



DEPARTMENT OF VETERANS AFFAIRS
Medical Center
2215 Fuller Road
Ann Arbor MI 48105

Weber

DEC 20 1994

In Reply Refer To: 506/OOR
Docket # 030-01987
License # 21-00159-04

* United States Nuclear Regulatory Commission
Region III
ATTN: John A. Grobe
Chief, Nuclear Materials Inspection, Section 2
801 Warrenville Road
Lisle, IL 60532-4351

Dear Mr. Grobe:

Per your request, a response regarding two areas of concern identified during a routine safety inspection by your agency are detailed below.

Concern #1:

a. We believe this concern pertains to failure of research staff to retain information as opposed to a weakness in training. Survey meter constancy checks are and have been a formal requirement of our internal Radiation Safety Program for Research Service since 1991. Written instructions are provided to researchers on how to perform constancy checks. Forms to document constancy checks are also provided to researchers. During initial and annual training, research staff are informed of this program requirement and are provided a demonstration, as well as the opportunity to perform such a task. Audits of Research Service are conducted on an annual basis, of which survey meter constancy checks and appropriate documentation is reviewed. Researchers are formally notified in person and in writing of any deficiency as per our internal violation policy. All deficiencies require written corrective action by the researcher and are reviewed by the Radiation Safety Committee. Supporting documentation is enclosed.

b. Realizing that retention of program requirements by research personnel presents potential concerns, annual performance audits of all authorized personnel in research have been added to our Radiation Safety Program in August 1994. Performance audits include the appropriate use of survey meters and being able to adequately perform a survey and a survey meter constancy check.

c. We are committed to good health physics practices for even those areas or items not specifically addressed in the regulations. We believe that the addition of performance audits will strengthen the overall effectiveness of the Radiation Safety Program and also demonstrate any areas that need additional emphasis. Items requiring additional emphasis will be handled directly with individuals or if necessary, additional training will be provided for all research staff.

Concern #2:

a. The location of lockers, in an area where large quantities of radioactive material are used and stored in Nuclear Medicine, was selected solely on the basis of space. Our facility lacks ideal space due to the nature of its design and age.

b. The lockers were moved to a non-radiation area during the course of the inspection. The inspector was provided an opportunity to view the new location of the lockers, but declined. The storage of personal effects in areas where radioactive materials are used and/or stored will be prohibited in Nuclear Medicine Service. The Chief of Nuclear Medicine was informed in writing of this change in the Radiation Safety Program.

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John A. Grobe

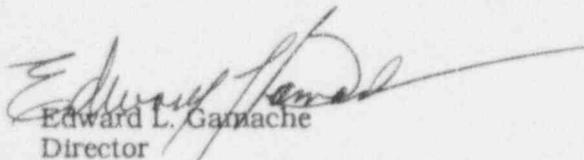
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c. Since the lockers have been moved, we believe the corrective action to be sufficient and we do not believe a policy or procedure is necessary. We have designed our new clinical space (due to start construction in 1995) to accommodate all regulatory issues, as well as incorporate good health physics practices.

Please direct any questions or requests for additional information to Ms. Melonie Payne, Radiation Safety Officer, at the above address or telephone (313) 761-7916.

Sincerely,



Edward L. Gamache
Director

Enclosures

cc: Milton Gross, M.D., Chairman (115)
Regional Radiation Safety Program Manager (132RS)
National Health Physics Program Director (115HP)

SURVEY METER CONSTANCY

1. This section contains a record for your laboratory survey meter(s). Maintain a separate constancy log for each survey meter in active use.
2. This record is to verify that the performance of your survey meter(s) was checked prior to being used. If the check source exposure rate varies by 10% or more, the survey meter must be serviced and survey results obtained from it are not valid.
3. Constancy must be checked in the following manner:
 - a. Check physical integrity of the survey meter.
 - b. Turn power on.
 - c. Check battery level and record result.
 - d. Record background level on most sensitive scale.
 - e. Record exposure rate of the check source.
 - 1) Use the source assigned to the survey meter (noted at the top of the constancy log).
 - 2) Distance from probe to source must be consistent.
 - f. Initial the performance of the check (must be performed by an authorized handler of radioactive materials).
4. If the constancy record is not kept up to date, your area survey records are effectively negated. Survey results can not be trusted if the instrument used for the survey is not checked for constancy.

