UNIVERSITY OF MINNESOTA

Twin Cities Campus

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

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

October 19, 1993

U. S. Nuclear Regulatory Commission
Nuclear Materials Safety Branch
Region III Office
799 Roosevelt Road
Glen Ellyn, Illinois 60137-5927

Attn: Roy J. Caniano, Chief

Dear Mr. Caniano:

This letter is written in response to your September 3, 1993 letter (copy attached) to R. Carter McComb, Associate Hospital Administrator, University of Minnesota, concerning the results of the June 21-22, 1993 safety inspection and the July 12, 1993 inspection report concerning the brachytherapy misadministration in the Department of Therapeutic Radiology, University Hospital.

The Notice of Violation enclosed with your September 3 , 1993 letter (see attached copy) listed two violations and requested that our response include for each violation: 1) the reason for the violation, 2) the corrective steps taken and results achieved, 3) the corrective steps that will be taken to avoid further violations, and 4) the date when full compliance will be achieved.

Reply to Notice of Violation:

A. The first violation involved the failure of individuals under the supervision of an authorized user to follow the written quality management program (QMP) of the Department of Therapeutic Radiology. The persons in question failed to verify that the radioisotope, number of sources, source strengths and loading sequence were in agreement with the written directive prior to administration of the treatment.

1. The primary reasons for this violation was a human error by the person responsible for the removal of the sources from inventory (removed wrong sources). In addition, the resident physician failed to perform the verification of the sources, sources strengths, and loading sequence in accordance with the QMP. Both individuals had received training in the QMP. As a result of this incident they were severely reprimanded. The details of the Department of Therapeutic Radiology's investigation and corrective actions are provided in a June 28, 1993 report sent with the June 29, 1993 letter to the NRC (see attached copy).

2. The immediate corrective steps taken are provided in sections III A. & III B. of the June 28, 1993 report, and in the June 17, 1993 memo (Appendix C of the report) from Dr. Seymour Levitt, M.D., Head of the Department of Therapeutic Radiology, to the staff of the Department.

3. The corrective actions taken to avoid further violations are given in sections III.B., III.C., III.D., & III.E. of the report.

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4. All of the corrective actions were implemented either immediately (June 17,1993) or by July 12,1993 with the exception of the new Isotope Transport Car[illegible]ppendix J) and the revised QMP Brachytherapy Checklist (Appendix I). Appendix J has been printed and was placed into use October 15, 1993. Appendix I was reviewed with the Human Use Subcommittee on October 18, 1993, and will be sent to Region III NRC for incorporation into the University's QMP. The projected date for submittal of this revised checklist to the NRC is November 1, 1993.

B. The second violation involved the incorrect determination of the number of sources and activities remaining in storage following source removal. This check is required to confirm that the correct number and activity of sources were withdrawn.

1. The reason for the incorrect determination was human error and failure to follow the QMP for source withdrawal.

2. With respect to corrective steps, as stated above, the individual involved was severely reprimanded. In addition, two individuals now jointly conduct and check the source removal and remaining inventory steps (instituted June 17,1993).

3. Steps taken to avoid further violations include the training of all staff concerning the violations that occurred, the review of the curator and checker responsibilities, the assignment of these responsibilities to fewer individuals who will rotate less frequently (every 3 months), and the requirement for each person to review the QMP procedures before assuming a rotation as curator or checker.

4. Full compliance was achieved for this item on July 12, 1993 when the training was c[illegible]ed.

If you require additional information concerning the actions taken to correct these items of violation, please contact me.

Sincerely,

Jerome W. Staiger

Jerome W. Staiger
Radiation Protection Officer

cc: R. Carter McComb, Assoc. Hospital Director
Gregory Hart, General Director, University Hospital
Paul Tschida, Asst. Vice-President, Campus Health & Safety
Seymour Levitt, M.D., Head, Dept. of Therapeutic Radiology
Kathryn Dusenbery, M.D.
Douglas Wangensteen, Ph.D., Chairperson, HUS
Faiz Khan, Ph.D.
Bruce Gerbi, Ph.D.
Fay Thompson, Ph.D.

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DCD/DCB

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

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

Dear Dr. Hasselmo:

SUBJECT: NOTICE OF VIOLATION DATED AUGUST 31, 1993

This acknowledges receipt of your letter dated October 19, 1993, in response to our letter dated August 31, 1993, transmitting a Notice of Violation.

