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January 15, 1993

Director
Office of Enforcement
Nuclear Regulatory Commission
Washington, DC 20555

REFERENCE: Docket 50-186
University of Missouri Research Reactor
License R-103

SUBJECT: Demand for Information (NRC Inspection Report NO. 50-186/92002 (DRSS))

Dear Sir:

This letter provides the information required by the NRC Region III December 2, 1992 letter. On December 17, 1992, NRC Region III approved an extension of the required reporting date to January 15, 1993.

The December 2 letter required 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.

Our understanding of question 1 is that the NRC wants to be informed of the results of our global review of the shipping program when completed and realizes that the review is still ongoing. Therefore, question 2 requires us to inform the NRC of the milestone schedule for completing the review. In response to 1, we will discuss the progress of the global review to date with the understanding that the requested results will not be completely available until later as outlined in the milestone schedule.

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1. SHIPPING PROGRAM REVIEW

ORGANIZATION, GOALS, AND STRATEGY

As described at the October 2, 1992 Enforcement Conference, a Shipping Task Force (STF) consisting of members of the Directors Office, Health Physics, Service Applications, Reactor Operations, Radiopharmaceuticals Group, Analytic Epidemiology, Nutrition, and Immunology Group, and our Procedures Consultant was established to conduct a global review of the MURR shipping program. The Task Force is the same group (with a few additional representatives) that was first assembled July 28 after the July 27, 1992 shipping incidents to determine root causes and to formulate immediate corrective actions. The group met several times during August to review procedures and determine the corrective actions discussed in the August 27 letter to the NRC and at the October 2 enforcement conference.

The long-term goal of the Task Force is to make proactive improvements in order to achieve a performance level in shipping that will earn MURR the recognition as one of the best shippers of radioactive materials. Previously our shipping program had evolved over the years in reaction to situations, such as new regulations, new requests for radioactive shipments, or a significant problem coming to our attention.

The expanded Task Force first met on September 10, 1992. The purpose and goals were stated and ideas of how to go about accomplishing them were discussed. An emphasis was placed on refining management control to ensure that receipt, irradiation and processing of target material, and shipment of the subsequent radioactive materials are completed in full compliance with regulations. The following strategy was adopted:

- Clearly define what is required to have a radioactive shipment meet regulations.
- Perform a task analysis to determine where in the process it can best be resolved that a requirement is being met.
- Determine the best way to ensure that the required information is matched to the appropriate shipment.
- Rewrite procedures to maximize the use of common actions, requirements and vocabulary.

Small groups or subcommittees have been assigned to work specific issues and report back to the Task Force. In this mode the Task Force can maintain an overview while making progress in different areas. As progress is reviewed, the Task Force will decide if a new area needs a group to review it or make recommendations on possible improvements. To date, three subcommittees/groups have been set up to address different issues:

- Shipping Procedures Subcommittee
- Irradiation Request and Shipping Request Group
- Irradiation Subcommittee

Our organization for this review likely will evolve as we progress through this review and improvement program.

ACCOMPLISHMENTS

The accomplishments to date of the Task Force are given below followed by more details on the efforts of the subcommittees:

- **Task Force**

The Task Force identified the following items as essential for a radioactive shipment to be in compliance with regulations: classification, packaging, shipping papers, markings, labeling, placarding. The following data are required to complete the above items properly for a radioactive shipment: material description, amount of material, isotopes, activity, destination, and authorization to receive.

The Task Force defined the major tasks involved in the overall shipping process. Representatives of the different groups that play significant roles in the overall process reviewed their process(es) with the rest of the Task Force. Because correct information for some shipments depends on information obtained with the receipt of the sample to be irradiated, the scope of the overall review extends from obtaining or making the target for irradiation to the package leaving the loading dock.

Several members of the Task Force visited DuPont-NEN, Best Industries, and Mallinckrodt. They reviewed procedures, check sheets, equipment, and training related to the preparation and shipment of radioactive materials. Many of the observed practices (such as preprinting the T.I. on the hazard labels and surveying only 25% of the packages) are only applicable to large volume repetitive shipments. MURR, on the other hand, ships a smaller volume of unique shipments. One company in the process of making major changes to reduce the possibility of human error has agreed to share the results of these upgrades with us. We intend to follow their progress actively.