RESEARCH LABORATORY RADIATION SAFETY INSPECTION REPORT

Authorized User _____

Date of Inspection _____

Date of Last Inspection _____

Laboratory Room(s) Inspected _____

Results: **Acceptable** **Not Acceptable** **See Comments**

A. CURRENT LICENSE

Documented	Y	N	N/A
Emergency Procedures	Y	N	N/A
Radiation Safety Procedures/Manual	Y	N	N/A
Procedure/Regulation Updates Current	Y	N	N/A

B. LIST OF AUTHORIZED PERSONNEL

All Staff Personnel Documented	Y	N	N/A
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C. TRAINING RECORDS-WORKER TRAINING REQUIREMENTS (10CFR19.12)

All Staff Personnel Trained with Documentation	Y	N	N/A
Refresher Training/Updates	Y	N	N/A

D. SUMMARY ISOTOPE INFORMATION SHEET

Documented	Y	N	N/A
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E. RECEIPT LOGS AND USE OF RADIOACTIVE MATERIALS (10CFR20 AND 10CFR35)

Daily use log of radioactive materials maintained	Y	N	N/A
Material Activity Within Possession Limits	Y	N	N/A
Record of Materials Received	Y	N	N/A
Record of Materials Transferred	Y	N	N/A
Materials Used in Secure Authorized Location	Y	N	N/A
Authorized Personnel Using Materials	Y	N	N/A
Report of Loss or Theft of Material	Y	N	N/A

F. WASTE DISPOSAL RECORDS (10CFR20.301 - 10CFR20.401)

Waste Properly Separated, Labeled and Stored	Y	N	N/A
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	Disposal Log Maintained	Y	N	N/A
	Waste Surveys Performed and Recorded	Y	N	N/A
G.	MONTHLY INVENTORIES			
	Monthly inventory reports current and submitted	Y	N	N/A
H.	LIST OF AREAS IN WHICH RADIOACTIVE ISOTOPES CAN BE USED			
	Documented	Y	N	N/A
I.	LABORATORY SURVEYS AND SWIPES (10CFR20 AND 10CFR35)			
	Area Surveys Performed and Recorded	Y	N	N/A
	Area Wipe Tests Performed and Recorded	Y	N	N/A
	Monthly survey reports submitted	Y	N	N/A
J.	SURVEY METER CONSTANCY LOG (10CFR35.12 - .51)			
	Survey Instruments Available as Licensed	Y	N	N/A
	Survey Instruments Operational and Calibrated	Y	N	N/A
	Record of Constancy Check	Y	N	N/A
	Protocols/Manuals for Instrument Use	Y	N	N/A
	All Personnel Instructed in Instrument Use	Y	N	N/A
K.	ANY APPLICABLE SPILL OR INCIDENT REPORTS			
	Documented	Y	N	N/A
L.	ALL MEMOS/CORRESPONDENCE TO OR FROM THE RADIATION SAFETY OFFICE			
	Documented	Y	N	N/A
M.	MISCELLANEOUS GENERAL RADIATION SAFETY			
	Lab Coats Used	Y	N	N/A
	Gloves Used During Radioactive Procedures	Y	N	N/A
	Decontamination Equipment Available	Y	N	N/A
	Available Shielding Adequate	Y	N	N/A
	Laboratory Housekeeping Adequate	Y	N	N/A
	POSTING REQUIREMENTS (10CFR20.203)			
	Radiation Signs Posted	Y	N	N/A

Doors	Y	N	N/A
Work Areas	Y	N	N/A
Storage Areas	Y	N	N/A
Fume Hoods	Y	N	N/A
Refrigerators	Y	N	N/A
Containers	Y	N	N/A
"Hot" Sink	Y	N	N/A
"Hot" Waste	Y	N	N/A
NRC Form 3 - Notice to Employees Posted	Y	N	N/A
10CFR19 - Report to Workers Posted	Y	N	N/A
10CFR20 - Dose Limit Standards Posted	Y	N	N/A

LABELING REQUIREMENTS

Radioactive Materials Labeled Correctly	Y	N	N/A
Radioactive Labels Defaced upon Disposal	Y	N	N/A

PERSONNEL MONITORING (10CFR20.405 and 10CFR35.315)

All Appropriate Personnel Badged	Y	N	N/A
All Personnel Wearing Badges	Y	N	N/A

SPECIAL REQUIREMENTS - VOLATILE RADIONUCLIDES (10CFR20 and 10CFR35)

Fume Hood Air Flow Rate Checked	Y	N	N/A
Bioassay Results Acceptable and Recorded	Y	N	N/A

COMMENTS AND RECOMMENDATIONS

RESEARCH LABORATORY RADIATION SAFETY INSPECTION REPORT

Authorized User _____

Date of Inspection _____

Date of Last Inspection _____

Laboratory Room(s) Inspected _____

Results: **Acceptable** **Not Acceptable** **See Comments**

1. CURRENT LICENSE

Documented	Y	N	N/A
Emergency Procedures	Y	N	N/A
Radiation Safety Procedures/Manual	Y	N	N/A
Procedure/Regulation Updates Current	Y	N	N/A

2. LIST OF AUTHORIZED PERSONNEL

All Staff Personnel Documented	Y	N	N/A
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3. TRAINING RECORDS-WORKER TRAINING REQUIREMENTS

