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Mr. Michael D. Waters, Chief  
Licensing Branch  
Division of Spent Fuel Storage and Transportation  
Office of Nuclear Material Safety and Safeguards  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555-0001

RE: Response to NRC Request for Additional Information (RAI) regarding the request by the MU Research Reactor for authorization to ship Type B quantities of material after August 31, 2012 in 6M and 20WC-1 packages, dated July 19, 2012 (ML 122001A355)

August 10, 2012

Dear Mr. Waters,

This letter is in response to the request for additional information submitted to the University of Missouri Research Reactor (MURR) regarding our request to extend our authorization from NRC to ship Type B quantities of radioactive materials in our fleet of 6M and 20WC-1 packaging after August 31, 2012.

#### **Background Information**

MURR is a multidisciplinary research center anchored by a 10 MW research reactor operated by the University of Missouri-Columbia. As part of a public land grant University MURR's mission includes providing radioisotopes for medical, research, and industrial applications. Over 1,000 radioactive material shipments per year originate at MURR in support of this mission. Recipients are located throughout the United States and in many foreign countries. Of these shipments, 200 to 300 are of Type B quantities of material. Most of MURR's Type B shipments are used in cancer related research or treatment of cancer patients.

MURR currently ships type B materials under DOT Special Permit SP 14657 and a parallel NRC authorization per RIS 2008-18. As of August 9, 2012, DOT has extended the Special Permit (Fourth Revision) to December 31, 2012, and provided a path to request further extension into 2013. MURR is actively working on the response to DOT to request further authorization to ship until at least the end of Q3 2013. Mr. Jim Williams is the Project Manager for this effort with DOT.

#### **Additional Information Requested by NRC**

1. Provide the information specified by RIS 2008-18 related to (a) package information, (b) identification of shipments, (c) reasons for requesting extended use, (d) safety justification for continued use and proposed compensatory measures, and (e) a plan and schedule to acquire replacement packages.



**(a) Package Information**

Please refer to Table 1, below for a listing of the DOT Specification Packages currently in use at MURR:

**Table 1 DOT Specification Package Fleet at MURR**

<b>Serial Number</b>	<b>Model</b>	<b>Year of Manufacture</b>
4016	20WC-1	1996
4018	20WC-1	1996
4021	20WC-1	1996
4023	20WC-1	1996
4025	20WC-1	1996
4001	20WC-1	2000
4002	20WC-1	2000
4003	20WC-1	2000
4004	20WC-1	2000
1802	6M (15 gallon)	1997
1803	6M (15 gallon)	1997
1820	6M (15 gallon)	1997
1824	6M (15 gallon)	1997
1863	6M (30 gallon)	1997
2256	6M (10 gallon)	1999
2162	6M (10 gallon)	2000
2257	6M (10 gallon)	2002
1866	6M (10 gallon)	2003
2161	6M (10 gallon)	2003
1864	6M (10 gallon)	2004
2160	6M (10 gallon)	2004
2165	6M (30 gallon)	2004
2991	6M (10 gallon)	2004
2992	6M (10 gallon)	2004
2993	6M (10 gallon)	2004
2994	6M (10 gallon)	2004



2995	6M (10 gallon)	2004
2996	6M (10 gallon)	2004
2998	6M (10 gallon)	2004
2999	6M (10 gallon)	2004
2258	6M (10 gallon)	2004
2990	6M (10 gallon)	2004
2997	6M (10 gallon)	2004

**(b) Identification of Shipments**

MURR currently ships a variety of medical and industrial radioisotopes in the 6M and 20WC-1 packages shown in **Table 1**.

**Table 2 Radioisotopes Shipped Under Special Permit**

Isotope	Packages Shipped per Week	Current Package Used	Form	Mode/Destination/Distance
Sm-153	1	6M	Solid	Charter Air/1300 miles/Boston Area
Ir-192	2	20WC and 6M	Solid	Ground (truck)/multiple destinations - New Orleans Area, Boston Area, Southern California/1000 miles - 1700 miles
<i>Ir-194</i>			Solid	<i>Impurity, see Table 3</i>
Ba-135m	1	20WC	Solid	Ground (truck)/Seattle area/2000 miles
<i>Ba-131</i>			Solid	<i>"Impurity," see Table 3</i>
<i>Cs-131</i>			Solid	<i>"Impurity," see Table 3</i>
P-32	1 every other week	20WC	Solid	Ground (truck)/Boston Area/1300 miles
Yb-169	1	6M	Solid	Ground (truck)/Boston Area/1300 miles

The radioisotopes shown in **Table 2** have the following uses:

**Table 3 Use of Radioisotopes Shipped Under Special Permit**

Isotope	Form	Use
Sm-153	Solid (powder in quartz vial in canister)	<b>Cancer Treatment</b>
Ir-192	Solid (wires or buttons in aluminum block or confinement)	<b>Cancer Treatments, Industrial Radiography</b>



