

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

University of Missouri
Missouri University Research Reactor

Docket No. 50-186
License No. R-103
EA 92-170

During an NRC inspection conducted from September 3-4, 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, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

10 CFR 71.5(a) requires that a licensee who transports licensed material outside the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 172.203(d)(1)(iii) requires that the description for a shipment of radioactive material must include the activity contained in each package of the shipment in terms of curies, millicuries or microcuries.

49 CFR 172.403(a) and (g)(2) require in part that the activity of each package of radioactive material must be entered on the radioactive label, unless the package is excepted from labeling.

1. Contrary to the above, on July 27, 1992, the licensee delivered a package containing 0.482 curies of holmium-166 to a carrier for transport to Dow Chemical Company in Freeport, Texas with the description on the shipping papers and the radioactive label stating that the shipment contained 0.0183 curies of holmium-166, and the package was not excepted from labeling.
2. Contrary to the above, on July 27, 1992, the licensee delivered a package containing 0.0183 curies of holmium-166 to a carrier for transport to the University of Texas, M. D. Anderson Cancer Center, Houston, Texas with the description on the shipping papers and the radioactive label stating that the shipment contained 0.482 curies of holmium-166, and the package was not excepted from labeling.

This is a Severity Level III problem (Supplement V).
Cumulative Civil Penalty - \$625 (assessed equally between the two violations).

Pursuant to the provisions of 10 CFR 2.201, University of Missouri (Licensee) is hereby required to submit a written statement of explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance is 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 actions as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

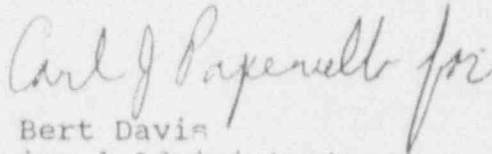
Notice of Violation

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Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20545 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

FOR THE NUCLEAR REGULATORY COMMISSION



A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this 2nd day of December 1992



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

December 2, 1992

Docket No. 50-186
License No. R-103
EA 92-170

University of Missouri - Columbia
ATTN: Dr. James T. Rhyne, Director
Research Reactor Facility
Operations
Research Park
Columbia, Missouri 65201

Dear Dr. Rhyne:

SUBJECT: MISSOURI UNIVERSITY RESEARCH REACTOR FACILITY NOTICE OF
VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -
\$625 AND DEMAND FOR INFORMATION
(NRC INSPECTION REPORT NO. 50-186/92002(DRSS))

This refers to the inspection conducted on September 3 through 4, 1992, at the Missouri University Research Reactor (MURR) facility. The inspection included a review of the circumstances surrounding the inadvertent switching of two aliquots of a holmium-166 (Ho-166) sample which resulted in two shipments of byproduct material to the wrong recipients. The report documenting this inspection was sent to you by letter dated September 23, 1992. During this inspection violations of NRC requirements were identified.

An open enforcement conference was held on October 2, 1992, to discuss the violations, their causes, and your corrective actions. The report summarizing the conference was sent to you by letter dated October 7, 1992. You voluntarily reported the event to NRC headquarters on August 26, 1992, and to Region III on August 27, 1992. Subsequently, you voluntarily submitted a detailed written report dated August 27, 1992.

On July 27, 1992, your staff inadvertently switched two aliquots of a Ho-166 sample from the Rare Earth Radiochemical research project that produces lanthanide radionuclides for medical research. The aliquot containing 18.3 millicuries of Ho-166 intended for the Dow Chemical Company in Freeport, Texas (Dow-Freeport) was sent to the University of Texas M. D. Anderson Cancer Center (M. D. Anderson) in Houston Texas. This package was externally labeled as containing 482 millicuries of Ho-166.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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December 2, 1992

On the same day, the aliquot containing 482 millicuries of Ho-166 intended for M. D. Anderson was sent to Dow-Freeport. This package was externally labeled as containing 18 millicuries of Ho-166. Although the external labels identified incorrect activities, the labels on the internal lead sample containers identified the correct activities. The destinations were switched when corrections were made to the labels for the lead sample containers by the Radiopharmaceutical (RP) Research Group.