The Task Force set up the Shipping Procedures Subcommittee to better formalize the shipping procedures to improve management control and facilitate training. The actions of this subcommittee are discussed later.

The Task Force asked Dr. Marcus Voth, Director, Radiation Science and Engineering Center, Penn State University, to conduct a peer review of the MURR radioactive shipping program. Dr. Voth also had pertinent previous experience for such a review from positions in Northern States Power Company, and, particularly, as Manager of Nuclear Operations for the Union Carbide Corporation-Medical Products Division (later named Cintichem) which conducted a similar, but larger, shipping program. Dr. Voth's review was performed on October 15-16, 1992. He found that the shipping program is being conducted in a safe and prudent manner. He also provided some recommendations for improvement which are being followed up.

The Task Force recommended that a feedback system be set up to ensure that management is informed of problems–even minor ones–in the processing of samples for shipment. The goal is to detect weaknesses in the process and correct them before they result in a significant problem or violation. An Incident Report system for MURR Services Applications was set up and is being tested. We are attempting to identify minor errors and trends which occur but which are corrected before a shipment is released. This can help us monitor how well our process is working and determine corrective actions such as changes in training or process revisions to ensure compliance with regulations.

The Task Force is reviewing a draft "MURR Radioactive Shipping and Receiving Policy." This document is to be guidance about MURR staff contacts and procedures that are applicable to shipping and receiving radioactive materials. It will also serve as a blanket document to describe how the preparation and shipping procedures of the various MURR groups are coordinated. This will document formally the existing policy.

The Task Force set up the Irradiation Subcommittee to review methods used to verify composition and final activity of irradiated samples, and also to review the procedures used to prepare targets for irradiation. The actions of this subcommittee are discussed later.

As recommended by the Task Force, a NaI gamma spectroscopic system is being developed as a final backup check to confirm the radioactive contents of completely assembled packages that are ready to be shipped. Nearly all Type 7A shipments have been submitted to this check since December 30, 1992, and results are very promising for qualitative confirmation of this type. Additional development and computer upgrades are needed to enhance the system's operation and to assess its capabilities and limitations. The additional computer hardware and software are being ordered. (The previous switches in samples have been with Type 7A shipments.)

- **Shipping Procedures Subcommittee**

The Shipping Procedures Subcommittee is composed of members representing the Directors Office, Service Applications, Health Physics and the Procedures Consultant. The first meeting was held on October 14, 1992. This subcommittee is charged with review of the handling of a sample from removal from the pool to offering to the carrier. This effort was divided into three stages:

- Validate that current procedures and practices meet regulations.
- Rewrite existing procedures to reflect a new style similar to procedures meeting INPO standards.
- Look at new ways to optimize shipping practices and incorporate them in new revisions to the shipping procedures.

Validation of current practices

A detailed flow chart of current practices was prepared. It was reconfirmed that all changes recommended in the review of the July 27 incident had been incorporated into current practices.

To determine if any additional immediate changes to current practices were needed, the Voth Peer Review Report was scrutinized, and the Procedures Consultant was instructed to point out immediately any major deficiencies that needed to be corrected during his review. During deliberations by Services Applications, potential changes were considered. No additional changes were found to be necessary to ensure compliance with regulations.

To document this validation, existing shipping procedures were approved by the Reactor Health Physics Manager, and were reviewed by the MURR Procedures Review Subcommittee of the Reactor Advisory Committee.

Improvements in the style of shipping procedures

The current shipping procedures are being rewritten by the Procedures Consultant in a style similar to procedures used at Callaway Nuclear Power Plant which meet INPO standards. Service Applications Shipping (SAS) procedures are being divided into three parts:

SAS-001 General and Administrative Information – This procedure contains general information pertaining to preparation and shipment of radioactive materials by Service Applications.

SAS-002 Preparation of Radioactive Material for Shipment – This procedure prescribes identification and removal of irradiated samples from the reactor pool, conveyance to the hot cell or hot lab, opening, and placement into a shielded container for shipment or transfer for further processing.