<i>Ir-194</i>	Solid (wires or buttons in aluminum block or confinement)	<i>Impurity with Ir-192</i>
<i>Ba-135m</i>	Solid (powder in canister)	<i>Impurity with Ba-131, dominant isotope for shipping</i>
<i>Ba-131</i>	Solid (powder in canister)	<i>Parent of Cs-131</i>
Cs-131	Solid (powder in canister)	<b>Cancer Treatment, daughter from Ba-131</b>
P-32	Solid (powder in canister)	<b>Tracer for biomedical research</b>
Yb-169	Solid (powder in quartz vial in canister)	<b>Industrial Radiography</b>

***(c) Reasons for Requesting Extended Use***

MURR has attempted to meet the requirements of 10 CFR 71 in a timely manner by contracting with a vendor for the design and manufacture of two replacement packages. These packages are not yet ready for use in transport; one design is currently being manufactured and the SARP for the second design is being prepared for submission by the end of Q3 2012.

MURR's use of the 6M and 20WC-1 shipping packages in the interim is crucial to our efforts to meet the radioisotope needs of the research and medical communities. Extended authorization from NRC to ship under the terms of DOT Special Permit SP 14657 is required to continue to meet those needs.

The following information is offered in support of our Application for Renewal of this Authorization:

Currently Approved Packages

There are four package designs approved by NRC which have been considered by MURR as possible alternatives to the existing package replacement program:

- **MIDUS** (NRC Certificate of Compliance 9320)
- **MDS Nordion F327 USA/0126/B(U)-96** (NRC Certificate of Compliance 0126)
- **AOS-25 and AOS-50** (NRC Certificate of Compliance 9316)

All four designs were eliminated as impractical or impossible choices for MURR when we began the package replacement program, and implementation of any of these designs remains impractical for a variety of reasons, including approved contents, delivery timeline, and budget.

**The MIDUS package** has many attributes MURR finds acceptable as a 20WC-1 replacement package. The package weighs more than is ideal, at 330 kg (727 lbs), but is well-shielded and the basic design is approved. However, MIDUS is designed to transport Mo-99 as sodium molybdate in liquid form, with no other radioisotopes currently approved for transport. The manufacturer of the



MIDUS submitted a response to the RFP issued in 2007, but their bid was not selected based on the grading scale used to award the contract (based on design factors related to the smaller package requested as part of the bid and on price). MURR approached the manufacturer of the MIDUS packages again after the July 11<sup>th</sup> Public Meeting with an inquiry regarding cost and schedule should MURR want to reconsider our approach. However, because the delivery schedule would not result in delivery of packages more quickly than the existing SAFKEG-HS program, and there would be significant regulatory hurdles, this option is not considered feasible.

**The MDS Nordion F327 package**, designated USA/0126/B(U)-96, is an analog of the 20WC-1 and meets some of MURR's needs for that type of packaging. It weighs 148 kg (326 lbs) and is approved for multi-radionuclide use, though it is not approved for P-32, Cs-131, Sm-153, or Yb-169, which comprise over 60% of MURR's current Type B shipping activity. MURR did pursue this option, however, during the initial phase of our Type B replacement program, Nordion consistently rejected our request to purchase these packages based on business competition concerns. Even if Nordion were to change their stance, MURR would not be able to gain approval for new contents, manufacture, test, and receive the packages sooner than the SAFKEG-HS packages are expected; therefore turning to Nordion is not considered feasible.

**The AOS-25 package** design could be considered an analog of the 6M and the SAFKEG-LS. As the SAFKEG-LS package is currently in production for delivery to MURR in Q4 2012, the AOS-25 design is not considered to be a realistic option at this stage.

**The AOS-50 package** design could be used as an analog of the 20WC-1. AOS submitted a bid to MURR during the acquisition phase of the package replacement program. The AOS proposal (which included both AOS-25 and AOS-50 models) was not awarded the bid due to very high costs. Upon review of this package after the July 11<sup>th</sup> meeting with NRC, assuming an amendment to add P-32 to the approved contents list, the package would be able to meet the needs of MURR's customers. The manufacturer of the AOS-50 package was approached with an inquiry as to cost and schedule should MURR want to reconsider our path. The cost estimate for a fleet of AOS-50 packages is roughly 5 times the price of the HS package fleet, with additional yearly fees of approximately \$100,000. The time it would take to manufacture, test, and receive the packages is not materially faster than the revised schedule proposed by Croft for delivery of the HS packages. Based on cost and schedule considerations, along with expected legal costs related to breaking the contract with Croft, it is not regarded as feasible to deploy a fleet of AOS-50 packages at MURR.

In summary, while package designs do exist that might be useful to MURR as replacements for the 20WC-1 (given sufficient time and resources to enhance them) MURR cannot deploy any of those designs significantly more quickly than the SAFKEG-HS under Croft's revised plan. In addition, the few available options are economically unfeasible for MURR, particularly in light of the already significant investment in the current pathway.



