

THE UNIVERSITY OF MICHIGAN

ANN ARBOR 48109-1340

(313) 764-3402

WILLIAM B. KRUMM
ASSOCIATE VICE PRESIDENT
FOR BUSINESS OPERATIONS

January 12, 1993

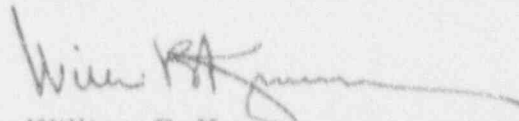
Director
Office of Enforcement
U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, D.C. 20555

Re: Notice of Violation
University of Michigan
NRC Inspection Report No. 030-01988/92001 (DRSS)
Docket No. 030-01988
License No. 21-00215-04
EA 92-185

Dear Director:

Enclosed is a check in the amount of \$3,750.00 submitted by the Regents of the University of Michigan in full payment of the civil penalty proposed in the above referenced Notice of Violation under date of December 14, 1992. Also enclosed is the Reply to the Notice of Violation. Thank you for your cooperation in this matter.

Sincerely,


William B. Krumm

enc. Payment of civil penalty (UM check # 959831)
Reply to Notice of Violation

cc: A. Bert Davis
Regional Administrator

140029

*Rae'd
Walt # 959831
for \$3,750.00*

9301140219 930112
PDR ADCK 03001988
C PDR

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THE UNIVERSITY OF MICHIGAN

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WILLIAM B. KRUMM
ASSOCIATE VICE PRESIDENT
FOR BUSINESS OPERATIONS

January 13, 1993

Director
Office of Enforcement
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
ATTENTION; Document Control Desk

RE: Reply to Notice of Violation - The University of Michigan
Byproduct Material License No. 21-00215-04
[NRC Inspection No. 030-01988/92001(DRSS)]

Dear Sirs:

Per your correspondence dated December 14, 1992, the University of Michigan (U-M) would like to address the apparent violations and concerns noted by the Nuclear Regulatory Commission (NRC) regarding the phosphorous-32 contamination incident which occurred on September 11, 1992. Please find below a description of the actions the University has taken and intends to take regarding each violation noted in the NRC inspection report.

1.0 VIOLATION FAILURE TO SURVEY HANDS & SHOES [CIVIL PENALTY]

The U-M Radiation Safety Manual is represented in the NRC Byproduct Material License (21-00215-04) as Item 10, Attachment 7. The general rules for working with radioactive material (pg.8) specifically state that individuals will wash hands and check hands & shoes with an appropriate survey meter before leaving a laboratory.

Contrary to above, individuals who had worked with radioactive material (P-32) failed to check their shoes with a survey meter before leaving laboratory. As a result, P-32 was subsequently spread by individuals' contaminated footwear through unrestricted areas in MSRB-I and to individuals' homes, clothing, and vehicles.

1.1 Admission of Violation

1.2 Reason for Violation - Research personnel failed to follow established radiological safety protocols as stated in the Radiation Safety Manual.

1.3 Corrective Steps Taken & Results Achieved - The corrective action steps noted below have been taken. The U-M Administration involvement after this contamination incident has significantly heightened the awareness level of Authorized Users and the U-M research community to their ultimate responsibilities and the importance of adhering to radiological safety protocols and regulatory requirements.

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Subsequent radiological safety audits at the U-M have identified improved compliance with protocols and regulations in research laboratories as a result of the corrective actions implemented after this contamination incident.

- Radiation Safety Officer (RSO) issued an immediate cease-and-desist to the Authorized User & staff responsible for the P-32 contamination incident.
- The Authorized User was required to submit written corrective actions to Radiation Safety Service (RSS) and the U-M Radiation Policy Committee (RPC) for approval.
- RSO & RSS health physicist conducted a comprehensive radiological safety/regulatory compliance re-training session for the Authorized User & staff responsible for the contamination incident (September 30, 1992).
- RSO met with U-M Medical School Administrators and detailed the events of the contamination incident and emphasized the importance of U-M biomedical researchers adhering to radiological safety protocols and regulatory requirements (October 9, 1992).
- RSS health physicist conducted a special in-house training session with the Dept. of Pathology authorized users at the request of the Pathology Chairman (October 19, 1992).
- RSO drafted & mass-mailed a correspondence (Attachment 1.0) to all authorized users emphasizing the need to adhere to radiation safety protocols and regulatory requirements (November 6, 1992).
- RSS continues to emphasize the importance of adhering to radiological safety & regulatory requirements during radiological safety training courses, radionuclide application review sessions, and laboratory radiological safety inspections/audits.
- Although quarterly radiological safety surveys and inspection/audits were being conducted by RSS personnel using an established checklist (Attachment 2.0) approach at the time of the P-32 contamination incident, RSS personnel are attempting to conduct more 'incisive & performance oriented' audits which could identify weaknesses in laboratory radiation safety programs; RSO will address serious or repetitive problem areas brought to his attention.

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The U-M Provost/Vice-President for Academic Affairs drafted and distributed a correspondence (Attachment 3.0) to the Deans, Directors, and Department Heads of all radioactive material users emphasizing the need to adhere to regulatory requirements and the U-M radiological safety protocols and that researchers handling radioactive material are properly trained & supervised by the Authorized User (December 8, 1992).

The Department of Pathology Chairman drafted and distributed to all Pathology Department Authorized Users a correspondence addressing the events which led to the W-32 spill and emphasizing the need to adhere to regulatory requirements and the U-M radiological safety protocols and the ultimate responsibilities of Authorized Users (October 19, 1992).

The Associate Dean of the Medical School drafted an article for the monthly Biomedical Newsletter (Attachment 4.0) emphasizing researchers' responsibilities with respect to safety & regulatory compliance issues (December 1992). The newsletter is mass-mailed to all biomedical laboratories on campus.

