



71-5979

May 16, 2011

ATTN: Document Control Desk
Director, Division of Spent Fuel Storage and Transportation
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-001

SUBJECT: REQUEST FOR EXTENSION OF AUTHORIZATION FOR LIMITED SHIPMENTS IN AOS 5979,
TYPE B PACKAGE, USA/5979/B ().

Dear Sir or Madam,

This letter serves as a request from Alpha-Omega Services, Inc. (AOS) for an extension of the expiration date of the Authorization for Limited Shipments for the AOS 5979 package, due to delays in the Safety Analysis Report (SAR) approval process. Alpha-Omega Services, Inc. requests that the NRC extend the Authorization for Limited Shipments from October 31, 2011 to June 30, 2012. A similar request has been sent to the DOT.

AOS currently operates a fleet, consisting of two packages, Serial Numbers AOS I and AOS II/IIIA, for the transportation of Cobalt 60 (CO-60) Special Form sources for use in medical applications under this Special Permit. AOS 5979 Packages are operated and maintained under AOS Quality Program PR9000, approved by the NRC under Docket No. 71-0086 with an expiration date of July 31, 2019. The proposed shipments under this license extension shall consist of Cobalt 60 (CO-60) in Special Form encapsulation, for the treatment of brain ailments at domestic hospitals. Because these shipments must meet the criteria of Radioactive Materials Quantities of Concern (RAMQC), they are subject to additional security measures, as defined in U.S. NRC Order EA-05-006. Shipment details cannot be published until the shipment has occurred. All shipments will be transported as "Exclusive Use." Shipments consist of one package per shipment and will originate at the source fabrication facility, and terminate at a hospital facility where the sources are installed into the treatment (Gamma-Knife) unit and where applicable the sources removed from the treatment unit in case of a re-load, will be transported from the hospital to the recycling facility. The projected estimate of number of shipments is 42.

The AOS-5979 container is used to transfer either 201 or 192, dependent upon Gamma-Knife model, of CO-60 sealed sources. Each source contains approximately 1.07 TBq (29.5 Ci) of CO-60. These sources are either installed or removed from the Gamma-Knife unit, which is manufactured by Elekta, a Swedish company. The AOS-5979 container is docked with the

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Gamma-Knife unit by use of a "Loading Machine," specifically designed for use with the AOS 5979 for domestically located Gamma-Knives, and the Croft 2773A container for internationally located Gamma-Knives. Without use of the AOS 5979 container, loading and unloading operations of CO-60 sources into/from the Gamma-Knife unit will be disrupted at best or completely stopped at worst, resulting in delays and/or suspension of this life-saving procedure to patients in need of this service.

The following measure will be taken to ensure package safety during the extension:

- 1) Conduct all shipments under the extended license as RAMQC, in accordance with U.S. NRC Order EA-05-006.

AOS has attempted to meet the regulations in a timely manner. In 2005, AOS contracted a vendor (GE Nuclear Energy) to develop a family of Type B packages to meet the regulatory changes that took effect October 1, 2008. A two-year effort culminated in October 2007, when the Safety Analysis Report (SAR) for these new packages was submitted to the NRC, under NRC Docket No. 71-9316. In April 2008, NRC staff informed AOS that major technical deficiencies were found in the application. In consultation with its vendor, AOS withdrew the application in April 2008, with the intention to correct the technical deficiencies and re-submit the application as soon as possible. Revision B of the SAR was submitted by AOS to the NRC in September 2009. AOS received a Request for Supplemental Information in July 2009. Revision C of the SAR and our response to the July 2009 RSI's were submitted to the NRC in September 2009. AOS then received 100 each RAI's in December 2009. Due to the number of RAI's, our response required a significant amount of work; however, we were able to submit Revision D of the SAR and our response to the RAI's on September 29, 2010. We received the last round of RAI's in March 2011 and expect to submit our response by August 15, 2011. Based on this schedule, we estimate to be granted the license in October, 2011.

The CO-60 Special Form sources, in Type B quantities, that AOS transports in its AOS 5979 Packages are used for brain cancer medical therapy at hospitals across the USA. A total of either 201 or 192 sources are transferred at one time. The transferred quantity depends upon the therapy equipment model. Each CO-60 source has strength of up to 1.2 TBq (33 Ci). The strength of each source alone exceeds the regulatory Type A quantity for CO-60 radioisotopes; therefore, breaking the shipment into Type A quantities is not possible.

Without the ability to transport these sources to the hospitals using AOS 5979 Packages, the medical treatment of many brain cancer patients will be disrupted at best, or completely stopped at worst. These hospitals and patients would then be forced to rely solely upon foreign sources transported by foreign packages. Most of the foreign packages cannot be coupled to the therapy unit, for its source loading and unloading operations. In addition, using foreign vendors will severely impact AOS and the current domestic chain suppliers economically.

If you have any questions concerning this request, please contact me at 562.804.0606, ext. 141.

Sincerely,

A handwritten signature in black ink, appearing to read 'Bob A. Robnett', with a stylized flourish at the end.

Bob A. Robnett
Director Operations & Regulatory Affairs
Alpha-Omega Services, Inc.
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Bellflower, CA 90706