Your response indicates that you have filed an application for an amendment to achieve corrective action for Violation No. 1.A. Requests for amendments to modify or add commitments and procedures are not effective until an amendment has been issued authorizing those changes. Therefore, we caution you regarding implementation of any new procedures before they have been approved by the NRC. Your corrective actions for the remaining violation appear adequate and will be examined during future inspections.

Sincerely,

Roy J. Caniano, Chief
Nuclear Materials Safety Branch

bcc w/ltr dtd 10/19/93:
PUBLIC

RIII
Jones/bt
11/ /93

RIII
Grobe
11/5/93

RIII
Caniano
11/8/93

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DCD/DCB

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University of Minnesota
Hospital and Clinics
ATTN: Mr. R. Carter McComb
Associate Hospital Administrator
C 559 Mayo Building - Box 247
420 Delaware Street
Minneapolis, MN 55455

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

Dear Mr. McComb:

SUBJECT: NOTICE OF VIOLATION DATED SEPTEMBER 3, 1993

This acknowledges receipt of your letter dated October 19, 1993, in response to our letter dated September 3, 1993, transmitting a Notice of Violation and an area of concern.

We have reviewed the actions taken to correct the violations and have not further questions at this time.

The area of concern was not specifically discussed as requested in our letter dated September 3, 1993. However, Item III C.1. of the document dated June 28, 1993 submitted with your response, adequately addresses actions you have taken to alleviate our concern regarding the provision of periodic Quality Management Program procedure training to your staff. No further response is required.

These corrective actions will be examined during a future inspection.

Sincerely,

Original Signed by Roy J. Caniano

Roy J. Caniano, Chief
Nuclear Materials Safety Branch

bcc w/ltr dtd 10/19/93:
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RIII
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JAN 2 1 1993

MetroHealth Medical Center
ATTN: John Stelma, Vice President
Clinic and Management Support
3395 Scranton Road
Cleveland, OH 44109

License Nos. 34-03749-07;
34-03749-10
Docket Nos. 030-00410;
030-13873

Dear Mr. Stelma:

This refers to the routine safety inspection conducted by W. J. Slawinski and T. F. Young of this office on August 13-14, 1992, of activities authorized by NRC Material License Nos. 34-03749-07 and 34-03749-10, and to discussion of our preliminary findings with you, E. Wiesen and S. Skubic of your staff at the conclusion of the inspection.

The inspection was an examination of activities conducted under your licenses as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your licenses. The inspection consisted of a selective examination of procedures and representative records, observations, independent measurements, and interviews with personnel.

In addition to the above areas, the inspectors examined actions described in your letter dated August 15, 1989, regarding violations of License No. 34-03749-10 found during our June 21, 1989, inspection. We have no further questions regarding the violation involving your survey meter calibration. However, your failure to check for external contamination is a repeat violation and is included in the enclosed Notice. In your response to this violation, please describe why your proposed corrective action is expected to be more successful in preventing future or similar violations than the corrective action specified in your August 15, 1989 letter.

During this inspection, certain of your activities under License No. 34-03749-10 were found to be in violation of NRC requirements, as specified in the enclosed Notice (Enclosure 1). A written response is required. No violations were identified for License No. 34-03749-07.

In addition to the violations identified during the inspection of license No. 34-03749-10, certain other radiation safety activities related to research uses of byproduct material were found to be of particular concern. These items were discussed with you at the conclusion of the inspection, and are listed in Enclosure 2. We request that you submit a written response to address each concern, along with your response to the Notice (Enclosure 1). The response to each concern should include a description of your plans to strengthen the weaknesses noted, and timetables for completing the necessary program improvements.

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In accordance with 2.790 of the Commission's regulations, a copy of this letter, the enclosures, and your responses to this letter will be placed in the NRC Public Document Room.

The responses directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

Original Signed by Roy J. Caniano

Roy J. Caniano, Chief
Nuclear Materials Safety Branch

Enclosures:
1. Notice of Violation
2. Radiological Safety Concerns

cc w/enclosures:
DCD/DCB (RIDS)

RIII	RIII	RIII	RIII
T. Young/jaw	W. Slawinski	B.J. Holt	R. Caniano
1/21/93	1/21/93	1/21/93	1/21/93

Enclosure 1

NOTICE OF VIOLATION

MetroHealth Medical Center
Cleveland, Ohio

License No. 34-03749-10
Docket No. 030-13873

During an NRC inspection conducted on August 13-14, 1992, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1992), the violations are listed below:

1. 10 CFR 20.205(d) requires that each licensee establish and maintain procedures for safely opening packages in which licensed material is received, and assure that such procedures are followed and due consideration is given to special instructions for the type of package being opened.