### Reconfiguring the Contents

MURR also investigated the possibility of dividing the radioactive material currently shipped in Type B quantities into multiple Type A shipments. Due to ALARA concerns about the increase in dose to workers, the nature of the material shipped, and a variety of handling issues, this is not regarded as feasible.

#### *ALARA Concerns – Applies to Sm-153, Ir-192 (Ir-194), Ba-135m (Ba-131, Cs-131), P-32, Yb-169*

As an NRC licensee, MURR is required to adhere to an “As Low As Reasonably Achievable” policy in regards to radiation exposure to staff per 10 CFR 20.1101(b). Exposure rates would increase dramatically under any plan that required MURR to break these materials into Type A quantities prior to shipping.

#### *Reconfiguring Contents and Exposure and Contamination Concerns – Applies to Sm-153, Ir-192 (Ir-194), Ba-135m (Ba-131, Cs-131), P-32, Yb-169*

After the designated irradiation period, the material (Sm-153, Ir-192, etc.) is allowed to decay for a period of time and then the canisters are removed from the reactor pool.

In the case of material encased in quartz vials, the irradiation canisters are opened inside a hot cell and the quartz vial removed. This quartz vial is enclosed in a shielded container which is then placed in a Type B package for shipment.

In the case of material that is held in only the aluminum canister, the canister is cleaned and placed directly into the Type B package.

To require MURR to open a welded or sealed quartz vial containing radioactive powder in order to divide the material into multiple Type A shipments invites a host of potential problems, including contamination control and increased dose to workers. For example:

- Free powder can contaminate the hot cell in which the work is being performed, requiring hours or days of decontamination and survey work and the associated additional radiation exposure to staff.
- Iridium wires or buttons are encased in aluminum blocks for irradiation positioning and shipping purposes. To saw, cut or dissolve the aluminum would require hours of work with intensely radioactive materials and would increase the radioactive waste stream, including generating mixed waste if the dissolution method was chosen. In addition, some individual wires or buttons exceed the  $A_2$  value and would be considered a Type B shipment by themselves.
- The extra hours spent to disassemble irradiation canisters or quartz vials for the purpose of reconfiguring the contents requires hot cell workers to endure more exposure. Currently, typical exposure rates for hot cell workers are 5-10 mR per hour.



Adding hours of processing time or decontamination work would quickly increase the radiation exposure to those workers.

- Each package must be surveyed after loading. Instead of five to seven heavily shielded Type B packages to survey, the shipping and health physics staff would now have at least twenty or more Type A packages to survey, increasing their exposure time and therefore dose.

*Material and Handling Issues – Applies to Sm-153, Ir-192 (Ir-194), Ba-135m (Ba-131, Cs-131), P-32, Yb-169*

The materials shown in **Table 2**, above, are sealed in welded aluminum canisters and leak-tested prior to being irradiated. Some materials, such as Sm-153, are sealed in quartz vials before being welded into the canisters. Other material, such as the Ba-131/Ba-135m/Cs-131 product, are sealed directly into the welded canister.

A variety of handling issues arise in subdividing these radioactive materials into Type A quantities. Any increase in complexity can have a direct impact on safety, either in handling or in end use. Some issues include:

- For our radiopharmaceutical clients, parceling out the radioactive powder into smaller quantities would make it unusable in a radiopharmaceutical that has been approved by the Federal Drug Administration (FDA). Some of our clients require a specific target material and sample size as part of their processing procedures as approved by the FDA or other regulatory bodies. Their quality programs require the use of a discrete sample etched with a QA number that must be confirmed by the radiopharmaceutical manufacturer before production can begin. Subdividing such quantities is not realistic for our clients' and partners' intended, approved, uses.
- Similarly, the radionuclides that are used in medical applications are sterilized by the intense gamma radiation exposure they experience during irradiation at MURR. Opening these sealed containers (to separate the material into Type A quantities) in a non-sterile environment allows for the introduction of both biological and non-biological contaminants. This invites a host of contamination issues and likely renders the samples unusable.
- The increased workload would result in delays in getting packages out the door as the number of packages shipped by MURR increased dramatically. This would result in delays and reduced efficacy of the radionuclides when used in cancer treatments, research or industrial uses.

The ALARA and materials handling issues raise significant concerns for workers and end-users, including patients. As a result, it is not feasible to subdivide all of MURR's Type B shipments into a greatly increased number of Type A shipments.



### Readjusting the Transport Schedule

As MURR serves medical, research and industrial customers on an ongoing basis, a readjustment of transportation schedules would not help alleviate the need for permission from the NRC to continue using the DOT specification packages past August 31, 2012.

### Efforts to Meet the Regulations

Upon the implementation of the new regulations in 2004, NRC speculated and MURR expected that industry would provide packages to the new regulatory standard. MURR planned to purchase approved designs in the open market.

