



71-5979

August 31, 2010

ATTN: Michele M. Sampson, Sr. Project Manager
Licensing Branch
Division of Spent Fuel Storage and Transportation
Office of Nuclear Material Safety
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

SUBJECT: RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION FOR
REVIEW OF THE MODEL NO. 5979 PACKAGE LIMITED
AUTHORIZATION

REFERENCES: DOCKET NO. 71-5979, TAC NO. L24454

Ms. Sampson:

In response to your letter dated August 23, 2010; "REQUEST FOR ADDITIONAL INFORMATION FOR REVIEW OF THE MODEL NO. 5979 PACKAGE LIMITED AUTHORIZATION", please find attached the additional information for the transportation package Model No. 5979, Certificate of Compliance No. 5979.

In addition, we request the Authorization for Limited Shipments be extended to October 31, 2011 rather than October 4, 2011.

Thank you for your consideration.

If you have any questions concerning this request, please contact me at (526) 804-0604, ext. 41.

Sincerely,

A handwritten signature in black ink, appearing to read "Bob A. Robnett", with a long horizontal stroke extending to the right.

Bob A. Robnett
Director Regulatory Affairs & Quality
Alpha-Omega Services, Inc.
9156 Rose Street
Bellflower, CA 90706

Enclosure: Additional Information

NMSS24

Additional Information
Alpha-Omega Services, Inc.
Docket No. 71-5979
Certificate of Compliance No. 5979
Model No. 5979

RAI-1 *“Provide shipment information, to include: number of shipments; number of packages per shipment; end use of the radioactive material; shipment origin and destination; mode; and general timeframe. This information should describe all shipments requested for approval during the period November 1, 2010, through the requested expiration date. The application does not provide a description of the requested shipments. Staff may only consider authorizing those specific shipments detailed in an application. This information is required to assess compliance with 10 CFR 71.31.”*

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 30.

RAI-2 *“Provide additional justification for continued use of the package to fully address all potential Reasons for Requesting Extended Use. If there are any adverse impacts that will result from failure to conduct the shipment, these should also be detailed. The intent of RIS 2008-18, was to allow a transition period for applicants who had made a good faith effort, but did not meet the October 1, 2008, transition date. The application does not provide a compelling reason as to why use of this expired package, nearly two years after the package expired, is still justified. The application should detail any actual adverse impacts that will result for each requested shipment, if the shipment were not authorized. This information is required to assess compliance with 10 CFR 71.31.”*

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 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 replacement container for the AOS-5979, the AOS-100 (a container within the AOS Transport Packaging System), has been under development since 2005. The Safety Analysis Report (SAR) documenting the AOS-100 will be re-submitted by September 20, 2010, with anticipated approval in April, 2011 and the first package ready for use 6-9 months later.

RAI-3 *"Provide a description of the compensatory measures that will be used to provide an equivalent level of safety for each shipment requested. Examples of compensatory measures that may be considered are detailed in RIS 2008-18. The Model No. 5979 expired package design may lack safety enhancements included in designs which meet all current regulatory requirements. The application does not - 2 - include a safety justification for continued use which details the measures which will be taken for each shipment to ensure safety. This information is required to assess compliance with 10 CFR 71.31."*

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.

RAI-4 *"Provide the plan and schedule to acquire a replacement package. AOS had indicated that the replacement package, Docket No. 71-9316, proposed in the previous application for continued use of the Model No. 5979 package, dated September 17, 2008, would be ready for use by November 1, 2010. The current application provides no information regarding the proposed implementation date for the replacement package. Staff notes that a RAI was issued for Docket No. 71-9316, on December 24, 2009, and that no response has been provided. An extended period of nearly eight months with no response to staff's request does not appear to show a continued good faith effort to transition away from the expired packaging. This information is required to assess compliance with 10 CFR 71.31."*

In February 2005, AOS entered into a contract with General Electric Nuclear (GE) to develop a Type B Transport Packaging System, in accordance with the provisions of 10CFR Part 71, to replace Packaging AOS-5979, Docket No 71-5979. The application for the Certificate of Compliance was submitted by AOS to the NRC in October 2007, and supplemented November 2007, under

Docket No. 71-9316. In a conference call between AOS and the NRC on April 7, 2008, the NRC staff informed AOS of major technical deficiencies found in the application. On April 29, 2008, AOS informed the NRC staff, by letter, of its withdrawal of the AOS Transport Packaging System application, and intent to re-submit the application upon revising it to address the open technical issues identified by the NRC staff.

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 was 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 has taken longer than expected, however we intend to submit Revision D and our response to the RAI's by September 20, 2010. Based upon this schedule, AOS estimates to be granted the license in April, 2011, with the first package ready for use 6-9 months later.