   Condition 19 of License No. 34-03749-10 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application dated February 24, 1984 and letter dated March 11, 1986 (with attachments).

   Item 1 of the application dated February 24, 1984, states that the licensee will establish the procedures found in Appendix F of Regulatory Guide 10.8 (1980).

   Appendix F of Regulatory Guide 10.8 (1980), entitled "Procedures for Safely Opening Packages that Contain Radioactive Material," requires the licensee to test for leakage, prior to opening, each package that contains radioactivity in excess of exempt quantities in liquid form. In addition, Appendix F requires the licensee to wipe the external surface of the final source container of all packages and remove the wipe to a low background area to assay and record the amount of removable radioactivity.

   Contrary to the above, as of August 13, 1992, the licensee routinely received packages containing radioactivity in excess of exempt quantities in liquid form and did not perform the required tests for leakage prior to opening the packages and did not wipe the external surface of the final source container.

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

   This is a repeat violation from the previous inspection conducted on June 6, 1989.

2. 10 CFR 35.315(a)(8) requires, in part, that a licensee measure the thyroid burden of each individual who helped prepare or administer dosages of iodine-131 in amounts that required the patient to be hospitalized for compliance with 10 CFR 35.75, and that the measurements be performed within three days after the administration of the dosage.

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Contrary to the above, on August 3, 1992, the licensee administered to a patient 153 millicuries of iodine-131, a dosage which requires hospitalization for compliance with 10 CFR 35.75, and the licensee did not measure the thyroid burden of the radiation safety technician who helped administer this dosage.

This is a Severity Level IV violation, Supplement VI.

3. 10 CFR 35.50(b)(3) requires, in part, that a licensee test each dose calibrator for linearity over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries.

Contrary to the above, the licensee did not test its dose calibrator for linearity to encompass the highest dosage that is administered to a patient. Specifically, the licensee administered a 143 millicurie iodine-131 dose to a patient on August 3, 1992, and the linearity test conducted prior to the administration did not extend beyond 48 millicuries.

This is a Severity Level IV Violation, Supplement VI.

4. Condition 19 of License No. 34-03749-10 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application dated February 24, 1984, and a letter dated March 11, 1986 (with attachments).

A. Item No. 11 of the licensee's application dated February 24, 1984, describes the licensee's facilities. The licensee's letter dated March 11, 1986, describes further changes to the licensee's facilities that were approved by NRC.

Contrary to the above, as of August 13, 1992, the licensee failed to describe additional facility changes to NRC and receive NRC approval prior to use of the changed facilities. Specifically, the licensee constructed a storage facility for brachytherapy sources that was not reviewed or approved by NRC.

B. Item No. 20 of the licensee's application dated February 24, 1984, describes the licensee's procedures for therapeutic use of sealed sources and requires the licensee to store Cs-137 brachytherapy sources in the MICRAD source cart that is locked and stored in the nuclear medicine department hot lab.

Contrary to the above, on August 13, 1992, the MICRAD storage cart was not locked. Specifically, the lock that secures the brachytherapy sources in the MICRAD cart was broken and the source access cover was unsecured.

This is a Severity Level IV Violation, Supplement VI.

5. 10 CFR 35.406(b) requires that a licensee make a record of brachytherapy source use, including: (1) the names of the individuals permitted to handle the sources; (2) the number and activity of sources removed from storage, the patient's name and room number, the time and date they were removed from storage, the number and activity of the sources in storage after the removal, and the initials of the individual who removed the sources from storage; (3) the number and activity of sources returned to storage, the patient's name and room number, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

   Contrary to the above, as of August 13, 1992, the licensee's record of brachytherapy source usage for did not include, (1) the names of the individuals permitted to handle the sources; (2) the number and activity of the sources in storage after the removal of sources; and (3) the number and activity of sources in storage after the return of sources.

   This is a Severity Level V violation, Supplement VI.

Pursuant to the provisions of 10 CFR 2.201, MetroHealth Medical Center is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois, 60137, within 30 days of the date of they 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. 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.

JAN 2 1 1993

Dated

Roy J. Caniano, Chief
Nuclear Materials Safety Branch

Enclosure 2

RADIATION SAFETY CONCERNS

During the routine safety inspection of NRC License No. 34-03749-10 at MetroHealth Medical Center, Cleveland, OH, several radiological safety and program development concerns associated with research uses of byproduct material were identified. The specific concerns are listed below.

