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August 27, 1992

Director of Nuclear Reactor Regulation
US Nuclear Regulatory Commission
Mail Station PI-137
Washington, DC 20555

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

SUBJECT: Report of Deviation from 10 CFR 71.5
Incorrect Activities listed on a Type A Package

Dear Sir:

On Monday, July 27, 1992, the University of Missouri Research Reactor (MURR) mistakenly switched two aliquots of a Ho-166 sample from the Rare Earth Radiochemicals 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, TX (Dow-Freeport) was sent to the University of Texas M.D. Anderson Cancer Center in Houston, TX (M.D. Anderson) externally labeled as 482 millicuries of Ho-166. On the same day, the aliquot containing 482 millicuries of Ho-166 intended for M.D. Anderson was sent to Dow-Freeport externally labeled as 18.3 millicuries of Ho-166. Both were Type A shipments with correct isotope and transport indices (TI) properly labeled on the package and shipping papers. The labels on the internal lead sample containers listed the correct amount of activity. Both Dow-Freeport and M.D. Anderson licenses authorize receipt of more than the 482 millicuries of Ho-166. The destinations were switched when the MURR Radiopharmaceutical (RP) Research Group[1] made corrections to the radioactive material labels for the two internal lead sample containers. The changes were being made to correct an error found when double-verifying the labels.

Chapter 10 CFR 71.5 requires licensees to follow the Department of Transportation regulations, Chapter 49 of the Code of Federal Regulations, in shipping radioactive materials. These two shipments did not meet the requirements of 49 CFR 172.203(d)(4) and 172 403(g)(2), because the activity contained was in error on the package and the associated shipping papers. Chapters 10 (NRC) and 49 (DOT) of the Code of Federal Regulations do not require a formal report in this situation, but we are providing this report describing our corrective actions for your information. We called Mr. Marvin Mendonca, NRC - Washington, D.C., August 26,1992 to inform the NRC of this discrepancy and let them know we were filing this report. Mr. Charles Cox, NRC - Region III, was also informed on August 27, 1992 Washington, D.C.

[1]Formerly called the Radioisotope Applications (RIA) Group.

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DISCREPANCY

M.D. Anderson opened their package Tuesday, July 28 at approximately 10:30 a.m. They transferred the sample into a dose calibrator for activity measurement and discovered that it contained only 11 millicuries in less than 0.5 milliliters when approximately 250 millicuries in 6.0 milliliters were expected based on decay of the amount recorded on the shipping documents. Since no evidence of leakage or contamination was found, our principal contact at M.D. Anderson called the RP Group's Senior Research Specialist to report the discrepancy. The specialist realized that M.D. Anderson had probably received the sample intended for Dow-Freeport, explained the assumed error to the caller, and called our principal contact at Dow-Freeport to alert him of the situation. Dow-Freeport had not yet received the other shipment in their laboratory, so the higher activity sample had not been opened. Dow-Freeport was instructed not to open the package until further notice.

Packaging documentation for both samples was reviewed. A comparison of the measured dose rate and labeled activities was supportive of the switched sample hypothesis. Our principal contact at M.D. Anderson was called again and was asked to read the label from the internal lead sample container. It listed the destination as M.D. Anderson, the activity as 18.3 millicuries, the volume as 0.2 milliliters, the date and time as 7/27/92 at 12:25 CDT, and the sample as lot HoN-23, vial 1. All this information was consistent with the sample received. However, the destination differed from the intended destination of the sample and from the Shipping Request that the RP Group gave to the MURR Service Applications (SA) Group[2]. This information confirmed the sample switch and pinpointed the error as originating in the RP Group (who had generated the label on the lead sample container).

RECOVERY

Dow-Freeport was authorized and equipped to ship the unopened package to M.D. Anderson. Since they were participating in a collaborative project with the researchers at M.D. Anderson and had planned to be present for the tests, they offered to relabel the package appropriately and transport it to M.D. Anderson on the following day. The loss of activity due to the delay was not considered a serious problem for the tests to be performed. The SA Group supplied Dow-Freeport with certification information for the Type A package so that the sample would not require opening and repackaging.

