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July 30, 2012

Pierre Saverot, Sr. Project Manager
Licensing Branch
Division of Spent Fuel Storage and Transportation
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-001

Copy to:

Associate Administrator for Hazardous Material
Safety
Pipeline and Hazardous Materials Safety
Administration
U.S. Department of Transportation
1200 New Jersey Avenue, S.E.
Washington, D.C. 20590-0001

Attn: Special Permits, PHH-31

Subject: RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION
Re. APPLICATION FOR LIMITED CONTINUED USE OF THE MODEL No. 1500
PACKAGE, CERTIFICATE OF COMPLIANCE No. 5939

References:

- 1) NRC Letter to GEH Re. Application for Limited Continued Use of the Model No. 1500 Package, Certificate of Compliance No. 5939, dated June 20, 2012.
- 2) GEH Letter to NRC, Request for NRC Public Meeting Re. Limited Continued Use of the Model No. 1500, Certificate No. 5939, dated March 30, 2012.
- 3) Application for Limited Continued Use of the Model No. 1500 Type B Package, Certificate of Compliance No. 5939, Dated December 5, 2011.

This letter is in response to the USNRC's letter of June 20, 2012, signed by Michael Waters, Chief, Licensing Branch, Division of Spent Storage and Transportation, Office of Nuclear Material Safety and Safeguards, concerning the Application for Limited Use of the Model No. 1500 Package, Certificate of Compliance No 5939, RAI 3 letter of clarifications of shipments that are critical and necessary between now and December 2012 to ensure public health and

safety, maintain national security interests, provide medical therapies and/or other crucial needs to materials licenses.

JL Shepherd and Associates (JLS&A) currently has seven clients requiring a total of ~72,146 Curies Cobalt-60, in various activities and source capsules to meet both the client's specific requirements and the Sealed Source and Device Registry requirements for the client's specific device to be shipped before December 31,2012. With the exception of Defense Microelectronics Activity's (DMEA) sources were specifically designed to be shipped in the GE 1500, the remainder of the client's sources are typically shipped to JLS&A's hot cell from GE Hitachi Nuclear Energy in the GE 1500 for source unloading, additional source adaptation for use specific to the device they will be loaded into, and then reloading into the device for Quality Assurance objectives and/or for loading into smaller Type B transportation containers for delivery to the client. The use of the GE 1500 is important to public health and safety for these applications as this package can deliver the six client sources in two shipments as opposed to ~ sixteen individual shipments in the smaller wattage Type B packages.

Four client shipments are important to maintain national security interests.

#1 Defense Microelectronics Activity (DMEA):

DMEA has a federal contract with JLS&A for DMEA's irradiator to be reloaded with two high activity Category 1 Cobalt-60 source capsules. Ted Glum, Director, Defense Microelectronics Activity, has previously submitted a letter concerning DMEA's requirements for these sources to Pierre Saverot, the substance of which is reiterated below.

"The Defense Microelectronics Activity (DMEA), under the Office of the Secretary of Defense (OSD), is the Department of Defense (DoD) center for microelectronics technology, acquisition, transformation, and support. DMEA provides microelectronic solutions for the full spectrum of the U.S. Government, its allies, and their defense contractors.

A major component of DMEA's mission is the production of microelectronic devices for DoD weapon systems which are no longer available through commercial channels. DMEA's Advanced Reconfigurable Manufacturing of Semiconductors (ARMS) foundries are able to generate these out-of-production devices, often with enhanced capabilities, to keep U.S. weapons systems effective and operational. As a Trusted Integrated Circuit (IC) Supplier, the ARMS foundries can also reduce the potential for counterfeit electronic parts to infiltrate U.S. weapons systems, which could compromise national security.

The ARMS foundries are responsible for producing radiation-tolerant/radiation-hardened (rad-tolerant/rad-hard) microelectronics devices. To verify that these devices meet their rad-tolerance/rad-hard specifications, they must be tested for Total Ionizing Dose (TID) in a Co-60 radiation field. DMEA's Science and Engineering Gamma Irradiation Test

(SEGIT) Facility provides this TID testing capability. The SEGIT Facility's two J.L. Shepherd & Associates (JLS&A) Model 81-22/484 irradiators, one for high dose work, and the other for low dose testing, are covered under NRC License No. 04-29107-01.

The SEGIT High Dose Irradiator must be reloaded frequently to provide the high doses necessary to support ARMS foundries' rad-tolerant/rad-hard TID testing requirements. Since its installation in 1994, this irradiator has been reloaded with new Co-60 sources in 1997, 2001 and 2005. Due to budgetary pressures, DMEA was unable to fund another reloading of this irradiator until this year. We now have a contract in place with JLS&A to provide new Co-60 sources for this irradiator (Contract No. H94003-12-C-1204). However, we have learned through JLS&A that the General Electric Model No. 1500 Package required to ship the new sources to DMEA's facility near Sacramento, CA is no longer certified for use.