- 1.4 **Corrective Steps to Avoid Further Violations** - As noted above, RSS personnel will continue to emphasize radiological safety protocols and regulatory compliance issues during radiological safety training sessions, radionuclide application review sessions, and laboratory audit/inspections. Proper in-house training & supervisory responsibilities on the part of authorized users over their own research activities will also be emphasized. In addition, RSS will continue to evaluate the approach used to conduct laboratory audit/inspections and implement a performance-oriented audit in an attempt to identify practical laboratory problems. The RSO will improve in-house training of the RSS health physics staff regarding 'performance oriented audit/inspections'.
- 1.5 **Date of Compliance** - Ensuring full-compliance with radiological safety protocols and regulatory requirements is an on-going task for any licensee; the U-M expects compliance from all radioactive material users at all times. After several more months of routine radiological safety training sessions and RSS performance-oriented audit/inspections, full-compliance should be realized. RSO has and will continue to address this compliance issue on a University-wide basis.

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2.0 VIOLATION INADEQUATE SURVEYS/UNRESTRICTED AREAS [CIVIL PENALTY]

NRC regulations (10 CFR 20.201(b)) require licensees to conduct radiation surveys which are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. In addition, the U-M Byproduct Material License (21-00215-04) specifically indicates that the acceptable radioactive contamination limits for beta/gamma contamination in an unrestricted area are 1,000 dpm/100 cm² (removable) and 15,000 dpm/100 cm² (maximum).

Contrary to the above, the NRC believes that the U-M did not perform adequate surveys to assure compliance with this regulation and that the specific condition of the Byproduct Material License regarding contamination levels were not in compliance.

2.1 Admission of Violation

2.2 Reason for Violation - The root cause of this violation was the failure of the researcher to conduct an adequate survey of himself and his work area prior to leaving his radioactive material laboratory. This failure to adequately conduct a radioactive contamination survey with smears/swipes or an appropriate radiation survey meter resulted in the spread of radioactive material (P-32) beyond the restricted area boundaries of the designated radioactive material laboratory.

It should be emphasized that the radioactive spill apparently occurred on Friday, September 11, 1992 and RSS personnel were not notified until approximately 4:30 pm on Monday, September 14, 1992; therefore, the spread of contamination had already taken place prior to RSS arrival.

In addition, preliminary investigations with MSRB-I 7th floor personnel who identified the contamination using G-M survey meters revealed that the researchers initially believed the contamination originated from a P-32 shipping box which had been opened late that Monday afternoon (09/14/92). Therefore, preliminary indications led RSS personnel to believe that the spill occurred only an hour or so before their arrival.

Therefore, RSS personnel believed the primary objective upon arrival was to assess the spread of contamination throughout the immediate facility and connecting buildings and decontaminate personnel (approximately 30) so they could depart the contaminated area (end of workday).

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The RSS staff initiated contamination surveys beyond the 7th floor of the MSRB-I using G-M survey meters within approximately an hour of the initial notification and did not detect contamination above natural background levels in tiled hallways of adjacent buildings or elevators exiting the Medical Science Complex. In addition, other items were surveyed on the 7th floor MSRB-I and discovered not to be contaminated: phones, books, desk tops, clothing, door knobs, etc. The contamination was deemed "below-ankle" contamination.

After assessing the preliminary data from the RSS health physicist staff that no contamination was detected on the tiled floors at multiple Medical Science Complex exits, the RSO made the early decision not to survey homes, cars, etc. of laboratory personnel and to concentrate on the immediate affected area of the MSRB-I.

While the delayed decision by the RSO to survey beyond the immediate MSRB-I area failed to identify in an expeditious manner the P-32 contamination in laboratory personnel homes, cars, etc., the RSO believes the significant spread of the radioactive contamination from the 7th floor MSRB-I area was stopped immediately upon arrival of the RSS staff. Contamination surveys beyond the immediate MSRB-I area (homes, cars, etc.) were conducted within approximately 30 hours after RSS arrival.

While the P-32 contamination levels exceeded the regulatory contamination limits of 1,000 dpm/100 cm² (removable) and 15,000 dpm/100 cm² (maximum), it should be noted that the maximum contamination levels observed during this incident [1,500,000 dpm (0.7 uCi)/100 cm² restricted area lab floor & 30,000 dpm (0.013 uCi)/100 cm² unrestricted area] posed minimal radiological consequences with respect to potential skin and/or internal radiation doses according to regulatory annual limit of intake (ALI) and health physics journal calculations. Urine bioassays performed on approximately 20 individuals directly involved with the spill and decontamination efforts revealed no apparent uptake of P-32.

2.3 Corrective Steps Taken & Results Achieved - The corrective action steps noted below have been taken and have proven to be effective in addressing quite rapidly whether radioactive contamination has spread beyond the immediate area of a spill.

As noted above, RSS continues to emphasize the importance of surveying personnel and work areas after conducting work with radioactive material in an effort to avoid the spread of radioactive contamination from a restricted area.

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- In responding to radioactive contamination incidents, RSS personnel currently concentrate initially on the source of the radioactive contamination and all possible individuals associated with the immediate work area in order to expeditiously evaluate the extent of the potential hazard and determine if contamination has been spread beyond the immediate area into cars, homes, etc. The RSS staff has learned a great deal from this P-32 contamination incident.

- The RSS health physicist staff has attended and successfully completed an intensive and comprehensive training seminar entitled Hazardous Waste Operations & Emergency Response (HAZWOPER) in accordance with OSHA 29 CFR 1910.120(p)(8)(iii) and (q)(iii). Therefore, RSS personnel have been professionally trained in responding to emergency situations involving hazardous materials; much of which can be related to radioactive contamination incidents.