DESCRIPTION OF EVENT

Plans for production of Ho-166 originated in the RP Group in response to a request from Dow. Earlier in July, the Senior Research Specialist in the RP Group received a phone call from our principal contact at Dow-Freeport requesting the production of Ho-166 for themselves and M.D. Anderson. Dow-Freeport is planning a new clinical trial in collaboration with M.D. Anderson to investigate the use of Ho-166 in the treatment of leukemia. Our principal contact at M.D. Anderson submitted a written request by facsimile on July 20, 1992 for approximately 500 millicuries to be shipped to M.D. Anderson on Monday, July 27, 1992. The upper acceptable activity limit for Ho-166 at M.D. Anderson is 3.0 Curies. The principal contact at Dow-Freeport requested the remaining activity from the Ho-166 process to be shipped to Dow-Freeport. The license at Dow-Freeport permits them to receive a maximum of 1.0 Curie of Ho-166. Therefore both Dow-Freeport and M.D. Anderson licenses authorize receipt of more than the 482 millicuries of Ho-166.

A quartz vial containing 2.0 mg of holmium (as holmium nitrate) was prepared by the RP Group and delivered to the SA Group on July 17, 1992. The target was identified with the unique

[2]Formerly called Reactor Services Group.

designation HoN-23, assigned by the RP Group, and engraved on the quartz vial. An In-house Irradiation Request was completed and submitted to the SA Group with the target. This request form identified the target by its Sample ID (HoN-23), material, weight, and other pertinent information.

Each in-pool irradiation is assigned a unique irradiation number (MURR ID #) and a can number. Irradiation number 90458 and can number 10 were assigned by the SA Group for the HoN-23 sample irradiation. The sample was irradiated following standard procedures. Following irradiation, the irradiation can was opened in the hot cell and the vial placed in a lead sample container labeled with the can number, companies, isotope, and MURR ID #. The critical steps were double-verified. The properly labeled lead sample container was delivered to RP Group personnel with the completed Irradiation Request.

RP Group personnel washed the exterior of the quartz vial in the vial cleaning station according to approved procedure. An empty clean lead sample container was labeled with the date, isotope, expected activity, and Sample ID (HoN-23). After cleaning, the quartz vial was transferred to a prelabeled lead sample container for transfer to the processing laboratory.

An SOP for processing Ho-166 in a remote processing facility was in draft form, so the Health Physics Group had approved a Radiation Work Permit (RWP) utilizing this draft procedure. The process was performed by a Senior Research Laboratory Technician and supervised/witnessed by a Senior Research Specialist. Critical steps of the process, initialed by technician and witness, included dissolution of the target in hydrochloric acid solution, transfer of the solution via syringe pump into three empty serum vials, and measurement of Ho-166 activity using a dose calibrator inside the remote processing facility. The serum vials were not labeled or marked in any way. They were identified on the process check sheet as Vial 1, 2, and 3.

Prior to the activity measurement step, empty lead sample containers marked with the designations 1, 2, and 3 were placed in the processing facility pass-through area. The vials were removed from the filling area in sequence. Each vial was lowered into the dose calibrator, the activity reading was recorded as vial 1, 2, or 3 by the technician and verified by the witness, and the vial was moved into the lead sample container marked with the number corresponding to its designation (1, 2, or 3) on the process paperwork. The transfer of each vial into the correct lead sample container was also verified by the witness. The three lead sample containers were removed from the processing facility pass-through and taken to another area of the laboratory.

Vial 1 is typically retained for Quality Assurance testing in this type of process. However, Vial 3 contained a slightly higher activity (21.0 millicuries compared to 18.3 millicuries in Vial 1). Since the retained sample would be analyzed for long-lived radioactive impurities, the Senior Research Specialist decided to retain Vial 3 and ship Vial 1 to Dow-Freeport. Vial 2, containing 482 millicuries, was intended for shipment to M.D. Anderson. These shipment destinations were communicated to the technician and recorded on the process paperwork. The lines where the vial numbers and destinations were recorded in the process paperwork had "2/M.D. Anderson" listed above "1/Dow-Texas." The information recorded in this order on the process form could have contributed to the technician's error described below.