It became clear after implementation of the new regulations that industry would not be stepping forward to design, gain approval for, and manufacture packages suited to the varied needs of MURR's research, medical and industrial partners. MURR then attempted to prod the market by initiating contract bids. During 2005, MURR initiated two Requests for Bid, soliciting industry for a contract to design, test and fabricate packages meeting 10 CFR 71. The first bid met with no response. The second bid produced one response that could not be implemented due to excessive costs. "Excessive" in this case was judged in terms of the approximately \$7 million design and delivery cost being many multiples in excess of our projections and in excess of NRC's estimate of \$340,000 - \$390,000 per design (not including individual package costs) provided as part of the NRC evaluation of the impact to industry of the new regulations.

In 2006, MURR formed an investigative team to determine the feasibility of obtaining the necessary licensing to design, test and build packages to the 10 CFR 71 standard in-house. The team concluded that this was not feasible in terms of expertise, experience and financing.

MURR then issued a Request for Proposal in March of 2007 which resulted in four vendor responses. Croft Associates, Ltd. was awarded a contract in August of 2007 for the design, testing and fabrication of two Type B Package designs to satisfy 10 CFR 71.

The designs MURR requested from Croft were their existing 2799E and 2835A packages. These Croft designs are approved in Europe and compliant with the IAEA standard to which the U.S. has harmonized. After a pre-meeting with NRC staff in October of 2007, our vendor was informed that the designs needed to be changed considerably for consideration by NRC. Due to the design changes, MURR needed to negotiate a contract change order for Croft to develop two completely new designs (later designated SAFKEG-LS and SAFKEG-HS).

As we prepared to submit the Safety Analysis Report for Packaging (SARP) for the two designs, MURR made a project management decision to delay filing of the HS SARP, with the intention to improve the HS SARP filing based on the RAIs and lessons-learned from the LS SARP process.

The SARP for the SAFKEG-LS was submitted in August of 2009 and a certificate of compliance was issued in January of 2011 (Model 3979A, Certificate of Compliance 9337).



Because of the design changes, a significant cost overrun occurred. As a result, MURR spent much of the middle of 2011 in a contract renegotiation process with Croft and in negotiation with University fiscal authorities arranging for further funding of this project. The new contract was finalized, funding secured, and manufacturing began in late 2011. As of this writing, the SAFKEG-LS package is scheduled for delivery to MURR in late November of this year. Please see **Attachment A** for the current Manufacturing Schedule.

The SARP for the SAFKEG-HS (Model 3977A, NRC docket number of 71-9338) has not been filed as of this writing. Due to ongoing lessons-learned from the SAFKEG-LS manufacturing process, we determined it would make for a better SARP to await final manufacture of the LS packages prior to submittal. This decision has been rescinded in response to the July 11<sup>th</sup> meeting. Croft has committed to submit the SARP for the SAFKEG-HS no later than September 28, 2012.

#### Adverse Impacts

If MURR is denied permission to continue using DOT specification packaging, it will severely impact the domestic supply of radioisotopes for medical uses, industrial applications and research and will have dramatic consequences for MURR as it currently operates. Details of the impact on customers, cancer patients, and other end-users are provided in the Customer Statements provided as attachments to this response.

MURR relies on the 6M and 20WC-1 packaging for roughly 30% of its Products & Services revenue. Losing this revenue will result in significant, unsustainable budget shortfalls. Such a significant loss of revenue, combined with the large sums already spent (**\$3 million** as of this writing) and budgeted (**\$6.7 million total**) for the Type B package replacement project could not be absorbed by MURR.

Losing the ability to ship would end our ability to fund our package replacement program, result in significant lay-offs, and endanger the continued operation of MURR.

MURR is the largest university-owned research reactor in the United States at 10 MW<sub>th</sub> (The Massachusetts Institute of Technology Research Reactor is second at 6 MW<sub>th</sub>). The size, high flux, and consistent operating schedule are unparalleled in the worldwide research reactor community, and our deep experience in radioisotope production, materials investigation, and basic research make the MU Research Reactor a destination for researchers from across the United States and around the globe. Shutting down the reactor would impact a wide array of federally sponsored research, and have severe impacts on the operations of several U.S. corporations and many research institutions.

#### Effects on Individual Isotopes

MURR is the sole domestic source for Sm-153, Ir-192, Cs-131, P-32, and Yb-169. MURR's relatively high flux, consistent operating schedule (averaging 150 hours/week, 52 weeks per year since the



late 1970s), and our central geographic location make us the only reliable and efficient source for many of the high-activity radionuclides needed for medical, industrial and research use.

The Sm-153 provided by MURR is the radioactive component of a cancer-fighting radiopharmaceutical, Quadramet®. Without the ability to ship the Sm-153 in a DOT specification package, that product cannot be produced and provided to cancer victims.