SAS-003 Shipment of Radioactive Materials – This procedure prescribes the packaging of radioactive material in a shielded container for shipment, preparation and handling of all associated paper work, and transfer to a carrier.

The completion schedule for the above procedures is detailed in answer 2 describing the Milestone Schedule.

Analyze and optimize shipping practices

After we adopt the more formalized procedures, the shipping process and procedures will be carefully reanalyzed for beneficial changes. This will include suggestions for consideration from the Voth Report, and practices observed at the major shippers.

Prime areas under consideration for changes in the new procedures are the various numbering systems associated with samples and packages, improvements in reading can identifications in the reactor pool and hot cell, enhancement and simplification of shipping forms, reduction in checklist sign-offs, and possible reduction of the number of significant steps so that fewer double sign-offs are required. We feel that the current system has the redundancy to enable us to comply with regulations, but feel improvements may be possible to make this process more efficient. Changes will be made only after careful review and consideration.

- **Irradiation Request and Shipping Request Group**

This subgroup reviewed existing documents used to submit samples for irradiation and to request radioactive shipments from MURR to outside locations. The group's mission was to define standard criteria so that critical information regarding irradiations and shipments could be reported consistently for all users and requesters. Standardization will ensure appropriate control and management oversight of information which is essential for completing irradiations and shipments in compliance with applicable regulations. Essential information for each task is being incorporated into a draft certification statement to be presented to the appropriate managers for review and approval.

- **Irradiation Subcommittee**

The Irradiation Subcommittee (IS) was appointed during the December 10, 1992, Shipping Task Force meeting. This was done in recognition of the importance of target characterization in ensuring the accuracy of information entered into shipping papers and on labels for radioactive materials shipments.

The IS has reviewed the irradiation process at MURR, which includes requests for irradiation services, receipt and characterization of targets, and verification that targets are authorized for irradiation. The subcommittee has identified weaknesses in parts of this process and has recommended corrective action where desirable. Subjects that have been and continue to be examined are:

1. Assurance of target composition, especially for targets encapsulated prior to receipt by MURR and for targets from new requesters.

2. Assurance that targets fit within the enveloping conditions of approved safety analyses prior to irradiation.
3. Recommendation of improvements for determining and reporting post-irradiation acti ity, including measurements and calculations.

Assurance of target composition is extremely important because it determines the types and quantities of radioactive byproduct material created in the irradiation process. Service Applications' review of target materials previously irradiated at MURR revealed that we have not uniformly required the level of detail in target material descriptions that we now feel is necessary, particularly with respect to isotopic enrichment or known impurities.

Requesters of irradiation services are now being asked to ensure that MURR is aware of isotopic enrichment of targets and any impurities or encapsulation that could result in reportable shipping activity. The IS has reviewed a mechanism to provide more uniform guidance to requesters of MURR irradiation services. More comprehensive information will be required from requesters to improve documentation of target composition, isotopic enrichment and encapsulation. This can be used to assure that all targets are covered by existing safety analyses and that all significant radioactivity produced can be calculated adequately.

The Service Applications Isotopes group is carefully reviewing existing and new target composition information provided by requesters to ensure that all targets irradiated at MURR fit within the limits of approved safety analyses (Reactor Utilization Requests).

Accurate target composition information is also necessary for the determination of irradiated target activities used for radioactive shipping information, and this area of IS review indicated a need for improvement. In reviewing targets irradiated during the past year, the IS found cases where new calculations indicate that additional isotopes could have been reported. In some cases, this was because MURR had accepted requesters' calculations of major activities to be produced in their targets, without comparing them to MURR calculations of expected activities. Several other cases involved requester inaccuracy in their target descriptions with regard to isotopic enrichment or known impurities.

In order to upgrade the quality of reported shipping activities, the IS established a two phase program for improving the determination of these activities. Phase 1 (already implemented) requires identification and reporting of all significant radioisotopes–those that make up 90% of the total activity at time of shipment. While implementing Phase 1 requirements, the Service Applications group identified 17 targets where 90% of the total activity had not been reported previously. These identified additional activities are now being reported as Phase 1 corrective actions.