The inadvertent switching of the Ho-166 packages was discovered by M. D. Anderson upon opening of its package on July 28, 1992. M. D. Anderson contacted the RP group regarding the discrepancy. The RP group then contacted Dow-Freeport to alert them of the discrepancy. Dow-Freeport had not yet received the higher activity shipment and was instructed not to open the package. Both Dow-Freeport and M. D. Anderson were authorized to receive the quantities contained in these shipments.

Two violations are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice). The violations involve two instances of failure to indicate the correct isotopic activity on the shipping papers and shipping labels for two shipments of holmium-166. The violations occurred after personnel in the RP group inadvertently switched the names of the recipients designated on the labels of two lead sample containers. These sample containers were subsequently delivered to the Service Applications (SA) Group to be prepared for transport. Although the names of the recipients on the labels were incorrect, the labels did indicate the correct isotope and activity. Had the SA group used the information on the label to determine the isotopic activity to be entered on the shipping papers and shipping labels, the violations would not have occurred (although the packages still would have been sent to the wrong recipients). Instead, the SA Group copied the isotopic activity from a separate form keyed to the recipient name. Since the recipient names on the lead sample containers had been switched, the SA Group designated the wrong isotopic activity on the shipping papers and labels of both shipments.

Proper shipping papers and labeling allow civil authorities, in case of an accident during transport, to properly identify the type, quantity, and form of material; allow the carrier and recipient to exercise adequate controls; and minimize the potential for overexposure, contamination, and improper transfer of material. The events described above involve significant noncompliance with shipping paper and labeling requirements. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, these violations are classified in the aggregate as a Severity Level III problem. The violations have

been aggregated into one problem because they are factually related and arose from the same cause.

In addition to the violations noted above, the fact that the shipments were sent to the wrong recipients is a matter of significant regulatory concern. In cases where the wrong isotope, activity, or chemical/physical form is shipped, serious consequences can result during package opening, initial handling, or subsequent use. Recipients who are not authorized to possess or are not expecting to receive certain nuclides, quantities, or forms may not have the facilities or properly trained personnel to recognize and deal with the health physics consequences of such inadvertent shipments. Further, your shipment of isotopes to the wrong recipients is a recurring problem which was the subject of previous enforcement action (EA 91-113), and the corrective actions that you instituted at that time were not effective in preventing this latest occurrence.

We acknowledge your immediate corrective actions which included notifying Dow-Freeport and requesting that they not open the mislabeled package, which contained higher activity than indicated on the package label and shipping papers; arranging for Dow-Freeport to ship the sample to M. D. Anderson; and stopping the processing of samples by the RP Group until its procedures were revised and reviewed. Other groups that routinely request shipments by the Service Application Group were made aware of the incident and also began double verifying the appropriate information on the Shipping Request and verifying the Shipping Request against the sample container label.

We also acknowledge your longer-term corrective actions which include modifying procedures to ensure that the information on all the items associated with the shipment agrees and is accurate. Also, any group submitting radioactive materials to the Service Applications Group for shipment must now double verify critical information on the Shipping Request. In addition, the Service Applications Group now requires other groups to add alphabetic designation to the end of the MURR identification number for multiple shipments made from a single irradiation target and the preprinted package identification labels for their shipments now include the activity.

Further, due to the repetition of problems involving materials being sent to the wrong recipients, you have begun a global review of your shipping program, including establishing a task force to determine the best way to ship the broad diversity of isotopes that your operation involves, hiring a consultant to assist in improving procedures and related training, and conducting a peer review of your shipping program on October 15-16, 1992.

December 2, 1992

To emphasize the importance that the NRC places on attention to detail while preparing byproduct material for shipment in accordance with NRC and Department of Transportation (DOT) requirements, and on ensuring that corrective actions are effective, I have been authorized after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$625 for the Severity Level III problem.

