

July 26, 2012

Mr. Bob A. Robnett
Director, Regulatory Affairs & Quality
Alpha-Omega Services, Inc.
9156 Rose Street
P.O. Box 789
Bellflower, CA 90706

SUBJECT: AUTHORIZATION FOR LIMITED SHIPMENTS IN THE MODEL
NO. 5979 PACKAGE, CERTIFICATE OF COMPLIANCE NO. 5979

Dear Mr. Robnett:

As requested by your application dated May 1, 2012, supplemented June 5 and July 18, 2012, and pursuant to 10 CFR Part 71, Alpha-Omega Services, Inc. (AOS) Certificate of Compliance No. 5979, for the Model No. 5979, package is amended to authorize the following limited shipments, subject to the conditions listed below.

1. Packaging. Model No. 5979 packagings, conforming to Alpha-Omega Services, Inc. (AOS), Drawing Nos.: 0094, Rev. 1; 0095, Rev. 0; 0096, Rev. 0; and 0097, Rev. 1.
2. Contents
 - (a) Type and form of material

Cobalt-60 as sealed sources that meet the requirements of special form radioactive material.
 - (b) Maximum quantity of material per package

7,000 curies and 110 watts decay heat.
3. The Model No. 5979 packagings are limited to Serial Nos. AOS I, and AOS II Cask/IIIA Overpack and Pallet.
4. Shipment must be by truck as exclusive use shipment, with a maximum of one package per shipment.
5. For any package shipped under this approval that contains greater than a Type A quantity of radioactive material, the shipment must be subject to continuous and active monitoring.
6. In addition to the requirements of Subpart G of 10 CFR Part 71:

- a) Each package must meet the Maintenance Inspection Program of the supplement dated February 9, 2009; and
 - b) The package must be prepared for shipment in accordance with the Operating Procedures of the supplement dated February 9, 2009 [ML090570576].
7. This authorization is for a maximum of 5 shipments, for the period beginning July 1, 2012, through December 31, 2012, to (i) the Cleveland Clinic Foundation, (ii) the Akron General Medical Center, (iii) the University of Minnesota-Fairview, (iv) the Barrow Neurological Institute – St Joseph, and (v) the University of California - San Francisco. The shipment to the Akron General Medical Center is for the delivery of a new source for the operation of a newly installed Gamma Knife unit while shipments to the other four facilities include the return of used sources.
8. This authorization expires December 31, 2012.

All other conditions of Certificate of Compliance No. 5979 remain the same. AOS has been issued Quality Assurance Program Approval No. 0086 for Radioactive Material Packages under the provisions of 10 CFR Part 71.

As stated in our June 25, 2012, letter, staff does not intend to grant any other authorization for this expired package. All activities pertaining to the use of the Model No. 5979 package will be terminated on December 31, 2012.

If you have any questions regarding this matter, please contact Pierre Saverot at (301) 492-3408.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

/RA/

Michael D. Waters, Chief
Licensing Branch
Division of Spent Fuel Storage and Transportation
Office of Nuclear Material Safety
and Safeguards

Docket No. 71-5979
TAC No. L24645

Enclosure: Safety Evaluation Report

cc w/encl: R. Boyle, Department of Transportation

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SAFETY EVALUATION REPORT
Docket No. 71-5979
Model No. 5979 Package
Alpha-Omega Services, Inc.
Authorization for Limited Shipments

SUMMARY

By application dated May 1, 2012, supplemented June 5 and July 18, 2012, Alpha-Omega Services, Inc. (AOS) requested authorization to continue the use of the Model No. 5979 packages beyond the package authorization expiration date of October 1, 2008.

Based on the statements and representations in the application, the staff agrees that the extension of use of the package, with the additional conditions stated below, meets the requirements of 10 Code of Federal Regulations Part 71 (10 CFR Part 71).

BACKGROUND

NRC amended the regulations in 10 CFR Part 71, effective October 1, 2004, to be compatible with the 1996 edition of the International Atomic Energy Agency (IAEA), "Regulations for the Safe Transport of Radioactive Material" (TS-R-1, as amended in 2000). As a result, certain transportation packages that are compatible to the IAEA 1967 edition are no longer authorized for use under the 10 CFR Part 71 general license after October 1, 2008.

By application dated September 17, 2008, AOS requested authorization to use its Model No. 5979 package beyond the package authorization expiration date of October 1, 2008. A total of 82 shipments were authorized for the period October 21, 2008, through October 31, 2010. A revised authorization for limited continued use of serial numbers AOS I and AOS II Cask with IIIA overpack and pallet was issued on October 8, 2010 for 15 shipments during the period November 1, 2010, through February 28, 2011. Another revised authorization was issued on February 25, 2011, for a total of 27 additional shipments during the period March 1, 2011, through October 31, 2011. AOS finally requested, and staff granted, a total of 42 additional shipments for the period November 1, 2011, through June 30, 2012.

EVALUATION

On March 8, 2012, Alpha-Omega Services, Inc. (AOS) advised staff of a planned request for extension of the Model No. 5979 package, from June 30 to December 31, 2012, because of unexpected delays in the fabrication of the Model No. AOS-100 replacement package and of the loading machine to be used with this package.

