

September 30, 2011

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 16, 2011, 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 42 shipments for the period beginning November 1, 2011, through June 30, 2012. Shipments must be for the purpose of providing sources for installation into a Gamma-Knife unit or removal of sources from a Gamma-Knife unit.
8. This authorization expires June 30, 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.

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. L24539

Enclosure: Safety Evaluation Report

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

- 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 42 shipments for the period beginning November 1, 2011, through June 30, 2012. Shipments must be for the purpose of providing sources for installation into a Gamma-Knife unit or removal of sources from a Gamma-Knife unit.
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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 16, 2011, Alpha-Omega Services, Inc. (AOS), requested authorization to continue 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, supplemented on October 6, 2008, AOS requested authorization to use its Model No. 5979 packages beyond the package authorization expiration date of October 1, 2008. AOS provided the information 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 package was authorized for transport by NRC letter dated October 21, 2008 [ML082960023], which amended Certificate of Compliance No. 5979, for the Model No. 5979 package, to authorize limited shipments. AOS submitted a revision request on February 9, 2009, supplemented on February 19, 2009, to restrict the packaging serial numbers authorized for use, provide updated drawings, and updated operating and maintenance instructions. A revised authorization for limited continued use of serial numbers AOS I and AOS II Cask with IIIA overpack and pallet was issued on February 26, 2009 [ML090580104]. A total of 82 shipments were authorized for the period October 21, 2008, through October 31, 2010. On June 29, 2010, supplemented August 31, 2010, AOS submitted a request authorization to use its Model No. 5979 beyond the previous authorized time period. 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 [ML102810278]. A total of 15 shipments were authorized for the period November 1, 2010, through February 28, 2011. By application

dated December 15, 2010, AOS requested authorization to continue use of the Model No. 5979. A revised authorization was issued on February 25, 2011 [ML110590492], for a total of 27 additional shipments during the period March 1, 2011, through October 31, 2011.

EVALUATION

By application dated May 16, 2011, AOS requested authorization to continue use of the Model No. 5979 packages beyond the package authorization expiration date of October 1, 2008. AOS requested a total of 42 additional shipments for the period November 1, 2011, through June 30, 2012. AOS provided updated information to supplement the information previously provided as described in RIS 2008-18.

- (1) **Package Information.** The packagings to be used are Model No. 5979 packagings, limited to Serial Nos. AOS I, and AOS II Cask/IIIA 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 42 shipments for the period beginning November 1, 2011, through June 30, 2012. The shipment origin and destination points are unchanged. These shipments are made from the source fabrication facility to the end user, which is a hospital facility. The radioactive sources are installed into Gamma-Knife devices that are used for brain cancer treatment. Return shipments from re-loads are transported from the hospital to the recycling facility. The shipping mode is by truck.
- (3) **Reasons for Requesting Extended Use.** The AOS application states that extended use of the package is needed due to delays in the certification and fabrication of replacement packages. AOS stated that the Model No. 5979 container is docked with the Gamma-Knife unit by use of a loading machine that is specifically designed for use with the 5979 package. Without use of the container, loading of Gamma-Knife units would be disrupted and possibly stopped. AOS identified that the replacement container has been under development since 2005.
- (4) **Safety Justification for Continued Use and Proposed Compensatory Measures.** AOS proposed specific compensatory measures to assure that shipments would have equivalent safety. These measures are unchanged, and include limiting the maximum package contents to 7,000 curies of cobalt-60 only; to limit the number of packagings used, and to conduct all shipments in accordance with applicable security orders. Shipments will be made by truck, and all shipments will be made as exclusive use shipments. The application stated that each shipment would consist of only one package.
- (5) **A Plan and Schedule to Acquire Replacement Packages or Complete Necessary Shipments.** AOS provided an update on the schedule for obtaining a replacement package, Docket No. 71-9316. The application identifies that development of a replacement package was initiated in February 2005, by contract with General Electric Nuclear. AOS submitted an application to the NRC in October 2007, which was supplemented in November 2007. In April 2008,

AOS withdrew the application due to the identification of major technical deficiencies.

In June 2009, AOS submitted a revised application for the replacement package under Docket No. 71-9316. Supplemental information was provided by AOS in September 2009. Staff issued a Request for Additional Information (RAI) for Docket No. 71-9316, on December 24, 2009. AOS submitted the response to the RAIs on September 29, 2010, approximately 9 months after receipt. An additional RAI letter was issued to AOS in March 2011, and AOS is currently developing the RAI responses. The application anticipates the Certificate of Compliance for the replacement package will be issued in October 2011; however, due to delays in RAI response, the date for issuance of the package approval may be subsequently delayed.

The justification for continued use of an expired package, as described in RIS 2008-18, must describe good-faith efforts to acquire replacement packages that meet the current package performance requirements and any adverse impacts that will result if shipments are not conducted. The application notes the possibility that use of the Gamma-Knife devices for cancer treatment could be disrupted if shipments of the package are not made. Transition to a replacement package meeting the current regulatory requirements is the mechanism AOS has proposed to ensure continued shipments. AOS has anticipated the replacement package to be authorized in October 2011. The quality of the RAI submittal, the potential that staff may have additional RAIs on the replacement package, and the time that AOS may take to respond to future RAIs, all will have bearing on the schedule for the replacement package authorization to be issued.

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
 - (a) Type and form of material
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 - (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 42 shipments for the period beginning November 1, 2011, through June 30, 2012. Shipments must be for the purpose of providing sources for installation into a Gamma-Knife unit or removal of sources from a Gamma-Knife unit.
8. This authorization expires June 30, 2012.

CONCLUSIONS

Based on the statements and representations in the AOS application dated May 16, 2011, 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 9/30/2011.