2.4 **Corrective Steps to Avoid Further Violations** - the following corrective action steps will be implemented to avoid further violations:

- RSO will draft and implement guidelines for RSS staff members which will address the logistics of responding to radioactive spills in research laboratory settings.

- RSO and RSS staff will conduct an annual emergency response training session involving departmental technicians and health physicists to improve upon emergency response situations.

2.5 **Date of Compliance** - With respect to drafting emergency response guidelines and conducting emergency response training sessions, full compliance is anticipated by March 31, 1993.

3.0 **VIOLATION** **FAILURE TO WEAR EXTREMITY MONITORING [LEVEL IV]**

The U-M Radiation Safety Manual states that extremity monitoring (ring badge) is required when an individual handles greater than 1.0 millicurie of phosphorous-32. Contrary to this requirement, two individuals used > 1.0 mCi of P-32 and did not use extremity monitoring.

3.1 **Admission of Violation**

3.2 **Reason for Violation** - Research personnel failed to follow established radiological safety protocols as stated in the Radiation Safety Manual.

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- 3.3 **Corrective Steps Taken & Results Achieved** - The Authorized User has indicated to RSS and the RPC in his corrective action measures that extremity monitoring is required of his personnel whenever they handle > 1.0 mCi of P-32 in accordance with the Radiation Safety Manual requirements. To date, the laboratory personnel identified as not having worn their extremity badges at the time of the inspection are wearing the appropriate dosimeters when handling > 1.0 mCi P-32.

In addition, as noted in Section 1.3 above, authorized users and researchers have been reminded in-writing by various U-M Administration levels of the importance of following radiological safety protocols and regulatory requirements. The correspondences emphasized that the authorized users of radioactive materials are responsible for ensuring their research staffs adhere to radiological safety protocols and regulatory requirements.

RSS performance-oriented radiological safety audits conducted since the contamination event have noted laboratory compliance in this area.

- 3.4 **Corrective Steps to Avoid Further Violations** - As noted above, RSS personnel will continue to conduct performance-oriented audits / inspections of research laboratories and correct identified regulatory problems with respect to wearing dosimeters.

In addition, RSS will continue to notify authorized users in-writing which research staff members will be required to wear whole body and/or extremity dosimeters after RSS and the RPC have reviewed / approved their radionuclide authorization.

RSS will continue to emphasize the proper use of radiation monitoring dosimeters during radiological safety training courses and authorized users application review sessions.

- 3.5 **Date of Compliance** - Full compliance with respect to the laboratory personnel identified during the inspection as not having worn their extremity monitoring badges has been in effect since September 24, 1992. RSS has and will continue to address this compliance issue on a University-wide basis.

4.0 VIOLATION FAILURE TO AMEND EXISTING AUTHORIZATION [LEVEL IV]

The U-M Radiation Safety Manual states that changes in physical place of radionuclide use (new laboratories) normally require submission of a supplemental Form RCS-101. This authorization allows a specific authorized user to use materials at specific locations for specific purposes.

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Contrary to this requirement, two individuals used radioactive materials in a laboratory room (7514 MSRB-I) which had not been approved by the authorized user's previously approved radionuclide authorization and a supplemental Form RCS-101 had not been submitted prior to the P-32 spill.

4.1 Admission of Violation

- 4.2 Reason for Violation** - The authorized user failed to appropriately amend his radionuclide authorization to include Room 7514 prior to using the laboratory for his specific purposes.

It should be noted, however, that Room 7514 had been approved for radionuclide work by an authorized user in the same department (Pathology) as the apparent violator and who conducted very similar biomedical research as the apparent violator. The two Pathology Dept. authorized users merely initiated the sharing of the laboratory approximately 4 days prior to the date of the P-32 spill and prior to submitting an official amendment to his radionuclide authorization (October 1, 1992).

- 4.3 Corrective Steps Taken & Results Achieved** - The authorized user responsible for the unauthorized use of the laboratory amended his radionuclide authorization to include Room 7514 after the decontamination and recovery efforts had been completed. The authorized user was verbally reprimanded by RSS and reminded of the required protocols for using radioactive materials in RSS/RPC approved locations only. Authorized user currently understands the conditions of his authorization and has been cooperative with RSS and RPC requirements.

In addition, as noted in Section 1.3 above, all authorized users were reminded in-writing by the RSO and various Administration representatives of the importance of adhering to the specific protocols and regulations with respect to radionuclide use.

The results of the mass-mailed correspondences to authorized users and researchers and the added emphasis expressed during training sessions and authorization review sessions apparently has been quite effective. RSS has observed a greater awareness of and respect for radiological protocols and regulatory requirements in the past few months. Administration involvement since this incident has heightened the awareness of authorized users and researchers to their responsibilities in working with radioactive materials.

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4.4 Corrective Steps to Avoid Further Violations - The following corrective action step is currently being evaluated by the U-M Administration, RPC, and RSS:

- Having departmental management personnel (Deans, Directors, Department Heads, or Chairs) become more actively involved in the review, reporting, and oversight of the current radionuclide authorization process (RCS-101 application submittals) and use of radioactive materials within their respective areas or departments. Increased accountability by departmental management personnel for research activities involving radioactive materials should improve adherence to radiological safety protocols and regulatory requirements.

4.5 Date of Compliance - Full compliance is anticipated by August 1, 1993 after review by the U-M Administration and two quarterly meetings (March & June) by the RPC.

5.0 VIOLATION FAILURE TO SECURE RADIOACTIVE MATERIAL [LEVEL IV]

NRC regulations require that licensed radioactive material stored in an unrestricted area be secured against unauthorized removal from the place of storage (10 CFR 20.207(a)). In addition, the regulations prohibit licensees from disposing of licensed radioactive material except by authorized means (10 CFR 20.301).