1. Authorization and permit files maintained by the Radiation Safety Officer (RSO) do not contain completed application forms and signatures of the Radiation Safety Committee (RSC) chairperson and the RSO. Although the RSC minutes indicate approval by the RSC, the approved applications were not available for review during the inspection.

2. The RSC does not perform a periodic review of approved protocols to evaluate the current radiation use program of each authorized user.

3. The RSC has no formal mechanism to convey required radiation safety policies and practices to the researchers e.g. a radiation safety manual.

4. The RSO lacks an inventory and tracking system to account for the receipt, storage, transfer, and disposal of radioactive material. Although procurement and disposal records are available, the radiation safety staff is unable to provide cumulative radioactive material inventory and accountability data at any given time. The RSC does not review the quantities and kinds of radioactive material that are procured, possessed, and disposed of by the research projects that the RSC has authorized.

5. The level of staffing for the Radiation Safety Officer technical and clerical tasks may be insufficient for current program needs and may not be adequate for an increase in the use of licensed materials. Radiation Safety Officer space and equipment limitations are also of concern.

6. During monthly surveys of laboratories, the Radiation Safety Office staff does not assay wipe samples that may be contaminated with tritium with the appropriate instrumentation, e.g. liquid scintillation counter.

MetroHealth Medica .nter
3395 Scranton Road, Cleveland, Ohio 44109

216 398-6000

Radiology

February 2, 1993

Roy J. Caniano, Chief
Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission
799 Roosevelt Road
Glen Ellyn, Illinois 61037

Re: License Nos. 34-03749-10 34-03749-07
Dockets Nos. 030-00410 030-13873

Dear Sir:

This letter is in response to your letter of January 21, 1993, Dockets Nos. 030-00410 and 030-13873. The following paragraph numbers refer to the paragraph numbers of Enclosure 1 of Docket Nos 030-00410 and 030-13873

1. We believe that we are in compliance with the spirit of 10 CFR 20.205(d). This regulation states "that procedures are followed and due consideration is given to special instructions for the **type of package** being opened." The package is delivered by a messenger in a private automobile from the Commercial Radiopharmacy providing the unit dose vials to Nuclear Medicine. It is inspected by the pharmacy and delivered in person from the pharmacy. At no time is the package delivered by a common carrier. The package consists of suitcase lined with foam. The foam has several indentations that are the exact shape of the lead containers that hold the radioactive vials. In addition, the vials are sealed inside the lead containers with heat shrink plastic tubing. The suitcase is secured by straps that prevent the suitcase from opening if the lock should fail. It is nearly impossible to have a vial leak to the outside without some evidence of damage to the suitcase.

   After the June 6, 1989 inspection, we instituted a procedure modeled after Appendix L, Regulatory Guide 10.8 (August 1987). A procedure was written and placed in the room were the material is received. A copy is enclosed. Please note that our procedures and parts of Appendix L are nearly identical.

   We do not believe that this is a repeat violation. Procedures were put into effect after the last inspection that obeyed the spirit of the law with due consideration to who is delivering the package and "**for the type** of package being opened."

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2. We neither prepare the dose nor administer the dosage. The patient self administers the dosage and it is totally prepared by the supplying vendor. Dosages of iodine-131 for therapy are received from the vendor in one or more capsules. The capsules are in a plastic bottle, inside a lead container. To assay the dosage, the technologist will remove the plastic bottle using tongs and place it inside the dose calibrator to verify the dose. When the dose is to be given to the patient, the radiation safety technologist removes the plastic bottle from the lead container using special tongs. The patient removes the cover from the container and takes the capsules per os. The radiation safety technologist never comes into direct contact with the iodine-131. For these reasons, we do not feel it is necessary to measure the thyroid burden. The radiation safety technologist does not prepare the dosage and the patient administers it to themselves. The reason that capsules are used was because we feel it is inherently safer. However, for all iodine-131 therapy administrations that are over 30 millicurie, thyroid burden will be measured effective March 1, 1993.

3. Dose calibrator linearity was tested for the maximum diagnostic activity given. We have altered our procedure to include the maximum therapeutic dose, increasing the initial activity to about 150 millicurie. We have been in compliance with the 150 limit since August 1992.

4A. A storage facility was established to house in a safe manner the additional brachytherapy Cs-137 tube sources that were purchased by our institution. Such purchase did not require NRC approval since the additional amount of Cs-137 did not cause our inventory to exceed our license possession limit for this radioisotope. The storage facility was approved by the Radiation Safety Officer and the Chairman of the Radiation Safety Committee prior to storing sources. An area survey conducted after the sources were in the facility documents that radiation exposure levels are within acceptable limits. It was our belief that our broad-scope license permitted independent action of the sort described without prior notification of the NRC.

