Research Reactor Center
University of Missouri-Columbia

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Dr. Magdy El-Sibaie
Associate Administrator for Hazardous Materials Safety
Attention: Special Permits, PHH–31
Pipeline and Hazardous Materials Safety Administration
U.S. Department of Transportation
East Building, 1200 New Jersey Avenue, SE.
Washington, DC 20590–0001

22 April 2014

Dear Dr. El-Sibaie,

This letter serves as a timely renewal request for Special Permit **DOT-SP 14657 (Rev. 6)** which is scheduled to expire on June 30, 2014. We request that the special permit be renewed for a period of sixty (60) days from June 30, 2014 until August 30, 2014. Details associated with Revision 6 of this permit remains accurate.

Contact Information:

University of Missouri Research Reactor
1513 Research Park Dr.
Columbia, MO 65211
D&B #: 030000603

Business Contact: Michael Flagg, flaggm@missouri.edu, (573) 882-5364

Director of the Reactor: Ralph Butler (CEO Equivalent)

All shipments of radioactive material in the packages covered under this special permit will originate from the University of Missouri Research Reactor (MURR), at the address above and MURR will act as the shipper (offeror) under the terms of this special permit.

Special Permit SP 14657 (Revision 6) Renewal Request

MURR was granted Special Permit SP 14657, which is scheduled to expire on June 30, 2014. We request that the special permit be renewed for a period of **sixty (60) days** from June 30, 2014 until August 30, 2014.

Class 1 materials are not covered by this request and our shipping personnel will not participate in the transportation of Class 1 material under this permit.

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Replacement Efforts

We continue our efforts (through our vendor, Croft Associates, Ltd.) to replace our fleet of DOT Specification packages with a new fleet that is compliant with 10CFR71.

SAFKEG-LS

The SAFKEG-LS (Croft Model 3979A) has been issued a Certificate of Compliance by NRC (CoC) and a Competent Authority Certification by **DOT (USA/9337/B(U), Revision 0**). The packages have been in routine use since January of 2013 for radioisotopes that are allowed under the NRC Certificate of Compliance associated with the packaging.

SAFKEG-HS

The SAFKEG-HS (Croft Model 3977A) was issued a Safety Evaluation Report (SER) and Certificate of Compliance (CoC) by NRC on 31 March 2014. Croft has also applied for a competent authority certification, that we expect to be designated **(USA/9338/B(U), Revision 0)** upon approval.

You will find a list of the DOT Specification Packaging associated with this renewal request, along with the details of those shipments, provided in **Attachment A**.

Current Transition Activities

With licensing complete, the remaining tasks are to take delivery of the packages from the vendor and to make preparations for transition of customers to the new packaging. The fleet of fifteen (15) SAFKEG-HS packages ordered by MURR are in final fabrication and are expected to ship to MURR by the first week of June, 2014.

Rationale for the Renewal Request

While MURR expects to receive the packages prior to the expiration of SP-14657 (Rev. 6), the short period between package receipt and the expiration date will not allow for adequate transition time for either MURR or our end users to properly and safely implement use of the new SAFKEG-HS packaging.

Transition activities include:

- Formal examination, receipt, and acceptance of the packages under MURR's Quality Assurance Program for Type B Shipments under NRC License No. 0108 (Rev. 9)
- Comparison of delivered packages to assumptions made when the package use Standard Operating Procedure (SOP) was written and update/revision of the SOP as necessary
- Delivery of SAFKEG-HS packages to all potential end-users, accompanied by appropriate tooling and instructional materials on the use and handling of the packaging and associated inserts
- Support of end-users as they test the packages with their existing infrastructure

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- Receipt of the packages from the end-users, examination, and formal implementation of use

Our previous experience with the implementation of the SAFKEG-LS packages indicates at least sixty (60) days are necessary to properly move through all the necessary tasks.

Demonstration of time-dependent life, health, safety, property, security, extreme economic, or other critical impact, if transport were not to be allowed, prepared by MURR and the affected client entity(ies)

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.

Even with the SAFKEG-LS in service, MURR still relies on the 6M and 20WC-1 packaging for roughly 25% 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 ($3.5 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 will end MURR's ability to fund our package replacement program, result in significant lay-offs, and endanger the continued operation of MURR.

MURR is the largest university research reactor in the United States at 10 MW_{th}. 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.

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 has fully transitioned to routine shipment in the SAFKEG-LS packaging.

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. The SAFKEG-LS package is not rated to carry the current activity demanded by our customer to supply this radioisotope.

