amendment application is currently being prepared for submission to the NRC to authorize radioactive waste compaction at the IWMF.

d. Full compliance was achieved at the time of the inspection with the hold on all radioactive waste compaction at the IWMF until the amendment to authorize radioactive waste compaction is received.

If you have any question concerning the above response to the enclosed Notice of Violation or if you require additional information, please call me at 612/626-6764.

Sincerely,

Jerome W. Staiger

Jerome W. Staiger
Radiation Protection Officer

cc: US Nuclear Regulatory Com., ATTN.: Document Control Desk, Washington, D.C. 20555
Paul Tschida, Asst. Vice-President, Campus Health & Safety
Richard Lively, Chairperson, All-University Radiation Protection Advisory Committee
Seymour Levitt, M.D., Head, Dept. of Therapeutic Radiology
Faiz Khan, Ph.D., Dept. of Therapeutic Radiology
Duane Hall, Health Physics Services, 3M Center



December 11, 1996

Mr. Jerome Staiger
University of Minnesota
W-140 Boynton Health Service
410 Church Street SE
Minneapolis, MN 55455

Dear Mr. Staiger:

This is to confirm the procedures discussed between yourself and Frederick Entwistle of this office yesterday for handling radioactive materials being used at 3M Center under the U of M NRC Broad Scope License. These measures are in place and will be applied during the next such use of radioactive material, scheduled for tomorrow, December 12, 1996.

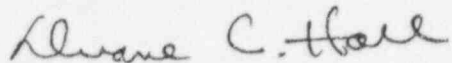
Specifically, these measures include:

- Prior to the administration of the radioactive material to the subjects, the transfer of the radioactive material from 3M's possession to the U of M license, number 22-00187-46, will be documented including the signature of an authorized U of M permit holder. A copy of this documentation will be faxed to the U of M the same day.
- At the conclusion of each day's work, a survey will be made to determine radiation exposure rate levels in all areas where the radioactive material was handled, stored, or disposed of as waste.
- A survey for removable contamination will be performed at least weekly when radioactive material is being used under the U of M license.
- These surveys will be documented in accordance with 10CFR35.70(h).
- All radioactive material placed in to decay in storage will be handled, surveyed and documented as required by 10CFR35.92.

A report summarizing all activities carried out under the broad scope license by 3M on behalf of the U of M will be submitted to your office on a quarterly schedule.

If you have any questions regarding this request please direct them to Fred Entwistle of this office (612) 736-0740.

Sincerely,

A handwritten signature in cursive script that reads "Duane C. Hall".

Duane C. Hall
Corporate Radiation Safety Officer

DCH/fbe

cc: C. L. Leach - Pharma-Path & Tox - 270-3S-05



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

December 20, 1996

Nils Hasselmo, Ph.D.
President
University of Minnesota
410 Church Street, S.E.
Minneapolis, MN 55455

SUBJECT: NRC INSPECTION AND NOTICE OF VIOLATION

Dear Dr. Hasselmo:

This refers to the inspection conducted on November 18 through 21, 1996 at the University of Minnesota, Minneapolis, MN and Roseville Business Commons locations. This also refers to the inspection conducted on December 6, 1996, at your authorized location at the Minnesota Mining & Manufacturing (3M) Center, St Paul, Minnesota. The purpose of these inspections was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. At the conclusion of the November 1996 inspection, the findings were discussed with members of your staff. Inspection findings regarding the December 6, 1996 inspection were discussed with Mr. Jerome Staiger in a teleconference on December 10, 1996.

The inspection was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selective examinations of procedures and representative records, interviews with personnel, independent measurements and observation of activities in progress.

In addition to the above areas, the inspection examined actions described in your letter dated January 26, 1996, regarding violations found during our November 1995 inspection. With the exception of not performing personal or area contamination surveys following procedures in laboratories, security and control of material in laboratories and the use of check sources on survey meters in laboratories, we have no further questions regarding these matters. The excepted areas remain open items, and will be reviewed during future inspections.

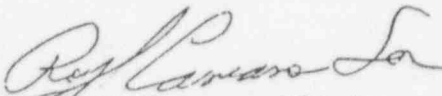
Based on the results of these inspections, the NRC has determined that violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice). A written response is required.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, the enclosure, and your response to this letter will be placed in the NRC Public Document

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Room (PDR). To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction.

Sincerely,



Cynthia D. Pederson, Director
Division of Nuclear Materials Safety

Licenses No.: 22-00187-46
22-00187-49
Docket Nos.: 030-00842
030-13175

Enclosure: Notice of Violation

cc w/encl: Jerome W. Staiger, Radiation Safety Officer

NOTICE OF VIOLATION

University of Minnesota
Minneapolis, Minnesota

License No. 22-00187-46
Docket No. 030-00842
License No. 22-00187-49
Docket No. 030-13175

During an NRC inspection conducted from November 18 through 21, 1996 and December 6, 1996, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violations are listed below:

License No. 22-00187-46

1. 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in unrestricted areas. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in an unrestricted area and that it not in storage. As defined in 10 CFR 20.1003, unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Contrary to the above, on at least November 20, 1996, the licensee did not secure from unauthorized removal or limit access to packages containing approximately 2.0 millicuries of chromium-51, 14.6 millicuries of sulfur-35, 18 millicuries of phosphorous-32, and 0.2 millicuries of iodine-125, located in a closet in the Boynton Health Services Building, an unrestricted area, nor did the licensee control and maintain constant surveillance of this licensed material.

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

2. 10 CFR 35.32(a)(1)(iii) requires, in part, that the licensee establish and maintain a quality management program (QMP) which must include written policies and procedures to meet the objective that, prior to administration, a written directive is prepared for any brachytherapy radiation dose.

10 CFR 35.2 defines a written directive as an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation and containing certain information including for brachytherapy the radioisotope, number of sources, and source strengths.

Contrary to the above, since at least April 1996, written directives were not dated prior to administering brachytherapy treatments involving iridium-192 and cesium-137 implants.

This is a Severity Level IV violation (Supplement VI).

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3. 10 CFR 35.70(b) requires that a licensee survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored.

Contrary to the above, from August 13, 1996 through December 6, 1996, the licensee had not surveyed areas where radiopharmaceuticals or radiopharmaceutical waste, comprised of millicurie quantities of technetium-99m, was stored at its authorized location of use at 3M Center, St. Paul, Minnesota, Building 270, Rooms SC344 and SC348.

This is a Severity Level IV violation (Supplement VI).

4. 10 CFR 35.70(e) requires that a licensee survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

Contrary to the above, from August 13, 1996 through December 6, 1996, the licensee had not surveyed for removable contamination areas where technetium-99m radiopharmaceuticals were routinely prepared for use, administered, or stored at its authorized location of use at 3M Center, St. Paul, Minnesota, Building 270, Rooms SC344 and SC348.

This is a Severity Level IV violation (Supplement VI).

License No 22-000187-49

License Condition No. 18. requires, except as specifically provided otherwise in the license, the licensee to conduct its program in accordance with the statements, representations, and procedures contained in the documents listed on the license.

Items 1.b. and 2 of the letter dated November 7, 1994, listed in License Condition No. 18.B, were excepted as procedures which included radioactive waste compaction at the licensee's Integrated Waste Management Facility.

Contrary to the above, on numerous occasions since November 7, 1994, the licensee has compacted radioactive waste at the Integrated Waste Management Facility.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, the University of Minnesota is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351

within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

Dated at Lisle, Illinois
this 20 day of December 1996