The technician generated radioactive materials labels for each of the three lead sample containers. The sample retained for quality assurance (3) was not destined for shipment; its radioactive label identified the isotope, lot number (identical to the Sample ID, HoN-23), activity, date and time of measurement. The remaining two samples were intended for shipment. Their labels identified the destination, isotope, activity, volume, date and time of measurement, lot HoN-23, and vial number (Vial 1 or Vial 2).

To verify the sample container labels, the RP Group technician showed the labels to another RP technician before placing them on the lead sample containers. The second technician noticed that the entry on each label identifying the sample as Vial 1 or Vial 2 was incorrect. The sample for M.D. Anderson containing 482 millicuries was marked as Vial 1 rather than Vial 2, as it was listed on the paperwork. The 18.3 millicuries sample for Dow-Freeport was similarly mislabeled as Vial 2. Two new labels were generated and shown to the other technician. This time the identification of 482 millicuries for Vial 2 and 18.3 millicuries for Vial 1 was correct, so the labels were placed on the sample containers. Neither technician noticed that the new labels identified the destinations incorrectly–the new labels still had Vial 1 label destination M.D. Anderson and Vial 2 destination Dow-Texas. Each label was placed on the lead sample container corresponding to its correct vial number and activity, but intended destinations were switched. The MURR ID # from the irradiation request (90458) was written on the top of both sample containers which were then delivered to the SA Group's hot lab to be packaged for shipment.

The RP technician then generated a Shipping Request for each shipment. Both technicians checked item on these request forms against the process paperwork, then signed and dated the forms. The forms correctly requested the 482 millicuries of Ho-166 to be shipped to M.D. Anderson and the 18.3 millicuries to be shipped to Dow-Freeport. The forms were taken to the SA Group's office where the information was used to generate shipping documents.

The SA Group's packaging of the lead sample containers was initiated one at a time after the technician was given a packaging packet for the desired shipment. Each packet was generated by a shipping technician using information supplied on the Irradiation Request and sample receiving sheet. A packet included: a 7A Container Control Check Sheet, a shipping document, unmarked package certification labels, and two package certification labels. Each Control Check Sheet, Shipping Request and package identification label contained the following information about the shipment: destination, isotope, and MURR ID #. The package identification labels were double-checked against the label and markings on the lead sample container. The same package identification label was placed on the outside each layer of the packaging material–can, expanded polystyrene, and box–to insure that the identity of the shipment was maintained as each successive layer of the package was assembled.

Upon completion of assembling each package, the package dose rate measurements were recorded. These dose rates along with the Shipping Request supplied by the RP Group, were used to complete the required shipping documentation: the address label, shipper's declaration, and primary and subsidiary risk labels. This documentation was reviewed and placed on each package corresponding to the set of information identifying the shipment: destination, isotope and MURR ID #. Both steps were independently verified before the package was released by the SA Group to Federal Express for shipment.

ANALYSIS

A meeting was held at 2:30 p.m. July 28, shortly after being called by M.D. Anderson. It was attended by all full-time isotope production staff of the RP Group and by the Health Physics Manager and Assistant Manager, Service Applications Manager and Supervisor, the Reactor Manager, Assistant Director, and Associate Director. The purpose was to analyze the cause(s) of this error and to plan procedure modifications to avoid reoccurrence. Personnel at this session and follow up sessions during the past month focused not only on the specific error that caused this situation, but on any potential weaknesses in recording or communicating that might allow misidentifications to occur, and root cause(s) why an error of this nature could occur after previous corrective actions concerning shipping errors had been implemented.

Due to the previous errors, management had implemented a line-item double verification for all critical items in the processing and shipping of samples in the SA Group. They handle most of

the radioactive sample processing and all of the shipping. This incident showed that there were weaknesses in how corrective actions were identified and implemented in other groups that do processing of samples and request shipments of radioactive material by the SA Group. The RP Group personnel were asked to revise procedures and Shipping Requests to be used for their next processes that were scheduled the following week. A follow-up meeting was held at 1:30 p.m. July 30 to review the procedure modifications.