The Ir-192 provided by MURR is used for both brachytherapy applications and industrial radiography needs. These companies could rely on foreign reactors for this material, but MURR is a preferred supplier to them due to our reliable schedule. Without the ability to ship Ir-192 in DOT specification packages, the United States loses a major domestic source of this isotope, and the only source that can reliably produce it week after week.

The Cs-131 provided by MURR is the radioactive component for a variety of cancer treatments. We are the sole domestic source for this radionuclide. If we lose the ability to ship this radionuclide in DOT specification packaging, the manufacturer of the cancer therapy agents will be forced to turn to foreign reactors for supply.

MURR is the sole domestic source for P-32 used by thousands of hospitals and research laboratories across the U.S. as a tracer. Other reactors can provide it to our customer, but at the cost of relying solely on foreign reactors for this critical component of biomedical research.

Yb-169 is supplied to a customer for industrial radiography as well as continuing cancer medicine research and therapies. As with the other radionuclides, MURR is the sole domestic source for this material.

If MURR loses the ability to ship these radioisotopes in the 6M and 20WC-1 packaging, the ripple effects will extend across various industries and into the lives of patients receiving cancer therapies.

***(d) Safety Justification for Continued Use and Proposed Compensatory Measures***

MURR operates the existing fleet of DOT specification packages in compliance with DOT Special Permit SP 14657. This requires MURR to operate the existing package fleet in accordance with 49 CFR 173.416(c), requiring MURR to conform "in all aspects to the requirements of this subchapter in effect on October 1, 2003." MURR has operated packages meeting these specifications for four decades with an exemplary safety record.

MURR is aware of no safety concerns associated with the continued use of 6M and 20WC-1 packaging either from our operating experience or from the literature. In its justification for the original rule change, NRC cited "*enhanced safety enrichments*" of new package designs, rather than any weakness in the old packaging, as the reason for discontinuing use of the specifications in Safety Series No. 6, 1967. A four-year transition period was originally proposed, because NRC recognized that there was "*not necessarily an immediate need to discontinue use of packages that*



*were approved under previous revisions of the regulations.”* There was no mention in the rulemaking or related documents of any instances where these specification packages failed to contain their contents, nor is there any reason to think they would begin to do so. While continuous improvement is certainly desirable, there is a learning curve with any change which brings with it the potential for error; from that perspective, the packages currently in use are proven safe and effective with over forty years’ track record.

Compliance with the applicable regulations and the existing DOT Special Permit is implemented through a variety of inspection, operation and maintenance activities. In addition, MURR operates the package fleet under an NRC-approved Quality Assurance (QA) program.

#### Inspection, Operation, and Maintenance

Upon the return of a 6M or 20WC-1 package to MURR by a customer, each package is surveyed for contamination, then inspected by a Certified Shipping Technician; its condition recorded on the “Type B Cask Inspection Log” which is maintained for each 6M or 20WC-1 package.

If minor repairs or maintenance are needed, the package is removed from service until maintenance is performed under the appropriate procedure.

The DOT Specification Packages are integrated into MURR’s facility-wide preventive maintenance program. MURR schedules and tracks maintenance using a standard industry software package (MAXIMO), which generates work orders, assigns the task to a responsible party, and facilitates tracking and status reports of the work.

Maintenance and inspection is intimately tied to Operation, requiring recurring review of all packages in service to assure each shipment occurs in a safe manner.

#### NRC Quality Assurance Program

MURR operates the Type B package fleet under NRC QA Certification No. 71-0108, Revision No. 9, issued April 6, 2009, and the associated QA Plan. This QA program allows for procurement, maintenance, repair, and use of Type B packaging.

The QA plan provides a quality system framework for compliance with 10 CFR 71, Subpart H. This QA Program applies to all activities affecting the DOT specification packages and their components. The program comprises the planned and systematic actions necessary to provide confidence that the package will perform satisfactorily while in service.

#### Proposed Compensatory Measures

In 2008, MURR proposed significant compensatory measures as requested under RIS 2008-18 in the form of drastically reducing the number of radioisotopes that would be allowed to ship in the



6M in 20WC-1 and setting limits to the allowed activity based upon multiples of  $A_2$  values (from 49 CFR 173.435).

In addition to the existing restrictions, MURR proposes the following additional restrictions be included in the DOT Special Permit and NRC Authorization for continued use of the 6M and 20WC-1 on a limited basis:

- P-32: Reduce allowable  $A_2$  Multiple from 400 to 40
- Yb-169: Reduce allowable  $A_2$  Multiple from 200 to 100

These additional restrictions on allowable shipments provide a tighter boundary within which MURR is allowed to operate while not interrupting the medical radioisotope supply in North America.

As an additional compensatory measure, MURR is considering an accelerated schedule outlined in Section (e) below.