"If the new Co-60 sources cannot be shipped to DMEA in the near future, our ability to adequately test ARMS-produced devices will be significantly impacted. The importance of the SEGIT Facility's role in rapidly assessing the rad-tolerant/rad-hard aspects of ARMS-generated microelectronics, and allowing ARMS processes to be modified/reassess to meet critical delivery schedules, cannot be overstated."

#2 Honeywell International:

Honeywell has an existing contract with JLS&A for their irradiator to be reloaded with three each high activity Category 1 Cobalt-60 source capsules. Jacob Groves, Technical Manager Component & Radiation Test has previously submitted a letter concerning Honeywell's requirements for these sources to Pierre Saverot, the substance of which is reiterated below:

"Honeywell Aerospace in Clearwater, Florida uses three Cobalt-60 irradiators ... supplied by J.L. Shepherd and Associates for conducting total ionizing dose radiation testing to meet space and defense program and contractual requirements in adherence to military standards.

Because the Co60 decays over time, to meet our radiation dose requirements, these irradiators require periodic reloading. The only entity licensed to perform this service is J.L. Shepherd and Associates. We are currently at a critical juncture with our model 484C irradiator, which is used to support all of Honeywell's high dose irradiations. The acceptable dose rate over a useful surface has shrunk and immediate replenishment is required to resolve.

We have an existing contract to reload our 484C irradiator with ... Co-60. Not extending the Special Permits ... will significantly impact our operations and ability to meet existing contractual obligations."

#3 Hill Air Force Base:

Hill AFB has a federal contract with JLS&A for the Little Mountain irradiator to be reloaded with eight high activity Category 1 Cobalt-60 source capsules.

JLS&A has found this description on the Hill AFB website: "Part of Hill AFB. The Little Mountain Survivability and Vulnerability Integration Center is part of the Air Materiel Command's sprawling Ogden Air Logistics Center. It accomplishes simulation testing of nuclear hardness, survivability, reliability and electromagnetic interference and compatibility. It simulates six environments: nuclear radiation, airblast, shock and vibration, in-flight vibration, electromagnetic pulse and electromagnetic interference and compatibility. Advanced satellite technology is utilized and tested effectively from this location, along with R&D associated with propellants and radioactive materials."

#4 Si-Rel:

Leo M. Bobek, Vice-President, Si-REL, LLC, has previously submitted a letter on June 8, 2012 concerning Si-Rel's requirements for these sources to Pierre Saverot, the substance of which is reiterated below.

"Si-REL is a small business, incorporated in Massachusetts to provide radiation effects testing of electronics used in radiation environments. Most semiconductor devices and microelectronics manufactured for use in radiation environments must be tested for radiation hardness assurance (RHA). There is an increasing demand for RHA electronics for use in space by the Department of Defense and commercial satellite providers. Correspondingly, there is an increasing demand for radiation test facilities capable of RHA testing.

Si-REL has established contracts for RHA testing with Microsemi Corporation, Analog Devices Incorporated, International Rectifier, Symmetricom, and other electronics manufacturers. Each of these listed companies provides RHA electronics to the Department of Defense, many of which would be tested at Si-REL.

Si-REL has a license for RAM by the Massachusetts Radiation Control Program. The viability of this small high-technology start-up business is vitally dependent on the ability to procure a self-shielded Cobalt-60 irradiator in the next few months. In order to perform tests to military specification standards, the self-shielded irradiator must contain" Category 1 of Cobalt-60 sources.

"If the irradiator and source cannot be procured, the principal means for generating income for Si-REL will be lost, along with the loss of four start-up employees, several future hires, and the ripple effects on the RHA electronics divisions the aforementioned companies. One of the companies mentioned has indicated to us that if Si-REL does not become viable for testing this year, their company will establish a radiation testing facility in the Philippines.

JLS&A is the only domestic manufacturer of high specific Cobalt-60 self-contained irradiators. Their existing shipping system is the only viable mechanism for Si-REL, LLC to procure the self-contained with the required high specific activity Cobalt-60. The alternative proposal for shipments after October of 2012 to ship quantities of less than 3320 Ci per shipment would require 4 shipments instead of the single shipment. This would be cost prohibitive and require almost 2 months of additional labor and delay in startup of operations.

We greatly appreciate the tremendous responsibility entrusted in both the NRC and DOT for protecting the environment and the health and safety of the public from unnecessary radiation exposure. However, when evaluating this Authorization for Shipment approval, please also consider the economic impacts to multiple businesses. Such impacts should be compared to the low relative risk associated with allowing the use of the JLSA shipping packages which have been used safely and without incident for many years.”

“If the irradiator and source cannot be procured, the principal means for generating income for Si-REL will be lost, along with the loss of four start-up employees, several future hires, and the ripple effects on the RHA electronics divisions the aforementioned companies. One of the companies mentioned has indicated to us that if Si-REL does not become viable for testing this year, their company will establish a radiation testing facility in the Philippines.

Three client shipments are important to maintain medical therapies or other crucial biomedical research.