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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. Due to shielding limitations, the SAFKEG-LS cannot transport the quantities of P-32 we provide to customers.

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. Shipments of this radioisotope that are within the limits of the NRC Certificate of Compliance, are transported in the SAFKEG-LS.

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.

Demonstration that there is no other suitable method to conduct the transport in accordance with the HMR (e.g., rearrange into Type A shipments, wait for radioactive decay or approved replacement packagings, alternate vendor or supplier, etc.)

MURR has 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 Ir-192 (Ir-194), Ba-135m (Ba-131, Cs-131), P-32

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 Ir-192 (Ir-194), Ba-135m (Ba-131, Cs-131), P-32

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:

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- 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 Ir-192 (Ir-194), Ba-135m (Ba-131, Cs-131), P-32

The materials shown in **Table 2, Attachment A**, 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 materials, 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.

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- 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.

Waiting for Decay

The radioisotopes we produce are mostly short-lived and destined for medical purposes. These require a high specific activity. In addition, the materials we ship under the special permit, as described above, are bulk shipments destined for radiopharmaceutical producers or brachytherapy distributors. Waiting for decay to reduce the activity below Type B quantities would render the material useless.

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 to continue using the DOT specification packages past June 30, 2014.

Alternate Vendors/Suppliers

As described in 3(a), above, MURR is either the sole world-wide supplier, sole domestic supplier, or a major source for several of the radioisotopes shipped under this special permit. Having our customers shift to alternate suppliers would result in significant delays and disruptions of supply, as well as result in severe economic consequences for MURR.

Demonstration that there is no available alternative packaging allowed by the HMR that may be used. A current search must be conducted and the details of that search must be provided

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 upon review of these packages in Q3 of 2013, implementation of any of these designs remains impractical for a variety of reasons, including approved contents, delivery timeline, and budget:

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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 natrium 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).

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 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 in service at MURR and this package would not expand that capability.

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. 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. 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. In addition, the few available

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options are economically unfeasible for MURR, particularly in light of the already significant investment in the current pathway.

Quality Assurance Program. The current Quality Assurance Program under which the use, repair, and maintenance of the DOT specification packagings will be conducted

MURR operates the Type B package fleet under NRC QA Certification Approval No. 0108 (Docket Number 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.

Package Implementation Summary

We are in the final phases of the transition effort which has been conducted while using our DOT Specification Packages under SP-14657. Upon receipt and implementation of the SAFKEG-HS fleet, MURR will request termination of Special Permit SP-14657 if such implementation occurs prior to August 30, 2014.

Contact

The point of contact for inquiries is Mr. Michael Flagg, who may be reached at **(573) 882-5364** or via email at **flaggm@missouri.edu**.

Thank you for your time and consideration of this request.

Sincerely,

Ralph A. Butler
Director, University of Missouri Research Reactor

22 April 2014
Date

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Attachment A

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Package Information - DOT Specification Package Identification (Model and Serial Numbers)

The information for each package covered by this special permit is provided in **Table 1**, below:

Serial Number	Model	Year of Manufacture
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

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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

Table 1 Package Information

Shipment Details - (a) Number of consignments; (b) number of packages per consignment; (c) package contents; (d) end use of the radioactive material; (e) origin and destination of transport; (f) approximate travel distance; and (g) mode

The number of consignments, number of packages per consignment, isotope shipped, destination, travel distance and mode are provided in **Table 2**. All packages originate in Columbia, Missouri. The end use for each isotope is provided in **Table 3**.

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/1000 miles – 1700 miles
Ir-194			Solid	*Impurity, see Table 3*
Ba-135m	1	20WC	Solid	Ground (truck)/Seattle area/2000 miles
Ba-131			Solid	*" Impurity," see Table 3*
Cs-131			Solid	*"Impurity," see Table 3*
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

Table 2 Shipment Information

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Isotope	Form	Use
Sm-153	Solid (powder in quartz vial in canister)	**Cancer Treatment**
Ir-192	Solid (wires or buttons in aluminum block or confinement)	**Cancer Treatments, Industrial Radiography**
Ir-194	Solid (wires or buttons in aluminum block or confinement)	*Impurity with Ir-192*
Ba-135m	Solid (powder in canister)	*Impurity with Ba-131, dominant isotope for shipping*
Ba-131	Solid (powder in canister)	*Parent of Cs-131*
Cs-131	Solid (powder in canister)	**Cancer Treatment, daughter from Ba-131**
P-32	Solid (powder in canister)	**Tracer for biomedical research**
Yb-169	Solid (powder in quartz vial in canister)	**Industrial Radiography**

Table 3 Use of Material