***(e) Plan and Schedule to Acquire Replacement Packages***

Assuming an uninterrupted ability to fund the Type B Package Replacement program at MURR, we expect delivery of forty-five (45) SAFKEG-LS packages to occur in **Q4 of 2012** and, contingent upon acceleration of the program as described below, delivery of fifteen (15) SAFKEG-HS packages in **Q3 of 2013**.

**SAFKEG-LS (Model 3979A)**

As described in the section "Efforts to Meet the Regulations" above and in **Schedule A**, MURR is told by our vendor that the SAFKEG-LS packages will be shipped from the subcontractor in North Carolina at the end of November. MURR already has on-hand two CALT-9 helium leak test devices to support use of the packaging and is in the process of training staff using a prototype package.

In addition, NRC is reviewing an updated version of the LS SARP that addresses a variety of issues raised during manufacturing. NRC has indicated that they expect to issue a revision to the Certificate of Compliance based on this revised SARP before the fleet is deployed at MURR.

MURR will require some transition period to train personnel and properly educate end-users who will receive the new packages. Once this transition period has ended, the following isotopes will move from 6M or 20WC-1 packaging into the LS:

- Sm-153 (weekly shipment)
- Cs-131 (weekly shipment)
- Yb-169 (weekly shipment)



SAFKEG-HS (Model 3977A)

As described in the section "Efforts to Meet the Regulations" above, the SARP for the SAFKEG-HS package has not yet been submitted as Croft had been including lessons-learned from the LS project as we moved through approval and manufacturing. This decision has been reconsidered in light of the July 11<sup>th</sup> meeting at NRC and Croft has committed to submit the SARP to NRC no later than **September 28, 2012**.

The current status of the SAFKEG-HS program as of this writing is:

*SARP Compilation and Licensing*

Work completed:

- Design
- Prototype manufacture
- Prototype testing
- FEA stress analysis [final draft]
- Thermal FEA
- Shielding calculations
- SARP Compilation [90% draft]
- Insert design and prototype production

Work outstanding:

- FEA stress analysis [final editing to be done and approved]
- SARP Compilation [estimated 10% remaining]
- Shielded Insert drop testing [In Process]

The current schedule allows for a review period of one (1) year at NRC, followed by a nine (9) month manufacturing process. Assuming issuance of the Certificate of Compliance in September of 2013, the SAFKEG-HS packaging would be delivered for use in Q2 2014.

*Program Acceleration Steps*

In response to the July 11<sup>th</sup>, 2012 meeting with NRC and the concern over the Q2 2014 delivery date for the SAFKEG-HS packages, MURR has ordered Croft to produce an accelerated production schedule. This schedule requires the following steps be taken in order to advance the delivery date of the SAFKEG-HS packages from 2014:

1. Procurement and manufacturing of the following components will begin "at risk" based on the following milestones:

Milestone #1: NRC authorization to continue shipping under SP-14657 into 2013



- Production Planning
- Purchase of Stainless Steel Materials for Inner Containment Vessel
- Procurement of O-rings
- Procurement of fasteners
- Procurement of inserts
- Pre-ordering steps for Depleted Uranium (DU) shielding material

Milestone #2: Receipt of first RAI for SAFKEG-HS SARP submission, assuming no significant questions related to the package body, cork material, and general Inner Containment Vessel Design

- Cork machining
- Manufacture of Stainless Steel body to completion
- Machining of Stainless Steel components for Inner Containment Vessel

Milestone #3: Satisfactory response to all RAI questions related to the DU Shielding Material

- Procurement of DU material
- Finishing work for the Inner Containment Vessel, including welding and leak testing of the vessel once the DU has been acquired

The above steps are considered "at risk" because MURR would be entering manufacturing prior to issuance of the Certificate of Compliance. The procurement of the items on the above schedule is considered an acceptable risk as the component fabrication or acquisition under Milestone #1 is exactly the same as, or very similar to, components used in the SAFKEG-LS package. MURR will bear the cost and schedule uncertainty if changes are made to the design. Procurement of the DU before regulatory review is regarded as an untenable financial risk.

2. Upon submission of the SARP to the NRC, Croft will request priority review of all issues relating to the DU shielding material. If this request is granted by NRC, this will enable us to place the order for manufacturing of the DU components "at risk" once NRC staff are satisfied this aspect of the package meets all requirements.

Croft indicates that delivery of the fifteen (15) SAFKEG-HS packages could be scheduled for **Q3 of 2013** assuming the following criteria are met:

- Six month review of the SARP by NRC followed by issuance of a Certificate of Compliance (this assumption is merely for planning purposes – we do not imply NRC has made any timeline commitment for the review of the SARP)



- Priority review of DU related items in the HS SARP completed promptly
- No delays encountered with procurement or manufacture of DU shielding materials
- "At risk" fabrication of components as indicated above.

**Please Note:** The risks associated with accelerating the schedule in the manner described above are considerable. Should a significant change be made to any of the items after production has begun, the delivery schedule could be severely impacted and increased costs would stress the procurement program.