The most significant case is an example where both inaccurate target description and MURR acceptance of requester calculations of major activities may have led to deficient reporting of radioactive material shipped. Some industrial users, we have found, request only the main radioisotope of interest in their target and not other isotopes and impurities. In this instance, a major user of irradiated ytterbium (Yb) from MURR that is primarily interested in Yb-169, ordered it as Yb-169 and was shipped the product labelled as Yb-169. During the IS reviews, conservative calculations (ignoring self shielding and flux perturbations) revealed that significant production of up to 5 Ci of Yb-175 (4.19 d), a much greater activity level at the time of shipment than the isotope of interest, Yb-169 (32.03 d), may have been produced in the target. MURR notified the user that both isotopes would be reported in the future.

Other examples where the IS reviews have revealed the need for reporting additional activity based on recent calculations are S-35 (87.2 d/0.1674 MeV β) activity in P-32 (14.28 d/1.709 MeV β) shipments and Sb-122 (2.70 d) activity in Sb-124 (60.2 d) shipments.

Phase 2 will be an investigation of the use of computer codes (e.g., ORIGEN) to generate lists of radioisotope activities for each target to provide additional qualitative assurance that all significant activity is accounted for in reporting shipping activities.

In conclusion the IS group reviews have determined that MURR has either used measurements by dose calibrator, performed calculations, or accepted the calculations of requesters to determine shipment activities in the past. The IS investigation has shown that requester calculations are not always accurate or complete, as shown in the examples above. There are limitations to dose calibrator readings, and calculations are subject to limitations due to flux perturbations caused by adjacent samples as well as self-shielding. For these reasons, the IS has established the following guidelines for determining activities:

1) Measure the activity when feasible.
2) For P-32 and S-35 use conservative, previously verified activities for identical targets with similar irradiation histories. This applies to targets that are moved to different flux positions during long irradiations. The subsequent activity is predominantly beta and MURR does not remove the encapsulation before shipment.
3) For all other targets the activities will be calculated.

These guidelines have been implemented by a Service Applications Standing Order.

2. MILESTONE SCHEDULE

As can be seen in answer 1, the global review and associated improvements are ongoing processes whose paths are not clearly known ahead of time, but are affected by the experience and knowledge we gain as we proceed. While the goal is well defined, how to get there is being discovered as we progress. To answer question 2, we have given our best estimate of the steps to be completed. As we progress, the steps and schedule may need to change in response to what we learn. We will keep you informed of any significant changes in the schedule.

The Milestone Schedule shown below depicts future activities to be accomplished through the efforts of the STF and MURR staff. A methodical review and rewrite (as beneficial) of key shipping and target preparation procedures in a more formal style continues. The shipping procedures are being validated by actual performance and are to be incorporated as this process proceeds. The IS is conducting a review of current methodology and procedures employed in the target preparation process and necessary improvements are being made. More long-term enhancement from this review will be incorporated in rewriting these procedures.

The Research Group procedures were reviewed and modified as part of the immediate corrective actions taken in August. These procedures will be reviewed again and rewritten if necessary to assure a good interface with target preparation and shipping procedures. The blanket MURR policy is in draft form now, but completion of it must occur in conjunction with completion of the other procedures to ensure compatibility.

Upon completion of the above procedure reviews and in parallel with possible improvements (as previously discussed under Shipping Program Review), a training plan based on job and task analysis will be developed and implemented. A plan for periodic audits of the entire shipping operation also will be developed and implemented.

ACTIVITIES	COMPLETION DATE
SHIPPING PROCEDURES	
SAS-003 (Hot Cell-Ship)	January 15, 1993
SAS-002 (Rx-Hot Cell)	February 12, 1993
SAS-001 (Admin)	April 9, 1993
Analyze for Improvement	July 16, 1993
TARGET PREP. PROCEDURES	
Review Current Procedures	March 26, 1993
Analyze for Improvement	June 18, 1993
RESEARCH GROUP PROCEDURES	July 16, 1993
MURR PROCEDURE	July 16, 1993
REVISE TRAINING PLAN	September 24, 1993
AUDIT PLAN	July 16, 1993

The Task Force will meet monthly through 1993 to review progress and reevaluate steps. The Reactor Advisory Committee will review the findings and progress of the Task Force.