Contrary to the above, a researcher apparently left a package containing a sealed vial of 1.3 millicuries of P-32 in an unrestricted area (MSRB-I hallway) on August 11, 1992 and the package was apparently inadvertently disposed of as normal trash; after an intensive and comprehensive search by RSS personnel, the package was believed to have been buried in a landfill. NOTE: The RSO properly notified the NRC of this apparent inadvertent disposal of radioactive material via a telephone call on August 12, 1992.

5.1 Admission of Violation

5.2 Reason for Violation - The root cause of the violation was the apparent failure of the researcher to ensure all vials of radioactive material were removed from a shipping package prior to disposing of the box as normal trash. A contributing cause of this inadvertent disposal of radioactive material into normal trash appears to be that the researcher failed to confirm the actual number of radioactive material vials in the shipping package against the number listed on the commercial vendor's shipping papers attached or enclosed with the shipping package.

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5.3 Corrective Steps Taken & Results Achieved - The corrective action steps noted below have been to-date:

- RSO issued a cease-and-desist order for all radioactive material work conducted by the MSRB-I authorized user responsible for the researchers who inadvertently discarded the radioactive material into the normal trash stream.

In addition, the RSO refused to allow the authorized user and his researchers to order additional radionuclides until written remedial action steps were submitted and approved by RSS and the RPC.

- The RSO drafted & mass-mailed a correspondence to all authorized users emphasizing that the inadvertent disposal of radioactive material indicates an apparent lack of control and accountability of radioactive material on the part of researchers and is a violation of RSS protocols and NRC regulations.

The correspondence (Attachment 5.0) was dated October 14, 1992 and was presented to the NRC Region III Office at the October 20, 1992 Enforcement Hearing in Glen Ellyn, Illinois.

- The RSS staff continues to emphasize to U-M authorized users and researchers the importance of maintaining radionuclide inventories and accounting for radioactive material during radiological safety training sessions, radionuclide application review sessions, and quarterly laboratory audits/inspections.

5.4 Corrective Steps to Avoid Further Violations - the following corrective action steps will be implemented to avoid further violations:

- RSS will revise its radioactive materials receipt/inventory/distribution procedure to include the verification of the number of vials or items listed on the package insert list as being enclosed with each commercial vendor's radioactive material shipment. If the package insert list indicates that more than one item is enclosed in the shipping package, RSS personnel will affix a very distinct (colorful) label indicating the number of vials or items in the package.

The label will be affixed in a conspicuous location on each shipping package and alert researchers that the package contains more than a single vial or item. In addition, the number of vials or items in each shipping box will be recorded on the daily RSS Incoming Package Manifest logsheet.

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In addition, as noted in Sections 1.4 and 3.4 above, the RSO will improve the training of the RSS health physics staff with respect to conducting performance-oriented audits/inspections and emphasize the need to secure radioactive material from unauthorized use or removal and prevent the inadvertent disposal of radioactive material in normal trash streams.

As noted during the NRC Enforcement Hearing, RSS personnel conducted a week-long pilot study which included package opening, radiological surveys, and contents verification. The problems encountered with this approach were numerous. The RSS staff believes a simpler approach (conspicuous label) can result in the same success rate. In 1992, approximately 9,000 radioactive packages were received at RSS; while two packages may have been inadvertently discarded into normal trash by research personnel, no radioactive material packages have been misplaced or lost by RSS personnel.

- 5.5 **Date of Compliance** - With respect to implementing the revised vial or item accountability procedure and in-house training of RSS personnel, full compliance is anticipated by March 1, 1993.

6.0 ADDITIONAL CORRECTIVE ACTION STEPS

In addition to the corrective action steps noted above and at the NRC Enforcement Hearing in Glen Ellyn, Illinois on October 20, 1992 (Attachment 6.0), the University of Michigan will implement the following corrective action steps:

- 6.1 Effective January 1, 1993, RSS has increased the length of the monthly Radiation Safety Orientation Course from 2-hours to 3-hours to ensure that the radiological safety protocols and regulatory requirements which were violated during this particular contamination incident can be emphasized to personnel in attendance.
- 6.2 RSS personnel and the RPC will modify the current training programs to include re-training of researchers and/or authorized users emphasizing research-specific radiological safety protocols, regulatory compliance issues, and researchers/authorized users responsibilities.
- 6.3 U-M Administration has committed two new staff member positions to the Radiation Safety Service staff: a senior health physicist and another radiation safety technician.
- 6.4 U-M Administration, RPC, and the RSO will evaluate future corrective action plans or penalties for researchers who violate radiological safety protocols or regulatory requirements.

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The University of Michigan has learned a great deal from this unfortunate incident. As an institution, we were able to identify our strengths as well as our weaknesses and we learned how we can improve our performance should such an incident occur in the future. As stated at the Enforcement Hearing on October 20, 1992, accidents can and will happen. Although such widespread contamination incidents are rare, the U-M will continue to improve on its emergency response and respond more effectively to such incidents in the future.

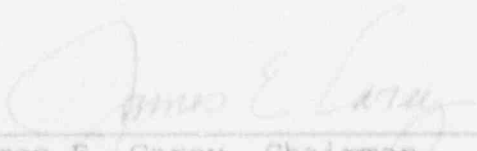
Thank you for your time and consideration with respect to this inspection response. The University of Michigan has attempted to respond completely and accurately to the violations and concerns noted in the NRC inspection report dated December 14, 1992 [NRC Inspection Report No. 030-01988/92001 (DRSS)].

Please do not hesitate to contact Radiation Safety Officer, Mark Driscoll, at Radiation Safety Service [(313) 764-4420] should you have any questions, comments, or concerns regarding any of the responses noted above.