All Staff Personnel Trained with Documentation	Y	N	N/A
Refresher Training/Updates	Y	N	N/A

4. SUMMARY ISOTOPE INFORMATION SHEET

Documented	Y	N	N/A
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5. ORDERING AND RECEIVING OF RADIOACTIVE MATERIALS

Purchase Request forms	Y	N	N/A
Material Activity Within Possession Limits	Y	N	N/A
Materials Used in Secure Authorized Location	Y	N	N/A

6. DAILY USE DOCUMENTATION

Daily use log of radioactive materials maintained	Y	N	N/A
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7. RECEIPT LOGS AND USE OF RADIOACTIVE MATERIALS

Record of Materials Received	Y	N	N/A
Package survey results in DPM	Y	N	N/A
Record of Materials Transferred	Y	N	N/A
Report of Loss or Theft of Material	Y	N	N/A

8. DISPOSAL RECORDS

Waste Properly Separated, Labeled and Stored	Y	N	N/A
Disposal Log Maintained	Y	N	N/A
Waste Surveys Performed and Recorded	Y	N	N/A

9. MONTHLY INVENTORIES

Monthly inventory reports current and submitted	Y	N	N/A
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10. LIST OF AREAS IN WHICH RADIOACTIVE ISOTOPES CAN BE USED

Documented	Y	N	N/A
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11. LABORATORY SURVEYS AND SWIPES (10CFR20 AND 10CFR35)

Area Surveys Performed and Recorded	Y	N	N/A
Area Wipe Tests Performed and Recorded	Y	N	N/A
Monthly survey reports submitted	Y	N	N/A

12. SURVEY METER CONSTANCY LOG

Survey Instruments Available as Licensed	Y	N	N/A
Survey Instruments Operational and Calibrated	Y	N	N/A
Record of Constancy Check	Y	N	N/A
Protocols/Manuals for Instrument Use	Y	N	N/A
All Personnel Instructed in Instrument Use	Y	N	N/A

13. ANY APPLICABLE SPILL OR INCIDENT REPORTS

Documented	Y	N	N/A
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14. ALL MEMOS/CORRESPONDENCE TO OR FROM THE RADIATION SAFETY OFFICE

Documented	Y	N	N/A
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15. MISCELLANEOUS GENERAL RADIATION SAFETY

Lab Coats Used	Y	N	N/A
Gloves Used During Radioactive Procedures	Y	N	N/A
Decontamination Equipment Available	Y	N	N/A
Available Shielding Adequate	Y	N	N/A
Laboratory Housekeeping Adequate	Y	N	N/A
Authorized Personnel Using Materials	Y	N	N/A

POSTING REQUIREMENTS (10CFR20.203)

Radiation Signs Posted	Y	N	N/A
Doors	Y	N	N/A
Work Areas	Y	N	N/A
Storage Areas	Y	N	N/A
Fume Hoods	Y	N	N/A
Refrigerators	Y	N	N/A
Containers	Y	N	N/A
"Hot" Sink	Y	N	N/A
"Hot" Waste	Y	N	N/A
NRC Form 3 - Notice to Employees Posted	Y	N	N/A
10CFR19 - Report to Workers Posted	Y	N	N/A
10CFR20 - Dose Limit Standards Posted	Y	N	N/A

LABELING REQUIREMENTS

Radioactive Materials Labeled Correctly	Y	N	N/A
Radioactive Labels Defaced upon Disposal	Y	N	N/A

PERSONNEL MONITORING

All Appropriate Personnel Badged	Y	N	N/A
All Personnel Wearing Badges	Y	N	N/A

SPECIAL REQUIREMENTS - VOLATILE RADIONUCLIDES

Fume Hood Air Flow Rate Checked	Y	N	N/A
Bioassay Results Acceptable and Recorded	Y	N	N/A

COMMENTS AND RECOMMENDATIONS

VIOLATIONS OF RADIATION SAFETY

1. Violations have been divided into three categories ("A", "B", and "C)", with Class "A" violations being the most serious.
2. The Radiation Safety Committee, along with the Radiation Safety Office, does not see spills or accidents as violations. However, failure to comply with the stated regulations does constitute a violation of your license to use radioactive materials.
3. **Class "C" violations**
 - a. Class "C" violations are the least serious and include, but are not limited to the following:
 - 1) Failure to maintain inventory records of radioactive materials.
 - 2) Failure to perform and record weekly contamination surveys.
 - 3) Not reporting a significant spill or incident to the Radiation Safety Office.
 - 4) Improper procedures used to open newly acquired radioactive materials.
 - 5) Improper labeling of radioactive materials.
 - 6) Improper packaging of radioactive waste.
 - b. Class "C" violations will result in:
 - 1) Verbal and written notification of the violation.
 - 2) A Class "B" violation if not corrected within 30 days, or if a similar violation is repeated within 90 days.
4. **Class "B" violations**
 - a. Class "B" violations are usually a result of repeat Class "C" violations. They include, but are not limited to the following:
 - 1) Failure to comply with notices from the Radiation Safety Office.
 - 2) Failure to notify the Radiation Safety Office concerning a change of identity of the contact person.
 - b. Class "B" violations will result in:
 - 1) Immediate verbal notice of the violation.
 - 2) Written notice of the violation. Copies of the notice will be sent to the Radiation Safety Committee Chairman and the appropriate member(s) of the committee.