On April 11, 2012, the U.S. Nuclear Regulatory Commission (NRC) staff met with AOS staff and Elekta A.B. representatives. On April 25, 2012, staff requested AOS to (i) clarify the reason for neither identifying nor informing the NRC of the need of a new loading machine, (ii) explain the good-faith efforts taken to minimize schedule delays, (iii) discuss contingency plans if, for any reason, the loading machine is not ready for use by December 2012, (iv) detail measures that would be either considered or proposed by AOS to complete shipments deemed to be critical, (v) explain the mitigation measures to be implemented if, for any reason, the planned shipment dates from July 1 to December 30, 2012, cannot be met, and (vi) address possible limitations for each site license regarding the possibility to use foreign sources transportable in certified packages.

On May 1, 2012, staff received a request for an extension for limited shipments, supplemented June 5 and July 18, 2012. The application addresses the information needs as described in U.S. Nuclear Regulatory Commission, Regulatory Issue Summary 2008-18, "Information on Requests for Extending Use of Expiring Transportation Packages" (RIS 2008-18). The supplements dated June 5 and July 18, 2012, address more specifically staff's request for additional information (RAI) letters dated April 25 and June 25, 2012.

Staff notes that (i) AOS has provided justifications, under oath and affirmation, that transport schedules cannot be adjusted so as to be conducted with other packages certified by the NRC, (ii) end-users also supported the justification of the requested shipments, and further explained the specific impacts of not receiving a planned shipment before December 31, 2012, (iii) AOS initial request for 22 shipments was reduced to 5 shipments in response to staff's RAIs.

AOS provided updated information as follows:

- (1) Package Information. The packagings to be used are Model No. 5979 packagings, limited to Serial Nos. AOS I, and AOS II Cask/III A Overpack and Pallet. The content is a maximum 7,000 curies of cobalt-60 in sealed capsules meeting the requirements of special form radioactive material. AOS did not request any change in the packaging serial numbers or content.
- (2) Identification of Shipments. AOS requested 5 shipments for the period beginning July 1, 2012, through December 31, 2012. The shipment's destination points are the following: (i) Cleveland Clinic Foundation, (ii) Akron General Medical Center, (iii) University of Minnesota-Fairview, (iv) Barrow Neurological Institute – St Joseph, and (v) the University of California- San Francisco. The shipment to the Akron General Medical Center is for the delivery of a new source for the operation of a newly installed Gamma Knife unit while shipments to the other four facilities include the return of used sources to the recycling facility.
- (3) Reasons for Requesting Extended Use. AOS will have its replacement package, i.e., the Model No. AOS-100 package, ready for use in the Fall of 2012, while the Elekta A.B. loading machine will be ready for use no later than December 31, 2012.
- (4) Safety Justification for Continued Use and Proposed Compensatory Measures. AOS proposed specific compensatory measures to assure that shipments would have equivalent safety. The package maximum contents are limited to 7,000

curies of Cobalt-60 only. Shipments will be made by truck, as exclusive use shipments, in accordance with applicable security orders.

- (5) A Plan and Schedule to Acquire Replacement Packages or Complete Necessary Shipments. The fabrication of the Model No. AOS-100 package will be completed in September 2012, and the fabrication of the loading machine will be completed in November 2012 for delivery in the U.S. in December 2012.

Staff approves this limited number of shipments because AOS has justified good faith efforts to have an NRC certified replacement package ready for use by December 31, 2012. AOS and the end-users have also justified the actual need for such shipments, that deliver medical isotopes for cancer therapy, during the July-December 2012 time frame. Staff does not intend to grant further authorizations for use of the Model No. 5979 beyond December 31, 2012, because the previously identified Model No. AOS-100 replacement package will be available, and sufficient time has passed to arrange alternate plans for the use of an expired package.

Staff finds that the package, subject to the conditions listed below, meets the requirements of 10 CFR Part 71.

CONDITIONS

1. Packaging. Model No. 5979 packagings, conforming to Alpha-Omega Services, Inc. (AOS), Drawing Nos.: 0094, Rev. 1; 0095, Rev. 0; 0096, Rev. 0; and 0097, Rev. 1.
2. Contents
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3. The Model No. 5979 packagings are limited to Serial Nos. AOS I, and AOS II Cask/III A Overpack and Pallet.
4. Shipment must be by truck as exclusive use shipment, with a maximum of one package per shipment.
5. For any package shipped under this approval that contains greater than a Type A quantity of radioactive material, the shipment must be subject to continuous and active monitoring.
6. In addition to the requirements of Subpart G of 10 CFR Part 71:
 - a) Each package must meet the Maintenance Inspection Program of the supplement dated February 9, 2009; and

- b) The package must be prepared for shipment in accordance with the Operating Procedures of the supplement dated February 9, 2009 [ML090570576].
- 7. This authorization is for a maximum of 5 shipments for the period beginning July 1, 2012, through December 31, 2012. Shipments must be to (i) the Cleveland Clinic Foundation, (ii) the Akron General Medical Center, (iii) the University of Minnesota-Fairview, (iv) the Barrow Neurological Institute – St Joseph, and (v) the University of California- San Francisco. The shipment to the Akron General Medical Center is for the delivery of a new source for the operation of a newly installed Gamma Knife unit while shipments to the other four facilities include the return of used sources.
- 8. This authorization expires December 31, 2012.

CONCLUSIONS

Based on the statements and representations in the AOS application dated May 1, 2012, supplemented June 5 and July 18, 2012, the staff agrees that the use by AOS of the Model No. 5979 package meets the requirements of 10 CFR Part 71, subject to the conditions listed above.

Issued on July 26, 2012.