Sincerely,



William B. Krumm, Associate Vice-President
Business Operations



James E. Carey, Chairman
Radiation Policy Committee



Mark L. Driscoll, Radiation Safety Officer
Radiation Safety Service / OSEH

THE UNIVERSITY OF MICHIGAN
OCCUPATIONAL SAFETY & ENVIRONMENTAL HEALTH
(OSEH)

1077 NORTH UNIVERSITY BLDG.
764-8310

TO: Radioactive Material Users
The University of Michigan

FROM: Mark L. Driscoll, Director *Mark L. Driscoll*
Radiation Safety Service
1101 North University Building 1057

DATE: November 6, 1992

SUBJECT: ADHERENCE TO RADIOLOGICAL SAFETY PROTOCOLS

Radiation Safety Service (RSS) is required by Nuclear Regulatory Commission (NRC) regulations to report radioactive contamination events which require access to a contaminated area to be restricted for more than 24-hours. By NRC definitions, restricting access means prohibiting entry into a contaminated area or by imposing additional radiological safety controls (plastic covering, shielding, etc.).

Please be informed that RSS recently reported such an event to the NRC after an exhaustive 10-day decontamination and recovery effort at the Medical Science Research Building-I (MSRB-I) September 14 - 24, 1992. In addition, an on-site investigation of this incident by three NRC inspectors will most likely result in the U-M receiving a Notice of Violation which will include at least six violations. The violations may result in a regulatory fine. Please ensure all lab personnel are aware of this incident.

In mid-September, RSS was notified of an apparent radioactive material spill involving phosphorous-32 (gamma-ATP) on the 7th floor MSRB-I. Phosphorous-32 is a high energy beta emitter with a 14-day half-life. An investigation revealed that the spill most likely occurred over a weekend and RSS was not notified until approximately 4:15 pm the following Monday. Therefore, a relatively minor contamination incident involving < 500 uCi of P-32 turned into a widespread contamination incident beyond the restricted area of the laboratory.

Radiation Safety Service personnel responded immediately upon notification and discovered widespread "below-ankle" P-32 contamination throughout the entire 7th floor of MSRB-I. Contaminated floor areas, equipment and apparel included: 3 general hallways, 9 laboratories, 3 utility rooms, 2 carpeted office suites, 2 rest-rooms, several tissue culture rooms, a large carpeted conference room, wheels of approximately 20 bench stools and utility carts, and approximately 25 pairs of shoes.

(OVER)

TO: Radioactive Material Users
FROM: Mark L. Driscoll, Radiation Safety Officer
DATE: November 6, 1992
PAGE: 2

Many of you are aware that the next ten exhaustive days resulted in the following: an intensive decontamination & recovery effort by RSS personnel, an NRC inspection, a cease-and desist issued by the Radiation Safety Officer (RSO), radiological surveys of homes / automobiles / vendors / adjacent buildings / personnel clothing & possessions, urine bioassay samples & analyses, news media attention, open public forums, counseling of concerned personnel, accusations, comprehensive re-training of lab personnel, re-authorization by U-M Administration and the Radiation Policy Committee (RPC) for radioactive material start-up work, an NRC conference hearing in Glen Ellyn, IL, destruction of office carpeting and lab tiles, confiscation of contaminated personal belongings, etc.

While accidents can and will happen, the NRC has expressed concern that this extensive contamination incident indicates an apparent lack of control and accountability of radioactive material at the University of Michigan. The aftershocks of this contamination incident will be felt for a long time. The costs of such an extensive contamination incident may result in tens-of-thousands of dollars.

The root cause of this widespread contamination incident was that a researcher failed to survey his work area, the immediate floor area, and himself after working with radioactive material. Please be reminded that this radiological survey requirement is specified on page 8 of the yellow Radiation Safety Manual and that the protocols specified in the Radiation Safety Manual are requirements of the U-M Byproduct Material License.

Authorized Users are ultimately responsible for the accountability, inventory, and control of procured radioactive materials. Failure to conduct research with radioactive materials in accordance with NRC regulations and RSS protocols will jeopardize your authorization to use radioactive materials and place the U-M in a state of non-compliance with regulatory agencies.

Please ensure that you and your lab personnel are aware of the following requirements specified by the NRC, RPC, and RSS:

- 1.0 Lab personnel **MUST** adhere to the protocols specified in the yellow Radiation Safety Manual. Contact RSS [764-4420] to obtain copies of this manual.
- 2.0 Lab personnel **MUST** monitor themselves (shoes/hands/clothing) and their work area with an appropriate survey meter or swipes prior to departing a laboratory after having worked with radioactive material.

TO: Radioactive Material Users
FROM: Mark L. Driscoll, Radiation Safety Officer
DATE: November 6, 1992
PAGE: 3

- 3.0 Radiation Safety Service **MUST** be notified immediately whenever radioactive contamination is discovered on floors, shoes, clothing, or skin.
- 4.0 Radiation Safety Service **MUST** be notified immediately whenever radioactive material is discovered to be missing and/or if contamination is discovered in or on shipping containers.
- 5.0 All radioactive materials **MUST** be secured from unauthorized use or removal when left unattended; ensure radioactive material is secured or laboratories are locked when left unattended. In addition, departmentally-shared facilities (counting, utility, culture, and cold rooms, freezers, etc.) **must** be locked when left unattended. **DO NOT** leave radioactive material in an unrestricted and unposted area or facility.
- 6.0 All laboratory personnel have obtained radiological safety training from Radiation Safety Service. The Radiation Safety Orientation Course is offered monthly by RSS; contact RSS for schedule of courses.
- 7.0 All locations of use for radioactive material **MUST** be approved by the Radiation Policy Committee prior to performing radioactive material work in the facility or laboratory.

Please do not hesitate to contact Radiation Safety Service [764-4420] should you have any questions, comments, or concerns regarding regulatory compliance or radiological safety issues.