2. Provide under oath and affirmation the information specified in "Reasons for Requesting Extended Use" in RIS 2008-18; i.e., "there are no alternative domestically approved package available, the contents cannot be reconfigured such that transport can be conducted in accordance with the regulations, and the transport schedule cannot be adjusted so as to be conducted in accordance with the regulations." Provide this information for both DOT Specification 6M package and DOT Specification package 20WC-1, and emphasize those reasons that make the DOT Specification 6M package necessary after SAFKEG LS (Model No. 3979A) becomes operational in December 2012.

We hereby affirm that the information specified in "Reasons for Requesting Extended Use" provided above as relates to "there are no alternative domestically approved package available, the contents cannot be reconfigured such that transport can be conducted in accordance with the regulations, and the transport schedule cannot be adjusted so as to be conducted in accordance with the regulations" to be true and accurate.

3. Identify the number of shipments per month, and the isotope(s) to be shipped, beyond August 31, 2012, which are needed to ensure public health and safety, National Security, medical therapies provided, and/or other crucial needs to material licensees on the plan and schedule requested in 1 (e) above; i.e, identify both the number of shipments and the isotopes shipped relative to the schedule for bringing the SAFKEG-LS into operation and submitting an application for the SAFKEG-HS.

**Table 4 Current Monthly Shipments from MURR in 6M and 20WC-1 Packaging**

Isotope	Packages Shipped per Month	Current Package Used	Form	Mode/Destination/Distance
Sm-153	4	6M	Solid	Charter Air/1300 miles/Boston Area
Ir-192	8	20WC and 6M	Solid	Ground (truck)/multiple destinations - New Orleans Area, Boston Area, Southern California/1000 miles - 1700 miles



<i>Ir-194</i>			Solid	<i>Impurity, see Table 3</i>
<b>Ba-135m</b>	4	20WC	Solid	Ground (truck)/Seattle area/2000 miles
<i>Ba-131</i>			Solid	" <i>Impurity, see Table 3</i> "
<i>Cs-131</i>			Solid	" <i>Impurity, see Table 3</i> "
<b>P-32</b>	2	20WC	Solid	Ground (truck)/Boston Area/1300 miles
<b>Yb-169</b>	4	6M	Solid	Ground (truck)/Boston Area/1300 miles

As described above, MURR will transition the following isotopes from 6M or 20WC-1 packaging into the SAFKEG-LS in Q4 2012:

- Sm-153 (weekly shipment)
- Cs-131 (weekly shipment)
- Yb-169 (weekly shipment)

This will result in the shipping profile shown in **Table 5**, below, beginning in 2013.

**Table 5 Shipments in 6M and 20WC-1 Packaging After Implementation of the SAFKEG-LS**

Isotope	Packages Shipped per Month	Current Package Used	Form	Mode/Destination/Distance
<b>Ir-192</b>	8	20WC and 6M	Solid	Ground (truck)/multiple destinations - New Orleans Area, Boston Area, Southern California/1000 miles - 1700 miles
<i>Ir-194</i>			Solid	<i>Impurity, see Table 3</i>
<b>P-32</b>	2	20WC	Solid	Ground (truck)/Boston Area/1300 miles

4. Provide letters of confirmation from the end-users, (i.e., recipient material licensees,) of the DOT Specification 20WC-1 and 6M packages to support the justification of any shipments needed beyond August 31, 2012. The letter should also further explain the specific impacts if a planned shipment after August 31, 2012 is not approved by the NRC.

Letters of Confirmation from QSA Global, PerkinElmer Life Sciences, IsoRay Medical, Alpha-Omega Services, and Lantheus are provided as **Attachment B** to this response.



### Conclusion

The University of Missouri Research Reactor has made every effort to obtain compliant packaging so that we may continue our safe and responsible shipment of Type B quantities of radioactive materials throughout the United States. We are in the midst of manufacturing one package design and on the cusp of submitting the SARP for a second package design, along with an accelerated manufacturing plan for that design.

We ask that in the short term, the NRC agree to authorize MURR to ship in tandem with what is allowed under DOT Special Permit SP 14657, and in addition, consider authorizing shipments into 2013 to allow for the delivery and deployment of the SAFKEG-HS packages.

As MURR serves radiopharmaceutical companies with some of the materials shipped in Type B quantity, we ask that NRC notify MURR as soon as possible if this request is going to be denied. We must provide our customers with as much lead time as possible to help them arrange for an orderly shutdown of production and for notification of cancer patients scheduled to receive treatments.

Your time and attention to this response is appreciated. If you have any questions or concerns, please do not hesitate to contact me at the address, phone number or email address above. Mr. Michael Flagg is the technical point of contact for this project at MURR and may be reached via email at [FlaggM@missouri.edu](mailto:FlaggM@missouri.edu) or by phone at 573-882-5364.