To rectify the deficiency, we hereby submit the facility for review and approval of the NRC. Attached is a copy of the radiation protection survey performed at time of first use of the facility. The area is in a limited access, low occupancy storage area that has both good lighting and ventilation. Both doors (positions C and E) are kept locked and are posted with radioactive material warning signs. The actual sources are kept in a locked lead safe (position X). To prevent future violations of this sort, we will submit all changes in facilities for review by the full Radiation Safety Committee (RSC). Where questions arise about whether the NRC must be informed, the RSO will contact the NRC for clarification. NRC review and approval will be solicited where appropriate.

4B. A lock for the MICRAD storage cart was procured and installed shortly after last August's inspection. Our facility has been in compliance since that time. To assure future compliance, the authorized handlers of the MICRAD sources have been instructed to notify the RSO if the lock becomes broken in the future. The integrity of the lock will also be checked at the time the inventory of the sources is taken and corrective action taken if needed.

5(1) A list of approved MICRAD source handlers has been posted in the Nuclear Medicine hotlab (the normal storage area for the MICRAD source cart). There is full compliance on this point. The list will be periodically updated to reflect the current approved list of source handlers.

5(2) and 5(3):

We dispute that our procedures are in violation on these points. Though perhaps not in the form preferred by the NRC inspectors, our source logging procedures show the patient's name and room number, the number and activity of sources removed from storage, and the initials of the individual who removed the sources. Likewise, the procedure logs the number and activity of sources returned to storage, the patient's name and room number, the initials of the person who returned the sources, and the time and date the source were returned. A full inventory sheet with current source activities is always present with the log sheets. Simple arithmetic provides the number of sources in the pig at any one time. Hence our logging and accounting procedures meets NRC requirements at the present time.

To prevent further misunderstandings on this matter, a new accounting sheet has been developed and is now in use. A copy of the new form is attached. We believe that the new form will be acceptable to the NRC.

The following paragraph numbers refer to your paragraph numbers in Enclosure 2.

Concern 1: Authorization and permit files maintained by the Radiation Safety Officer did not contain completed forms and signatures.
Response: Of the several primary user files examined only two did not contain the documents referred to in this concern. It is our usual practice to include this sheet, signed by the RSC and the Chairman of the RSC. We cannot account for the reasons these documents were not in the two files. During our annual audit, the task of verifying the completeness of the files will be added to the audit.

Concern 2: The RSC does not perform a periodic review of approved protocols to evaluate the current radiation use of each primary user.
Response: This is not required by current regulations. Good practice may suggest that the RSC should periodically review the activity of each primary user and renew the use permit if the RSC is satisfied. This will be discussed at the next meeting of the RSC and they will make recommendations for future action.

Concern 3: The RSC has no formal mechanism to convey required radiation safety policies and practices to the researchers e.g. a radiation safety manual.
Response: Each laboratory must have a safety manual before the Radiation Safety Office will approve the laboratory for use. This was true in August.

Concern 4: The RSO lacks an inventory and tracking system to account for the receipt, storage, transfer, and disposal of radioactive material.
Response: We had a computerized data base system working in August during the visit. When a primary user requests that he may be allowed to order material, that request is first entered into the data base. Before he can order that material, their possession limit is checked against current inventory, the disposition of the last order and the amount to be ordered. This too is entered. When the material arrives, the arrival is entered. One can interrogate the system to determine: the nuclide and quantities on hand, the nuclide and quantities received, and the nuclide and quantities disposed of and the method of disposal. The above information can be found for either any individual user or the cumulative amount for all users for any period of time. This will be reported to the RSC at each meeting.

Concern 5: The level of staffing for the Radiation Safety Officer technical and clerical tasks may be insufficient for current program needs and may not be adequate for an increase in the use of licensed materials.
Response: This concern will be presented and discussed at the next meeting of the RSC and will receive the attention of the hospital administration.

Concern 6: During monthly surveys, the RSO staff does not assay wipe samples for H-3 using a liquid scintillation counter.
Response: After each experiment using H-3, primary users are required to do a wipe test of all areas of possible contamination and record the results. The results are monitored during the periodic survey of the laboratory by the Radiation Safety Office. We currently do a wipe test and test for the presence of gamma and relatively high energy beta. Our current method will not detect the beta radiation of H-3 and C-14. We will institute a program of using a liquid scintillation counter to count these same wipes. We will be able to start this program June 1993.