MLD/mld
[AUTHUSE2]

cc: James E. Carey, Chairman
Radiation Policy Committee

Kenneth C. Schatzle, Director
Occupational Safety & Environmental Health

RADIATION SAFETY SERVICE
AUDIT CHECKLIST

RM#/BLDG. _____

DATE: _____

AUTH. USER: _____

RSS AUDITOR: _____

	YES	NO
DOOR LABEL(S): "CAUTION RADIOACTIVE MATERIAL"	_____	_____
REFRIGERATOR/FREEZER LABEL(S): "NO FOOD OR DRINK..."	_____	_____
NRC POSTING: "NOTICE TO EMPLOYEES"	_____	_____
RADIOACTIVE MATERIALS & WORK AREAS PROPERLY IDENTIFIED/LABELED	_____	_____
ABSORBENT PADS/TRAYS BENEATH RADIOACTIVE WORK/WASTE AREAS	_____	_____
RADIOACTIVE MATERIAL/WASTE SECURED FROM INADVERTENT DISPOSAL OR THEFT, NOT LEFT IN HALLWAY OR ON DOCK	_____	_____
LAB COATS & GLOVES USED WHEN HANDLING RADIOACTIVE MATERIAL	_____	_____
SHIELDING USED WITH γ AND HIGH ENERGY β EMITTERS	_____	_____
SURVEY METER AVAILABLE FOR γ AND HIGH ENERGY β EMITTERS	_____	_____
NO FOOD OR DRINK IN VICINITY OF RADIOACTIVE MATERIAL	_____	_____
DOSIMETERS WORN WHEN HANDLING γ AND HIGH ENERGY β EMITTERS	_____	_____
IN-HOUSE CONTAMINATION SURVEYS: >10mCi WEEKLY <10mCi MONTHLY	_____	_____

COMMENTS: _____



The University of Michigan

Gilbert R. Whitaker, Jr.
Provost and Vice President
for Academic Affairs

ATTACHMENT 3.0

3068 Fleming
Administration Building
Ann Arbor, Michigan
48109-1340 313 764-9290

MEMORANDUM

TO: J. Bernard Machen
Dean, School of Dentistry
1234 Dental 1078

FROM: Gilbert R. Whitaker, Jr. *Gil*

DATE: December 8, 1992

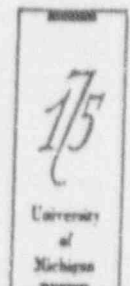
SUBJECT: Use of Radioactive Materials

As Dean, you oversee Departments that have faculty approved by the Radiation Policy Committee (RPC) to use radioactive materials in their teaching and/or research activities. It is imperative that these "authorized users" understand the need to comply with the conditions of their authorization. This is important not only from the standpoint of radiation safety but also to demonstrate to the Nuclear Regulatory Commission (NRC) that the University of Michigan is able to control its license sources. I request your support in our efforts to heighten the awareness of your Department's "authorized users" to their responsibilities.

The University of Michigan has been issued a "Materials License" by the NRC that allows an internal committee (the RPC) to approve authorized users and radioactive material uses. This delegation of authority by the NRC is of great advantage to the University and its faculty. However, the NRC does not delegate lightly and expects the University to adhere to the commitments made in our license application regarding the approval process. The NRC routinely inspects the University to assure compliance.

The Radiation Policy Committee, in turn, requires authorized users to adhere to the commitments made in their application for authorization to use radioactive material. The RPC has full authority to suspend or revoke uses that are in non-compliance with the conditions of approval.

The University has also identified a Radiation Safety Officer (RSO). The RSO works with the RPC to oversee the University's Radiation Safety Program and to ensure that the day-to-day radiation safety activities at the University are being performed in accordance with approval conditions. The RSO is also



authorized to suspend radioactive material uses that represent a regulatory noncompliance, a radiation safety concern, and/or a repetitive deficiency.

Recently, the RPC and the RSO have suspended or revoked a number of uses because of failure to comply with approval conditions. Administration fully supports their efforts and is seeking your support in preventing future problems.

Please affirm the following with your department chairs and faculty:

1. All users, uses, and locations of use are authorized by the RPC.
2. Authorized users remain aware of and in compliance with the conditions of their authorizations and Radiation Policy Committee/Radiation Safety Service (RSS) protocols.
3. That individuals working under an authorization are properly supervised by the authorized user and have received radiation safety instruction as required by the authorization.

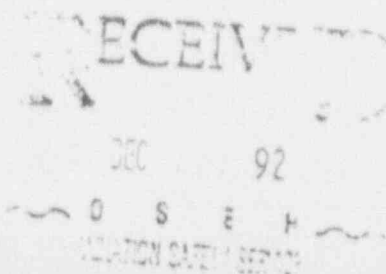
In addition, please be aware that authorized users must notify RSS prior to establishing, relocation, or vacating a radioactive material laboratory. All labs must be approved by the RPC and all vacated labs must be officially decommissioned by RSS.

Thank you for your cooperation in this matter.

GRW/cjj

cc: James E. Carey
Chair, Radiation Policy Committee

Mark L. Driscoll
Director, Radiation Safety Service/RSO



Biomedical News

FOR RESEARCH AND GRADUATE STUDIES

December 1992

Vol. X / No. 12

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BIOSAFETY: IT'S UP TO YOU

A number of recent on-campus incidences involving biosafety mishaps should serve to remind us of the risks we face as researchers and of the responsibilities we must assume on behalf of our own laboratories. These particular circumstances involved low-level radiation spills which individually did not present significant health hazards or represent alarming neglect of biosafety standards. Collectively, however, they represent a pattern involving a lack of oversight and failure to maintain strict biosafety standards at the individual laboratory level.

