



# OSEH

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Henry D. Baier, Director

June 20, 1997

Roy J. Caniano, Acting Director  
Division of Nuclear Materials Safety  
U.S. Nuclear Regulatory Commission, Region III  
801 Warrenville Road  
Lisle, Illinois 60632-4351

RE: **Reply to Notice of Violation - University of Michigan**  
**Byproduct Material License No. 21-00215-06**

Dear Mr. Caniano:

Per your correspondence dated May 20, 1997, the University of Michigan (U-M) would like to address the concern noted by the Nuclear Regulatory Commission (NRC) during the site inspection conducted February 13-14, 1997 with continued in-office review through May 2, 1997.

Please find below a description of the corrective actions the University has taken and intends to take regarding the violation noted in the NRC inspection report.

## NRC DESCRIPTION OF VIOLATION

10 CFR 71.12 states, in part, that a general license to transport licensed material, or to deliver licensed material to a carrier for transport, applies only to a licensee who has a quality assurance program approved by the Commission as satisfying the provisions of Subpart H of 10 CFR Part 71; has a copy of the certificate of compliance, or other approval of the package; and, submits in writing to the NRC, prior to the first use of the transport package, the licensee's name, license number, and package identification number.

Contrary to the above, on August 26, 1996, the licensee delivered licensed material, 10,740 curies of cobalt-60, to a carrier for transport under the general license pursuant to 10 CFR 71.12, and the licensee did not have a quality assurance program approved by the Commission, did not have a copy of the certificate of compliance, or other approval of the package and had not submitted in writing to the NRC prior to the first use of the transport package the licensee's name, license number, and package identification number.

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## DISCUSSION

At the time of the cobalt-60 (Co-60) shipment, it was our understanding that the U-M transferred possession of the Co-60 sources to the contractor while on-site at U-M prior to transport back to their facility. The U-M believes the transfer of the radioactive sources was conducted in the manner described in NRC HP Position Paper HPPOS-208, PDR-9111210363.

Therefore, it is our understanding that, upon transfer of possession, the contractor bore the responsibility attendant to the general license provisions of 10 CFR 71.12 and had satisfied those requirements by the establishment of its own approved QA program. We were unaware that the contractor, an Agreement State licensee, had not properly filed for jurisdictional reciprocity with the NRC pursuant to the provisions of 10 CFR 150.20 to take possession of the Co-60 sources onsite at the U-M.

In accordance with 10 CFR 30.41(b)(5), a licensee can transfer byproduct material to any person authorized to receive such byproduct material under terms of a specific license or general license or their equivalents issued by the Commission or an Agreement State. The contractor was appropriately licensed to receive the Co-60 sources as verified by the U-M in accordance with 30.41(d)(1).

NRC HP Position Paper HPPOS-208 PDR-911. 10363 states that:

"Pursuant to 10 CFR 30.41, DOE representatives may take possession of radioactive material from an NRC licensee if an authorized DOE employee or representative was present at the licensee's site to assume responsibility and control of the shipment from the site.

If onsite transfer to DOE is completed, the NRC licensee will no longer be in the position of delivering "licensed material to the carrier for transport" under the general license provisions of 10 CFR 71.11 and 71.12 and the conditions precedent (an NRC-approved QA program for shipping packages) to the licensee's use of such a general license would no longer be applicable."

Please note that the position described in HPPOS-208 derives from the authorization granted licensees under 10 CFR 30.41 to transfer materials to authorized persons and entities as listed in Sec. 30.41(b). Accordingly, the applicability of the reasoning in HPPOS-208 is not limited to transfers to DOE facilities.

HPPOS-208 supports our original understanding that possession of the Co-60 could be transferred to the contractor on-site at U-M with the contractor then being able to take responsibility as shipper. However, having not filed for reciprocity, the contractor was technically unable to take possession of the Co-60. This was not known to the U-M at the time of the shipment.



With respect to being in possession of the certificate of compliance (COC) for the shipping cask, it was the understanding of the U-M that we had the most recent copy of the COC on file at the time of the Co-60 shipment. The U-M had a copy of the COC dated March 21, 1996 (Amendment 27) on file at the Phoenix Memorial Laboratory at time of the shipment.

In any event, the Co-60 shipment from U-M was made using safety and packaging integrity procedures specifically addressing such shipments. These procedures are described within NRC License 21-00215-06 and were approved by the NRC as part of the license renewal process in 1993. In addition, the contractor and U-M conducted all the required inspections and tests included within the COC for the shipping container. Finally, it should be emphasized that the August 26, 1996 Co-60 shipment was conducted professionally, safely, and without complication.

#### **REASON FOR THE VIOLATION**

The reason for the violation was a misunderstanding of who served as the shipper for the Co-60 shipment. It was the U-M's understanding that the contractor responsible for exchanging and transporting the sources served as the shipper and that the U-M had transferred the sources to the contractor while their representatives were on campus.

Therefore, it was U-M's understanding that the quality assurance (QA) program used by the contractor to bring the new Co-60 irradiator sources to the U-M would cover the return shipment of the old Co-60 sources from the U-M.

#### **CORRECTIVE STEPS TAKEN AND RESULTS ACHIEVED**

Although the Co-60 irradiator sources are only exchanged about once every 5-years, the following corrective steps have been taken:

- (1) Various University departments that will be involved in future irradiator source exchanges have met, discussed the irradiator source shipment issues, and have strategically assessed how future source exchanges should take place to avoid recurrence. The U-M departments included: Phoenix Memorial Laboratory, Radiation Safety Service, Risk Management, General Counsel, and Purchasing.
- (2) The Radiation Policy Committee (RPC) has been informed of the Notice of Violation with respect to the Co-60 shipment.

#### **CORRECTIVE STEPS TO BE TAKEN TO AVOID FURTHER VIOLATIONS**

The following corrective steps will be taken to avoid further violations:

- (1) The current procedure (LP-106) used for the shipment of Co-60 irradiator sources will be revised to ensure that either the appropriate reciprocity agreement has been established with the NRC by the off-site contractor (if applicable) or that a QA program has been established prior to the next shipment.



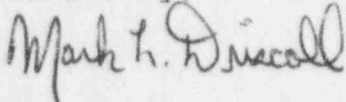
**DATE OF COMPLIANCE**

Full compliance will be established by December 31, 1997 and prior to any future shipment.

The University of Michigan has responded completely and accurately to the alleged violation noted in the NRC inspection report dated May 20, 1997 [License No. 21-00215-06].

Please do not hesitate to contact Rob Blackburn at the Phoenix Memorial Laboratory [(313) 764-6220] or me at Radiation Safety Service / OSEH [(313) 764-4420] should you have any questions, comments, or concerns regarding any of the responses noted in this NOV response. Thank you for your time and consideration.

Sincerely,



Mark L. Driscoll  
Director / Radiation Safety Officer  
Radiation Safety Service

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cc: Henry D. Baier, Director, Occupational Safety & Environmental Health  
Robert B. Blackburn, Asst. Lab Manager, Phoenix Memorial Laboratory  
James E. Carey, Chair, Radiation Policy Committee  
Ronald F. Fleming, Director, Michigan Memorial Phoenix Project  
Alan M. Jackson, Health Physicist, Radiation Safety Service  
Paul A. Spradlin, Interim Associate VP, Business Operations