Sincerely,

Ralph A. Butler  
Director, University of Missouri Research Reactor

Date

Docket Numbers: 71-9337, 71-9338, 71-9343  
TAC Number: L24657

Enclosures: Attachment A (Manufacturing Schedule for SAFKEG-LS Package), Attachment B (Letter of Confirmation from PerkinElmer Life Sciences, Letter of Confirmation from QSA Global, Letter of Confirmation from IsoRay, Letter of Confirmation from Alpha-Omega Services, Letter of Confirmation from Lantheus Medical Imaging)

cc: Jim Williams, Department of Transportation



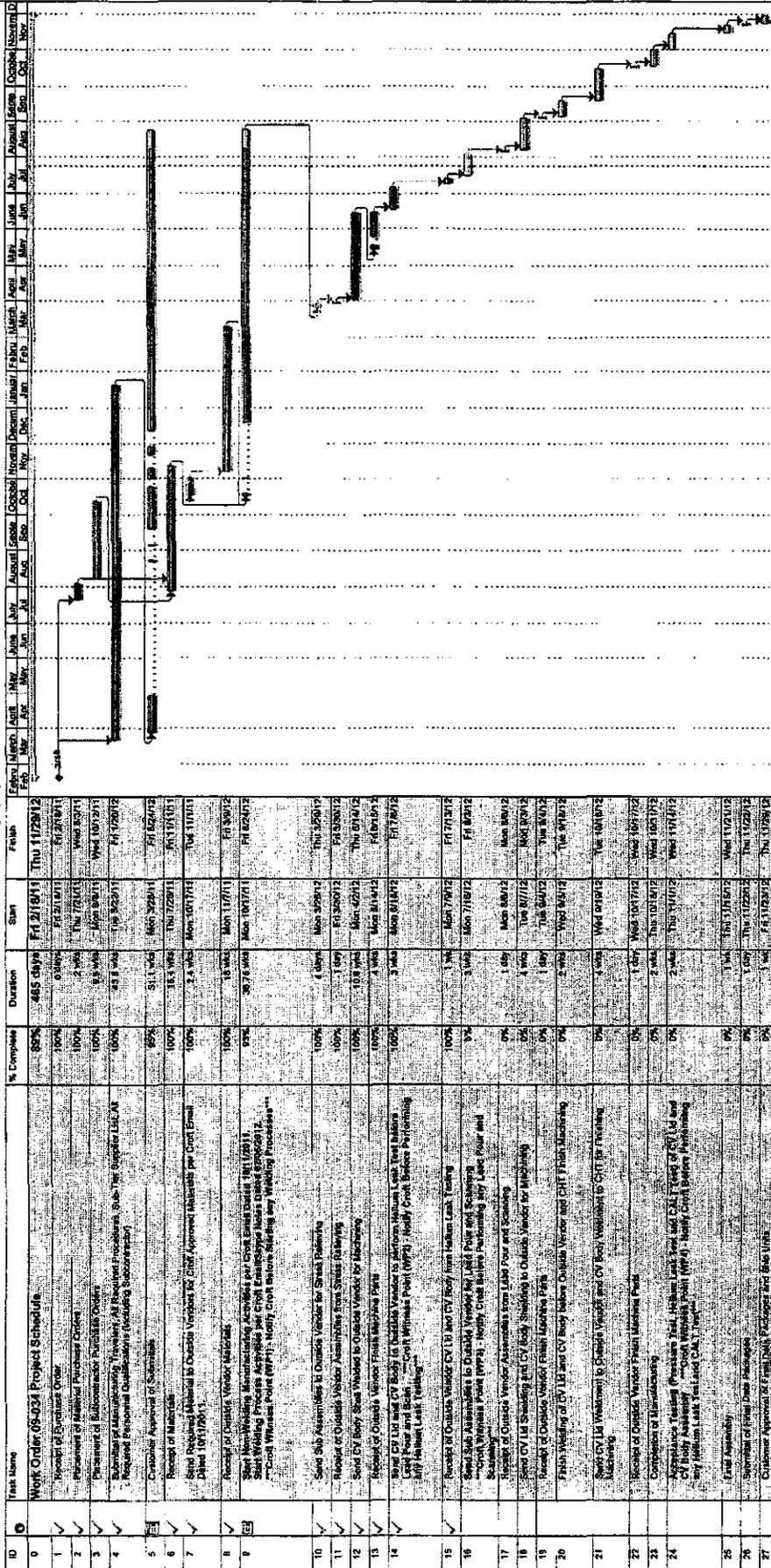
Research Reactor Center  
University of Missouri-Columbia

1513 Research Park Drive  
Columbia, MO 65211

Phone (573) 882-4211  
Fax (573) 882-6360

# Attachment A

**CRT Work Order: 09-034**  
**Croft Purchase Order 70131d**  
**Safety LS Packaging Design Number 3979A**  
**Qty: (85) Units**





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# Attachment B