The base civil penalty for a Severity Level III problem in the transportation area is \$500. The civil penalty adjustment factors in the Enforcement Policy were considered. The base civil penalty was mitigated 25 percent for identification in that, while the event was self-disclosing, you demonstrated initiative in identifying the root cause of the violations. The base civil penalty was further mitigated 50 percent for your good corrective actions as discussed above. The base civil penalty was escalated 100 percent for your poor past performance. A Notice of Violation and Proposed Imposition of Civil Penalty (EA 91-113) was previously issued to you on October 29, 1991, for similar events which occurred in 1991. The other factors in the enforcement policy were considered, and no further adjustment to the base civil penalty was considered appropriate. Therefore, based on the above, the base civil penalty has been increased by 25 percent.

Sections 3.b and 3.c of the inspection report describe two additional violations of NRC requirements. These involved failure to ensure that a package of radioactive material was labeled with a Yellow-III label when the Transport Index was greater than 1.0, and failure to ensure that the recipient's license authorized receipt of byproduct material prior to shipment. We recognize that you identified and corrected these violations, and that you reported them to NRC although you were not required to do so. Your efforts in this regard meet the criteria specified in Section VII.B of the Enforcement Policy; therefore the violations are being treated as non-cited violations.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In addition, given the diverse nature and the large volume of radioactive materials produced by MURR and provided to off-campus recipients (when compared to other research reactors), your projections of yearly growth in the volume of that activity, the number of mislabeled and misdirected shipments, and the failure of your previous corrective action to prevent recurrence, the NRC staff intends to closely monitor the initiative that you

are undertaking to conduct a global review of your shipping program and to improve your procedures and related personnel training for providing isotopes produced by MURR to off-campus recipients.

In order to more closely monitor your actions to review and improve these procedures, and in order to determine whether your license should be modified or other further enforcement action taken, you are hereby required, pursuant to sections 161c, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended and the Commission's requirements in 10 CFR 2.204 and 10 CFR 50.54(f), to provide the following information:

1. The results of the global review of your shipping program including lessons learned and recommendations for improving control over the preparation and shipment of radioactive materials produced by MURR for off-campus recipients.
2. A milestone schedule for completing the global review and providing the information described in 1. above to the NRC staff. Your milestone schedule should be provided within 30 days of the date of this letter.
3. A statement describing your position as to whether the procedures that you have established to control the preparation and shipment of radioactive materials produced by MURR should be incorporated into your NRC license, and if not, why not. This statement should be provided within 30 days of the date of this letter.

The information required above should be forwarded to the Director, Office of Enforcement, with a copy to the Regional Administrator, U. S. NRC Region III, at the addresses given in the enclosed Notice. If you have questions concerning this Demand for Information, please telephone Ms. Cynthia Pederson, Chief, Reactor Support Programs Branch, Division of Radiation Safety and Safeguards, U. S. NRC Region III, at (708) 790-5173.

After reviewing your responses to this Notice and Demand for Information, including your proposed corrective actions, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements. In this regard, the NRC staff intends to meet with you after receiving your responses to discuss the results of the global review and the revision of your procedures.

University of Missouri
- Columbia

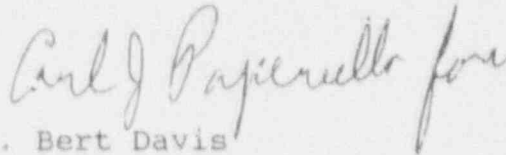
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December 2, 1992

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

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Sincerely,



A. Bert Davis
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc/enclosure:
PDR
DCD/DCB(RIDS)
OC/LFDCB
Dr. William Vernetson, Director
of Nuclear Facilities

University of Missouri
- Columbia

December 2, 1992

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EA File

DCS

State of Missouri

RAO:RIII

SLO:RIII

PAO:RIII

IMS:RIII

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Cumulative Civil Penalty - \$625 (assessed equally between the two violations).

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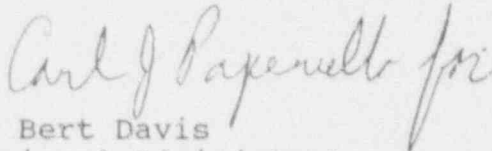
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In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

FOR THE NUCLEAR REGULATORY COMMISSION



A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this 2nd day of December 1992

University of Missouri
- Columbia

December 2, 1992

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*concurrence given by receipt of facsimile copy received

11/27/92. *WD* 11/27/92