

April 14, 2011

Mr. Donald R. Krause
Manager, Regulatory Compliance and EHS
GE Hitachi Nuclear Energy
Vallecitos Nuclear Center
6705 Vallecitos Rd.
Sunol, CA 94586

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

Dear Mr. Krause:

As requested by your application dated March 18, 2011, and pursuant to 10 CFR Part 71, Certificate of Compliance No. 5979, for the Model No. 5979, package is amended to authorize the following limited shipments for GE Hitachi Nuclear Energy, 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. Authorization is for a maximum of 25 shipments for the period beginning April 15, 2011, through October 31, 2011. 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 October 31, 2011.

All other conditions of Certificate of Compliance No. 5979 remain the same. GE Hitachi Nuclear Energy has been issued Quality Assurance Program Approval for Radioactive Material Packages No. 0170 under the provisions of 10 CFR Part 71.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

/RA/

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

Docket No. 71-5979
TAC No. L24525

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. Authorization is for a maximum of 25 shipments for the period beginning April 15, 2011, through October 31, 2011. 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 October 31, 2011.

All other conditions of Certificate of Compliance No. 5979 remain the same. GE Hitachi Nuclear Energy has been issued Quality Assurance Program Approval for Radioactive Material Packages No. 0170 under the provisions of 10 CFR Part 71.

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SAFETY EVALUATION REPORT
Docket No. 71-5979
Model No. 5979 Package
GE Hitachi Nuclear Energy
Authorization for Limited Shipments
April 15, 2011 – October 31, 2011

SUMMARY

By application dated March 18, 2011, GE Hitachi Nuclear Energy (GEH) 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 February 18, 2009, GEH requested authorization to use the Model No. 5979 package beyond the package authorization expiration date of October 1, 2008. GEH 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 March 3, 2009 [ML090580471], which amended Certificate of Compliance No. 5979, for the Model No. 5979 package, to authorize limited shipments. A total of 48 shipments were authorized for the period March 3, 2009, through October 31, 2010. On October 18, 2010, as supplemented November 15, 2010, GEH requested authorization to continue use of the Model No. 5979 package 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 November 19, 2010 [ML103260143]. A total of 11 shipments were authorized for the period November 19, 2010, through February 28, 2011.

EVALUATION

By application dated March 18, 2011, GEH requested authorization to continue use of the Model No. 5979 packages beyond the package authorization expiration date of October 1, 2008. GEH requested a total of 25 additional shipments for the period ending

October 31, 2011. GEH 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. GEH did not request any change in the packaging serial numbers or content.
- (2) **Identification of Shipments.** GEH requested 25 shipments for the period beginning in March 2011, through October 31, 2011. The shipments shall originate at GEH's Vallecitos Nuclear Center, Sunol, California. The shipments' destinations are domestic medical institutions identified by Elekta Instrument AB (a Swedish company), manufacturer of the Gamma Knife medical devices. Shipments may also originate at medical institutions, where GEH is the "shipper of record" for recovery of used sources. The shipping mode is by truck. The authorized period for shipments is April 15, 2011, through October 31, 2011.
- (3) **Reasons for Requesting Extended Use.** The GEH application states that extended use of the package is needed due to delays in the certification and fabrication of replacement packages. The Model No. 5979 package used to transport the Co-60 sources to the medical institutions; it is physically "docked" to the Gamma-Knife device upon delivery, by means of a "Loading Machine" specifically designed for use with the Model 5979. Without the availability of the Model No. 5979 packages, the medical treatment of brain cancer patients could be disrupted or completely stopped.
- (4) **Safety Justification for Continued Use and Proposed Compensatory Measures.** GEH 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.
- (5) **A Plan and Schedule to Acquire Replacement Packages or Complete Necessary Shipments.** GEH 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 between GEH and Alpha-Omega Services (AOS). 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 the review of the replacement package, on December 24, 2009. AOS identified that 100 RAIs were received, and due to the number, the response was delayed. AOS submitted the response to the RAIs on September 30, 2010, approximately

9 months after receipt. The application anticipates the Certificate of Compliance for the replacement package will be issued in October 2011.

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 GEH has proposed to ensure continued shipments. GEH has anticipated the replacement package to be authorized in calendar year 2011. The quality of the RAI submittal, the potential that staff may have additional RAIs on the replacement package, and the time taken 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. Authorization is for a maximum of 25 shipments for the period beginning April 15, 2011, through October 31, 2011. 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 October 31, 2011.

CONCLUSIONS

Based on the statements and representations in the GEH application dated March 18, 2011, the staff agrees that the use by GEH of the Model No. 5979 package meets the requirements of 10 CFR Part 71, subject to the conditions listed above.

Issued on April 14, 2011.