Ernest J. Wiesen
Radiation Safety Officer

Errol M. Bellon, M.D., Director
Department of Radiology

John M. Stelma, Vice President
Clinical/Management Support

MetroHealth Medical Center
Department of Radiology
Radiation Safety Office

Procedures for Receiving Packages in Nuclear Medicine Laboratory

1. Put on gloves to prevent hand contamination.

2. Visually inspect outer package for damage or any unusual appearance. If anything unusually is noted, call the Radiation Safety Office on Ext 4454.

3. Measure surface dose rate with survey meter. The surface exposure should be less than 50 mr/hr. Measure the exposure at one meter from the package, the exposure should be less than the transport index printed on the label.

4. Open package with the following steps:

a. Visually inspect all parts of the container for damage, wet spots, dents, broken seals, or discoloration of packing material.

b. If anything unusual is noted, call the Radiation Safety Office. They will inspect the package and perform the wipe tests.

c. Verify that the packing slip agrees with the contents.

d. Make a record of the receipt.

e. If the packing material is to be discarded, survey the material before it is put into normal trash. If anything is detected, call the Radiation Safety Office.

METROHEALTH MEDICAL CENT
DEPARTMENT OF RADIOLOGY

RADIATION PROTECTION SURVEY

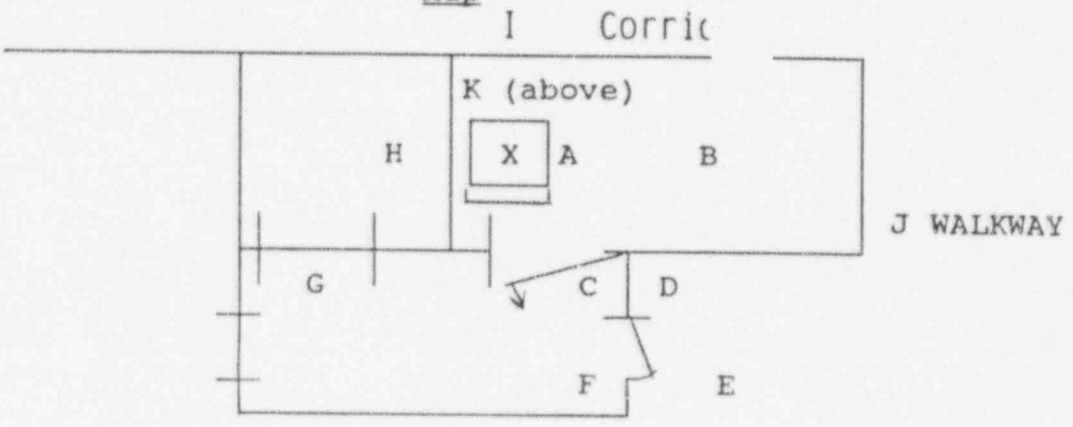
SURVEY PERFORMED BY Stanley E. Skubic, Ph.D. SURVEY DATE: SEPT. 12, 1991

Reason for Survey: New Cs-137 tube sources were placed in lead safe located in a storage room below Radiation Oncology.

Survey Instrument: Victoreen 450 Ion Chamber Survey Meter

Last Calibrated: 8-5-91

Map



LOCATION	EXPOSURE RATE (mR/hr)	LOCATION	EXPOSURE RATE (mR/hr)
A	.03	G	.02
B	.03	H	.04
C	.02	I	.02
D	.03	J	.02
E	.02	K (Floor Above)	.02
F	.02		

CONCLUSION: Radiation exposure levels are well within acceptable limits, Storage room and storage are both adequately posted with proper radiation warning signs.

A:RADPROSUR.MAP

DEPARTMENT OF RADIOLOGY

RADIATION ONCOLOGY SECTION

Micred CS-137 Source Inventory Record

PATIENT: _____ UNIT NO: _____ WARD: _____ RM: _____

LOADING & (Removal from Pig):

DATE: _____ TIME: _____ BY: _____

SOURCES IN PATIENT

Source Inventory	NUMBER	CIRCLE SERIAL NUMBER OF SOURCE INSERTED	NUMBER OF SOURCES REMAINING IN PIG
4 x 10	_____	76B 77B 78B 79B	_____
4 x 15	_____	82B 83B 85B 71D	_____
1 x 20 (GI86B)	_____	86B	_____
1 x 30 (GI81B)	_____	81B	_____
1 x 50 (GI87B)	_____	87B	_____
1 x 60 (GI62F)	_____	62F	_____
1 x 30 (IPL44.33-1)	_____	44.33-1	_____
1 x 40 (IPL44.33-1)	_____	44.33-2	_____
1 x 105 (GI80B)	_____	80B	_____
TOTAL	_____		_____