The short-term consequences have involved disruption to research in the labs where the spills occurred, shutdown of activities in adjacent areas, inconvenience in people's lives due to tracking of the spill into areas beyond the immediate labs, adverse effects on the investigators' reputations, and problems with colleagues. The long-term collective consequences of these recent incidences are likely to involve considerable penalties and significant fines, which will be borne by the departments involved.

In each of these instances, adherence to simple and necessary procedures by the laboratory investigators and their respective lab personnel would have allowed these situations to be avoided entirely. Bluntly stated, if we were as lax in our oversight of experiments and monitoring of data as some of our colleagues have been in the adherence to biosafety standards, our credibility as scientists would be destroyed.

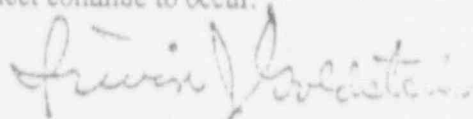
Biosafety constitutes one of the key components of our research infrastructure — the environment in which we have the privilege of performing research. When we become sloppy in any aspect of this endeavor, however, our colleagues and the institution at large can be affected. We have an obligation to be ethical, truthful, and fair in the actual conduct of our research. We each also have a duty to adhere to institutional standards regarding the use of animals or human subjects in our studies. There is no question that we also must assume responsibility for any risks presented by hazardous substances used in our research.

The Federal Occupational Safety and Health Administration (OSHA), Nuclear Regulatory Commission (NRC), and the State of Michigan Department of Public Health (MDPH) currently are enforcing safety standards referring to hazardous materials. These standards

require that each laboratory, department, and school have written guidelines and procedures for training all personnel involved in the proper use of these materials. The responsibility begins at the individual laboratory level. Every investigator who is responsible for an individual laboratory must have a chemical and hazardous chemical inventory, as well as posted procedures for use of all hazardous materials.

At present, all departments in the Medical School have received training and special information kits from staff in the University's Office of Occupational Safety and Environmental Health (OEH). OEH is prepared to offer any additional training or informational services requested by any department. They strongly encourage individual investigators to recognize their obligation to raise laboratory safety and regulatory compliance at laboratory staff meetings; to assign individuals in the laboratory to coordinate training and compliance; post guidelines and regulations clearly; and to offer standardized training to all personnel. At the department level, OEH strongly encourages the involvement of administrators in the regulatory process, as well.

This is our school. Our ability to function effectively as scientists in an effective and safe biomedical environment is entirely up to us. We must each be as vigilant as possible in our own laboratories to avoid the disruption that will certainly exist if incidences of avoidable neglect continue to occur.



Irvin J. Goldstein, Ph.D.

GRADUATE STUDIES UPDATE

Thomas Landefeld, Ph.D.

RECRUITMENT

I want to take this opportunity to provide an update on recent recruitment efforts. As I am sure that all of you are aware, most recruitment conferences are held between late September and early November. This allows the recruiters to "sell their wares" to students in a time frame that will facilitate their applications, typically due February-March for graduate school and summer research programs and even November-December for medical school. We

have just completed the bulk of these activities and thanks to the hard work of our staff, we are able to summarize the data for a preliminary presentation here.

This is the second year that our office has made a concerted effort to expand our recruitment beyond our initial focus on underrepresented minority students. This expanded effort has included participation in a series of conferences referred to as the GRE Fora. These are sponsored by the Educational Testing Service (ETS) and are held four times between September and November at different sites across the country. Students from all schools in the local areas are informed of these to facilitate as much attendance as possible. This past year, these were held in Raleigh, NC, New York City, Chicago and San Francisco, and as such, represented a "nationwide focus". Other recruitment conferences included Graduate and Professional School (GAPS) Days held at universities around the country. We have participated at Duke and Howard Universities for the past two years, the University of Southern California (last year) and Vanderbilt University (this year).

The minority-targeted conferences are very well established, and we have now succeeded in establishing ourselves as active participants in these conferences, a most important step in the recruitment network. These conferences include annual combined meeting of the Minority Access to Research Careers (MARC) and Minority Biomedical Research Support (MBRS) Programs combined meeting, the Association of Minority Health Profession Schools (AMHPS) Conference, the Beta Kappa Chi/National Institute of Science Meeting, and the Society for the Advancement of Chicanos and Native Americans in Science (SACNAS). We are regular attendees at these conferences and in fact are often participants on panels/discussions relating to graduate/professional school areas. We recently expanded our minority recruitment to the Atlanta University Complex Graduate/Professional School Day, the South Carolina Minority Student Forum, and the California Minority Student Forum (past two years).

Over these past two months, attendance at these conferences has resulted in a total of 1,333 inquiries from almost 500 students. Of that total, 503 inquiries were for our biomedical departments/programs, 319 inquiries were for our summer minority programs, and 222 inquiries were for medical school. This compares with a total last year of 1,464 inquiries with a breakdown of 665 for the Ph.D. programs, 312 for the summer minority program and 323 for medical school

THE UNIVERSITY OF MICHIGAN
OCCUPATIONAL SAFETY & ENVIRONMENTAL HEALTH
(OSEH)

1077 NORTH UNIVERSITY BLDG.
764-8310

TO: Radioactive Material Users
The University of Michigan

FROM: Mark L. Driscoll, Director *Mark L. Driscoll*
Radiation Safety Service
1101 North University Building 1057

DATE: October 14, 1992

SUBJECT: ACCOUNTABILITY OF RADIOACTIVE MATERIAL

Radiation Safety Service (RSS) is required by Nuclear Regulatory Commission (NRC) regulations to report the loss, theft, or unauthorized removal/disposal of radioactive material at the University of Michigan. Please be informed that RSS recently reported such an event to the NRC after an exhaustive investigation and search of the Medical Science Complex failed to locate a small stock vial containing approximately 1.3 millicuries of phosphorous-32. Please ensure all lab personnel are aware of this incident.