#1 National Institutes of Health (NIH), Rocky Mountain Laboratory:

NIH, Rocky Mountain Laboratories has an anticipated requirement with JL Shepherd & Associates for our irradiator to be reloaded with three high activity Category 1 Cobalt-60 source capsules within the next few months. Cathy Ribaud, Irradiator Security Manager, Division of Radiation Safety, NIH, Bethesda, MD, has previously submitted a letter on May 29, 2012 concerning NIH’s requirements for these sources to Pierre Saverot, the substance of which is reiterated below.

“The National Institutes of Health (NIH) possesses multiple Co-60 and Cs-137 sealed source irradiators which may require transport for relocation or disposal, and the Co-60 irradiators may require reloading. Several of these irradiators are manufactured by J.L. Shepherd and Associates, and as such, it is critically important that this company have the means to be able to service our source transportation needs as they arise.

The irradiators are used to support a wide variety of basic research, translational and clinical research needs, and their ready availability is crucial for biomedical research at the NIH.”

#2 Sanaria Inc.:

Sanaria has an anticipated requirement with JL Shepherd & Associates for our irradiator to be reloaded with two high Activity Category 1 Cobalt-60 source capsules within the year. Richard Stafford, Sr. Manager, Quality Operations, has previously submitted a letter on May 29, 2012 concerning Sanaria's requirements for these sources to Pierre Saverot, the substance of which is reiterated below.

"Sanaria Inc. uses a Model 494R-2" (JLS&A note SS&DR submodel B) "(serial number 7202) Co-60 irradiator containing a ... IAEA Category 1 Co-60 source supplied by J.L. Shepherd and Associates. This irradiator is an essential component in the manufacture of Sanaria's novel malaria vaccine. Every year malaria is responsible for over 750,000 deaths, mostly to children in sub-Sahara Africa and some 300 million people become ill with malaria including 30,000 international travelers and military personnel. The research, development and current clinical testing of our vaccine is a culmination of over 9 years of investment and close collaboration with the National Institutes of Health, National Institute of Standards and Technology, the Bill and Melinda Gates Foundation, and members of the European and African communities including the governments of Tanzania and the Netherlands, and the European Vaccine Initiative. This vaccine is currently in clinical trials at the NIH Vaccine Research Center and will soon be tested in a parallel trial in Tanzania.

The vaccine is composed of malaria parasites which are attenuated from radiation using the Model 494R-2 irradiator" (JLS&A note SS&DR submodel B). "To meet our vaccine manufacturing requirements this irradiator requires reloading of Co-60 in the near future which is performed by JL Shepherd and Associates, the only entity licensed to perform the service. The possibility of not being able to reload the Co-60 in a timely manner and thus shutting down the entire vaccine development enterprise is unconscionable, as currently there is no effective malaria vaccine available which results in the death of over 7000 children daily as a result of malaria infection."

#3 STAAR Surgical:

Alex Ossipov, Chief Chemist and RSO, has previously submitted a letter on May 18, 2012 concerning Staar Surgical's requirements for these sources to Pierre Saverot, the substance of which is reiterated below.

"STAAR Surgical Company develops, manufactures and sells ophthalmic devices implanted by surgeons in patients during refractive, cataract and glaucoma-related surgeries. Company's main products are unique foldable small incision ophthalmic implants. The Company has developed a unique (no other analogs in world) biocompatible Collamer material that greatly assists patients. The Collamer manufacturing process to create our Collamer material requires using of a high dose irradiator exclusively for the special synthesis phases. Such products are the back-bone to STAAR's proprietary products range and allow STARR to employ workers in the U.S. and compete effectively around the world.

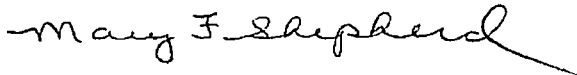
It is critical that STAAR's high dose irradiator be reloaded to provide enough of the high dose rates necessary to support our California-based manufacturing team in the production of our current medical devices and to enable our California-based research workers during their R&D efforts. Since its installation in 1997 the irradiator located in Aliso Viejo that we use has never been reloaded with new Co-60 sources. For STAAR to continue with its manufacturing and R&D efforts in the U.S., we need new Cobalt-60 sources.

STAAR's two J.L. Shepherd & Associates (JLS&A) Model 109-68 gamma irradiators are covered under NRC License Number: CA 6299-30.

STAAR now has a contract in place with JLSB/A to provide new Co-60 sources and replace the existing depleted sources for this irradiator. However, we have learned through JLS/A that the General Electric Model No. 1500 Package required to ship the new and de-commission the depleted sources to STAAR Surgical, CA is no longer certified for use.

If the new Co-60 sources cannot be shipped to STAAR in the near future, our ability to produce Collamer material will be significantly impacted, which will endanger our ability to provide medical devices to patients in the U.S. and around the world, as well as keep our manufacturing and R&D teams in the U.S. working."

Sincerely,



Mary F. Shepherd
Vice President, Licensing & Special Projects