This incident resulted from human error in labelling the lead sample containers that were delivered to the SA Group. The fact that the new error was not detected revealed weaknesses in certain policies and procedures used by the RP Group. Specific shortcomings included incomplete reverification of replacement labels and a missed opportunity to detect inconsistencies between the associated Shipping Request and sample container label.

The circumstances of previous shipping incidents, lessons learned and their associated corrective actions had been communicated to MURR staff and the MURR Reactor Advisory Committee and subcommittees. Discussions had included how corrective actions taken would impact the process of other groups requesting and providing information for the SA Group to make shipments. The application of similar corrective actions to procedures [illegible]ed by these groups prior to sample transfer to the SA Group for shipment had not been emphasized. The RP Group had begun instituting changes in their procedures, such as double verification. However, the need for standardizing the designation of critical information in the transfer of sample containers and Shipping Requests to the SA Group had not been thoroughly examined. The following paragraphs will explain each of the identified weaknesses in more detail.

Double verification of the sample container labels was performed by the RP Group technicians, but when an error was detected and replacement labels were generated, they should have been verified as new labels, with each entry double-checked for accuracy. This is much more obvious in retrospect than it was to the technicians at the time. Their new procedures specifically state all items must be reverified when corrections are made when finding an error.

Although the information on the Shipping Requests was correct for the intended shipments and had been checked and signed by two individuals, the sample container labels and Shipping Requests were generated at different times, then given to different members of the SA Group. They were never compared with one another, so an opportunity to catch the discrepancy between them was lost. Procedures have been revised to require comparing Shipping Requests against the sample container labels before packaging for shipment is started. Groups that routinely request shipments by the SA 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.

Groups submitting samples to the SA Group for shipment have been marking the destination, isotope, activity, and MURR ID # on each sample container to be shipped. The destination, activity, and MURR ID # were used by the SA Group on the preprinted package identification labels to track identity on each successive layer of packaging and used to match the complete shipping package to the appropriate shipping paperwork. In this instance, the two Ho-166 shipments were taken from a single processed target and sent to different receivers, so the two sample containers were labeled with the same MURR ID #. The paperwork given to the shippers for packaging each sample for shipment identified the sample by destination, activity, and MURR ID #. In this case the MURR ID # and the isotope were identical for the two samples in question. This left the one item in error on the sample container labels, the destination, as the unique identifier when the shippers matched the packaging packet to the lead sample container to be packaged and later to the shipping documentation. The preprinted package identification labels for all shipments coming from other groups now include the activity.

CORRECTIVE ACTIONS

The immediate corrective action consisted of notifying Dow-Freeport to request them to not open the mislabeled package, which contained higher activity than indicated on the package label and shipping papers. Arrangements were made for Dow-Freeport to ship the sample to M.D. Anderson in accordance with Federal Regulations as described above. The RP Group stopped processing samples for shipment until their procedures were revised and reviewed. Other groups that routinely request shipments by the SA 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. A review was immediately started to determine root cause(s).

Procedures have been modified to insure that the information on all the items associated with the shipment (sample container label, packaging packet, and shipping documentation) agrees and is accurate. Any group submitting radioactive materials to the SA Group for shipment must now double-verify critical information on the Shipping Request (destination, isotope, activity, and MURR ID #). The SA Group now requires other groups to add a letter designation to the end of the MURR ID # for multiple shipments made from a single irradiation tube and the preprinted package identification labels for their shipments now include the activity which, combined with the destination and isotope, provides additional opportunities to detect errors before shipments are released.

Sincerely,

J. Charles McKibben
Associate Director

xc: NRC Region III
Reactor Advisory Committee
Reactor Safety Subcommittee
Isotope Use Subcommittee
J. Sheridan, Vice Provost
J. Rhyne
Dow-Freeport
M.D. Anderson