In August, a researcher ordered and received approximately 2.5 mCi of P-32 in dry ice from a commercial vendor. Anticipating that the P-32 would arrive in a single vial, a second researcher from the same laboratory retrieved only one of two small vials from the dry ice filled styrofoam box and placed the shipping container and remaining contents into the hallway for collection by the custodial staff.

Within approximately 18 hours, the primary researcher noted that the shipping papers indicated that two small vials of P-32 were apparently shipped by the vendor. The shipping container suspected of containing the second vial of P-32 had been collected and discarded by the custodial staff. This inadvertent disposal of radioactive material indicates an apparent lack of control and accountability of radioactive material and is a violation of RSS protocols and NRC regulations.

Please note that although this is only the third such incident known by RSS to have occurred at the U-M in the past two years, the U-M received a Severity Level IV citation from the NRC in 1991 for the first incident because the radioactive material had not been "secured from unauthorized removal and not under constant surveillance and immediate control of the licensee."

This recent incident represents a **repetitive deficiency** which could result in escalated enforcement action (financial fine) by the NRC. The events of this incident will be investigated by the NRC during the next NRC inspection anticipated to be in November 1992.

(OVER)

Authorized Users are ultimately responsible for the accountability, inventory, and control of procured radioactive materials. Failure to conduct research with radioactive materials in accordance with NRC regulations and RSS protocols will jeopardize your authorization to use radioactive materials and place the U-M in a state of non-compliance with regulatory agencies.

At a minimum, please ensure that your laboratory personnel are aware of the following requirements specified by the Nuclear Regulatory Commission, Radiation Policy Committee, and Radiation Safety Service:

- 1.0 Radioactive material packages **MUST** be opened, inspected, and surveyed by radiologically trained laboratory personnel upon receipt (Refer to Rad Safety Manual; pgs.11-12).
- 2.0 Radioactive material inventories and package survey results **MUST** be documented and maintained by laboratory personnel. (Refer to Attachment 1.0 for a prototype inventory form).
- 3.0 Laboratory coats and disposable plastic gloves should be worn when opening/surveying radioactive material packages.
- 4.0 Discard or recycle shipping containers **ONLY** after ensuring:
(1) all radioactive material has been accounted for and removed, (2) no radioactive contamination exists in or on the container, and (3) radiation symbols and the wording "radioactive material" have been removed or obliterated.
- 5.0 Radiation Safety Service **MUST** be notified immediately whenever radioactive material is discovered to be missing and/or if shipping container contamination is discovered.
- 6.0 All radioactive materials **MUST** be secured from unauthorized use or removal when left unattended; ensure radioactive material is secured or laboratory doors are locked when left unattended. In addition, departmentally shared facilities (counting, utility, culture, and cold rooms, freezers, etc.) must be locked when left unattended. **DO NOT** leave radioactive material in an unrestricted and unposted area or facility.

Please do not hesitate to contact Radiation Safety Service (764-4420) should you have any questions, comments, or concerns regarding the proper protocols for conducting radiological surveys and inventories upon receipt of radioactive material packages. It is our goal at RSS to implement radiological safety protocols, ensure regulatory compliance, and provide the best service we can to the University community.

cc: James E. Carey, Chairman
Radiation Policy Committee

MLD/mla
[AUTHUSERS]

Attachment 6.0

The University of Michigan
Occupational Safety & Environmental Health
Radiation Safety Service
1101 North University Building 1057
Ann Arbor, Michigan 48109

NRC Enforcement Hearing October 20, 1992

Corrective Action Taken

- 1.0 RSO issued a cease-and-desist directive to the Authorized User & staff responsible for contamination incident; cease-and-desist was in effect September 14 - October 2, 1992.
- 2.0 Radiation Policy Committee (RPC) evaluated the events of the contamination incident.
- 3.0 RSO required authorized user to submit to RSS written corrective actions he and his staff would follow to prevent such a widespread contamination incident in the future.
- 4.0 Authorized User & staff were required to undergo comprehensive radiological safety & regulatory compliance retraining by the RSO and a RSS health physicist (September 30, 1992).
- 5.0 Authorized User was required to procure at least one more G-M survey meter/pancake probe for his labs.
- 6.0 Re-start activities required approval from RSO, RPC, Medical School administration, Business Operations administration, and Research administration.

Corrective Actions Planned

- 1.0 RSO will draft & mass-mail a correspondence to all Authorized Users at the U-M emphasizing the need to adhere to radiological safety protocols, regulatory requirements, and the conditions specified in the radiation safety manual regarding surveying laboratory work areas, hands, and personnel apparel after handling radioactive material.
- 2.0 U-M radiation safety manual will be revised and streamlined by RSS staff to reflect and emphasize current radiological safety practices, regulatory compliance issues, and RPC protocols.

Attachment 6.0
NRC Enforcement Hearing
October 20, 1992
Page 2

- 3.0 Radiation Safety Service will create & distribute to all Authorized Users a 3-ring binder which will contain the newly-revised radiation safety manual, required radiological safety records (contamination surveys, source inventories, etc.), and radiological safety protocols.

In addition, this binder may contain a copy of the Authorized User's application and other pertinent records.

Intended to assist lab and RSS personnel identify pertinent radiation safety records, protocols, license requirements, and authorized radionuclide limits using a single record-keeping approach. In addition, the intent is to facilitate instructional/training requirements placed on Authorized Users.

- 4.0 RSS personnel will continue to emphasize the need to adhere to regulatory requirements & radiological safety protocols during future training sessions and authorization application review sessions.
- 5.0 The U-M will conduct a "post-mortem" debriefing session with RSS personnel, Business Operations administration, Medical School administration, Medical School Facilities, and other key U-M officials to discuss what we learned from such an incident and how we can streamline our response and actions to such an incident in the future.

mld/cmb
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