3. INCORPORATION INTO NRC LICENSE

The Reactor license, License No. R-103, requires the University of Missouri to follow the appropriate regulations for shipping byproduct material. It states in Section 3 of the license that "[t]his license shall be deemed to contain and be subject to the conditions specified in ... Section 30.34 of Part 30..." Under 10 CFR 30.34: "Terms and conditions of licenses," the last sentence of paragraph (c) states: "Preparation for shipment and transport of byproduct material shall be in accordance with the provisions of Part 71 of this chapter." Paragraph 10 CFR 71.5(a) requires each licensee who transports licensed material to comply with the DOT requirements in 49 CFR Parts 170 through 189. It is in this way that the regulatory control over the preparation and shipment of radioactive materials produced at MURR is specified in the Reactor license.

The MURR procedures established to control the preparation and shipment of radioactive materials were written to meet the regulation applicable to our license. The requirement for procedures is incorporated into the reactor license (R-103) in accordance with Technical Specification 6.1. b. and c. These procedures are now reviewed and approved by the Manager, Reactor Health Physics and reviewed by the appropriate subcommittee of the Reactor Advisory Committee. This is consistent with the MURR procedures which are in effect for normal operation of the reactor, emergencies and radiological control. The license condition to have procedures does not mean, nor should it mean, the submittal of such procedures to the NRC for anything other than information purposes or as required by 10 CFR 50.59(b)(2) on how we are meeting our license and regulatory commitments. This level of control applies to procedures in all areas under the reactor license and is similar to the review of broad licenses,[1] where NRC's review should primarily be based on "...the administrative procedures and organizational qualifications of the licensee to operate safely under the license rather than on a detailed review by the NRC of the qualifications, equipment, and procedures for each use and user."

We have always recognized our license responsibility to prepare and ship radioactive materials in accordance with NRC regulations. Procedures for Type B shipments are required by regulation to be conducted under a Quality Assurance Program that satisfies Subpart H of 10CFR71. MURR applied to the NRC (in a letter dated June 27, 1978) for a Quality Assurance Program Approval to conduct shipping activities under the Research Reactor license. This Quality Assurance Program was approved by the NRC as Approval No. 0108 (Docket No. 71-0108) on September 10, 1980. The Quality Assurance Program Approval for MURR is currently approval number 0108, Revision 3, with an expiration date of February 28, 1996. Under the Quality Assurance Program, the Reactor Manager is assigned the responsibility of implementing the program; therefore these Type B shipping procedures are approved by the Reactor Manager and are reviewed by the Procedures Review Subcommittee of the Reactor Advisory Committee.

MURR Procedures for Type A shipments were designed to meet applicable NRC regulations (10 CFR 71) and DOT regulations referenced by 10 CFR 71.5(a). As a result of our review these procedures have radiological control approval by the Reactor Health Physics Manager and are reviewed by the appropriate subcommittee of the Reactor Advisory Committee. The performers of these procedures have been aware of our license responsibility to prepare and ship Type A quantities of radioactive material in accordance with NRC and DOT regulations.

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[1] Proposed Revision 2 to Regulatory Guide 10.5: "Guide for the Preparation of Application for Type A Licenses of Broad Scope," Feb 1985, Division 10, Task FC 408-4.

In summary:

- Required procedures exist for activities associated with the MURR reactor license.
- A comprehensive review and approval process is in place to assure adequacy and compliance.
- The procedures are reviewed routinely to incorporate MURR experience, the experiences of others, and changes in requirements.
- The procedures are open for inspection at any time and have been so inspected.

We believe that the above assures full compliance with NRC regulatory requirements. Accordingly, incorporating specific shipping procedures into the MURR license is not only unnecessary but would be counter productive.

If there are any questions or need for additional information please call me at 314/882-5204.

Yours truly,

J. Charles McKibben
Associate Director

cc: Regional Administrator, US NRC Region III
S. Weiss, NRC/NRR
Reactor Advisory Committee
Reactor Safety Subcommittee
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