- 3) Possible suspension of radionuclide ordering privileges, by the Radiation Safety Committee, until the violation is corrected.
- 4) A Class "A" violation if not corrected within 14 days, or if a similar violation is repeated within 180 days.

5. **Class "A" violations**

- a. Class "A" violations are usually a result of repeat Class "B" violations. They also include, but are not limited to the following:
 - 1) Falsifying required radiation safety records.
 - 2) Failure to comply with notices from the Radiation Safety Committee.
- b. Class "A" violations will result in:
 - 1) Immediate verbal notice of the violation.
 - 2) Written notice of the violation. Copies of the notice will be sent to the Radiation Safety Committee Chairman and the appropriate member(s) of the committee.
 - 3) Suspension of radionuclide ordering privileges.
 - 4) Possible suspension of authorization to use radionuclides, at the discretion of the Radiation Safety Officer, pending review by the Radiation Safety Committee.
 - 5) Possible termination of authorization, based on a majority vote of the Radiation Safety Committee.

PERFORMANCE AUDIT

INDIVIDUAL USER: _____

DATE: _____

AUTHORIZED USER: _____

1. EQUIPMENT

Battery Check	Y	N
Constancy Check	Y	N
Appropriate reading of meter face	Y	N
Appropriate survey of self and areas	Y	N
Use of LSC		
a) sample	Y	N
b) smear	Y	N

2. DOSIMETRY

Appropriate wear location	Y	N
Appropriate storage	Y	N
Results	Y	N
Adding/Deleting	Y	N
Pregnancy declaration	Y	N

3. WASTE

Knowledge of segregation	Y	N
Labeling of containers		
a) Radioisotope	Y	N
b) Radiation Symbol	Y	N

4. GENERAL RULES

Locked doors	Y	N
Labeled doors and items	Y	N
Documentation (mCi)	Y	N
Lab survey frequency (weekly)	Y	N
Training	Y	N
Clothing (labcoats and gloves)	Y	N
Spills/Incidents		
a) During normal working hours	Y	N
b) After-hours	Y	N

COMMENTS: _____

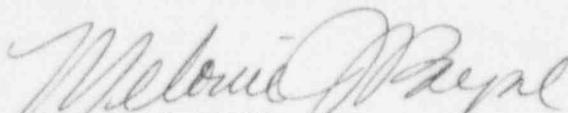
Audit Performed By: _____

Department of
Veterans Affairs

Memorandum

Date: DECEMBER 12, 1994
From: RADIATION SAFETY OFFICER (00R)
Subj: REQUIRED RECORD KEEPING RESPONSIBILITIES
To: AUTHORIZED USERS OF RADIOACTIVE MATERIALS (151) See Distribution.

1. This **MEMO** is directed to all researchers who are authorized to use radioactive materials. It is to remind you of your responsibilities concerning required surveys meter constancy checks and appropriate documentation. Please make sure that all authorized personnel are aware of the requirements as required in the Radiation Safety Record Book.
2. Prior to using radioactive materials (with the exception of H-3, C-14 & S-35), a survey meter constancy check must be performed. Instructions on the appropriate technique, as well as the appropriate form for documentation purposes is provided to you in your Radiation Safety Record Book and can be found in Section 12. The instructions specifically state that survey constancy check must be performed **each day of use**.
3. During a recent Nuclear Regulatory Commission (NRC) November 2-3, 1994, several research staff were not familiar with the necessary requirements as to the frequency of survey meter constancy checks.
4. If the constancy record is not kept up to date, your area survey records are effectively negated. Item, room and personal survey results can not be trusted if the instrument used for the survey is not checked for constancy.
5. Since all personnel have been previously trained and provided with written instruction and forms, deviations in the required surveys and records can not be tolerated if it places the license for this facility in jeopardy, particularly in regards to safety. This **MEMO** serves as an official notice that the current violation policy approved by the Radiation Safety Committee will be strictly enforced.
6. Thank you for your attention. Please contact the Radiation Safety Office at EXT. 7916, if you have any questions.


MELONIE J. PAYNE

Distribution:

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CC: ACOS/RESEARCH SERVICE (151)
CHAIRMAN, RADIATION SAFETY COMMITTEE (115)