RETURN (Return to Pig):

DATE: _____ TIME: _____ BY: _____

SOURCES REMOVED FROM PATIENT

Source Inventory	NUMBER	CIRCLE SERIAL NUMBER OF SOURCE INSERTED	NUMBER OF SOURCES NOW IN PIG
4 x 10	_____	76B 77B 78B 79B	_____
4 x 15	_____	82B 83B 85B 71D	_____
1 x 20 (GI86B)	_____	86B	_____
1 x 30 (GI81B)	_____	81B	_____
1 x 50 (GI87B)	_____	87B	_____
1 x 60 (GI62F)	_____	62F	_____
1 x 30 (IPL44.33-1)	_____	44.33-1	_____
1 x 40 (IPL44.33-2)	_____	44.33-2	_____
1 x 105 (GI80B)	_____	80B	_____
TOTAL	_____		_____

DCD/DCB

APR 22 1993

MetroHealth Medical Center
ATTN: John Stelma, Vice President
Clinical and Management Support
3395 Scranton Road
Cleveland, OH 44109

License No. 34-03749-10
Docket No. 030-13873

Dear Mr. Stelma:

SUBJECT: NOTICE OF VIOLATION DATED JANUARY 21, 1993

This acknowledges receipt of your letter dated February 2, 1993, in response to our letter dated January 21, 1993, transmitting a Notice of Violation. Subsequently, on March 16, 1993, a telephone conference was conducted between our respective staffs to discuss your corrective actions.

Your corrective actions for Violation Nos. 2, 3, 4.B, and 5 appear to be adequate and we have no further questions at this time. These corrective actions will be examined during a future inspection.

Together, we concluded that additional information is necessary to adequately describe satisfactory corrective actions for Violation Nos. 1 and 4.A. Please send additional information as indicated below.

Violation No. 1:

Your license indicates that you will implement Appendix F of Regulatory Guide 10.8 (1980), "Procedures for Safely Opening Packages that Contain Radioactive Material". Your February 2, 1993, response indicated that your current procedure is a modification of Appendix L, Regulatory Guide 10.8, Revision 2, "Model Procedure for Safely Opening Packages Containing Radioactive Material".

Please submit records to confirm that your Radiation Safety Committee reviewed this change in your procedures in accordance with 10 CFR 35.31(b). Otherwise, indicate that the procedure described by your license has been re-established and implemented until your license is appropriately amended or until your Radiation Safety Committee has reviewed and approved the change in your procedure.

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APR 22 1993

Violation No. 4.A:

Your license indicates that brachytherapy sources are stored in the MICRAD unit that is parked in the nuclear medicine hot lab. Your February 2, 1993, response included a description of an additional brachytherapy source storage facility that is located in Radiation Oncology. This additional storage location requires amendment of your license.

Please prepare a request to amend the license for the brachytherapy source storage facility located in Radiation Oncology. The license amendment request should be sent to:

George M. McCann, Chief
Nuclear Material Licensing Section
Nuclear Regulatory Commission, Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Your response to the aforementioned items should be submitted within 10 days from the date of this letter.

Should have any question regarding this matter, feel free to telephone me or B. J. Holt of my staff. Our respective telephone numbers are (708) 790-5612 and (708) 790-5624.

Sincerely,

Roy J. Caniano, Chief
Nuclear Material Safety Branch

bcc w/ltr dated 2/2/93:
PUBLIC

RIII
Young/bt
04/22/93
Yes

RIII
Holt
4/22/93

RIII
Caniano
4/22/93

MetroHealth Medica[illegible]nter
3395 Scranton Road, G[illegible]and, Ohio 44109

216 398-6000

Radiology

April 27, 1993

Roy J. Caniano, Chief
Nuclear Material Safety Branch
U.S. Nuclear Regulatory Agency
799 Roosevelt Road
Glen Ellyn, Ill 60137-5927

Re: License No. 34--3749-10
Docket No. 030-13873

Dear Mr. Caniano:

This letter is in response to your letter of April 22, 1993 regarding the submission of additional data for resolution of reported Violations No. 1 and 4.A.

Violation No 1:

A copy of the Radiation Safety Committee Minutes of the Quarterly meeting is included for October 16, 1989 where the issue of wipe testing was first raised with the committee and the committee approved the procedure. The minutes of this meeting are subject to interpretation so the Committee again took up the issue on the quarterly meeting of April 20, 1993. The Committee at this time voted unanimously to approve "Procedures for Receiving Packages in Nuclear Medicine Laboratory." A copy of the Minutes of the Meeting for April 20, 1993 is included.

Violation No 4.A:

Our current License expired and we are operating under a "deemed timely" letter. Our application to renew has been reviewed and the NRC has requested that more information be supplied. This information is currently being gathered and another response will be submitted shortly. We have had discussions with Thomas Young of your office and Cassandra Frazier concerning this matter. Rather than apply for an amendment, the additional location will be added to the facilities portion of the new license application that is currently being processed. A copy of the drawing that will be used for the renewal is included with this letter.

Should you have any questions concerning this response, please feel free to contact Ernest Wiesen at (216) 459-4454.

Sincerely,

John M Stelma

John Stelma, Vice President
Clinical and Management Support

MAY 5 1993

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METROHEALTH MEDICAL CENTER
DEPARTMENT OF RADIOLOGY

Radiation Safety Committee Minutes
Monday, October 16, 1989

Present:	C. Cline, V.P.	K. Shin, M.D.
	D. Frazee, CNMT	S. Skubic, Ph.D.
	P. Leno, R.N.	E. Wiesen, BSEE
	S. Miron, M.D.	L. Sprague, R.T.
	M. Sarasua, M.D.	
Absent:	E. Bellon, M.D.	L. Kass, M.D./Excused
	B. Damtew, M.D.	V. Sharan, M.D.

A meeting of the Radiation Safety Committee was held on October 16, 1989 at 8:00 a.m. in the Radiology Small Conference Room. Dr. Skubic chaired the meeting.

I. OLD AND ONGOING BUSINESS

A. Minutes of the previous meeting were approved as written.

B. Status of pamphlet on radiation protection:
The final version has gone to the printer. There has been some problem getting the pamphlet printed in the desired magenta and yellow colors, which has caused a delay in printing.

C. Policy for pregnant personnel who are exposed to ionizing radiation:
Upon review of the proposed policy, the committee approved the policy (Attachment I) as written.

Action: To implement the proposed policy:
A. Dr. Bellon will be asked to forward the policy to the Medical Executive Board (MEB) for discussion and implementation for the medical staff.
B. Ms. Cline will forward the policy to the Nursing Executive Board for implementation for the nursing staff.

At the next RSC meeting, Mr. Wiesen and Dr. Skubic will present a sample consent document and report on the progress of implementing the policy for the Radiology Department.

D. Wearing of film badges by angiographers:
Dr. Skubic presented a memo (Attachment II) distributed to the Radiology faculty on this subject and noted that this group was reminded of the need to wear film badges in the proper location during two Radiology staff meetings.

E. Status of Drs. Feiglin and Shin as human users of radioisotopes: Since MHMC has an NRC broad license, the actions of the RSC at its last meeting have successfully added Drs. Feiglin and Shin as human users of radioisotopes — no further committee action is needed. An amendment to the MHMC's teletherapy license has been sent to the NRC requesting the addition of Dr. Shin to the teletherapy license. The NRC has acknowledged receiving the amendment request but has not acted upon it.

F. NRC inspection of MHMC — Inspection report and MHMC response: The committee reviewed the official inspection report of the NRC visit (Attachment III) and MHMC's official response (Attachment IV). The violations were noted to be minor and the appropriate response has been taken.

G. Radiation Safety Officer's quarterly report (Attachment V). The committee reviewed the report and noted the relatively low Level I ALARA exposure readings of Ms. Potter, Ms. Dickerson, and Dr. Rashad. These readings are consistent with their normal duties and require no further action. Mr. Wiesen noted the increase in the number of drums of dry radioactive waste disposed of. This could a problem in a couple years as commercial disposal of such waste may cease in 1993. Informal counseling of radioactive material users are continuing in an effort to reduce the volume of such waste generated.

Action: The committee approved Dr. E. Kanta Subbarao as a primary user of radioactive materials with a possession limit of 2 mCi of H-3.

The committee approved the following increases in possession limits for current primary users:

Dr. R. Cleveland: 10 mCi of In-111 (from 0)
Dr. M. Ip: 4 mCi of I-125 (from 2 mCi)
Dr. J. Moore: 10 mCi of H-3 (from 5 mCi)
Dr. A. Tavill: 0.1 mCi of C-14 (from 0)