

**CERTIFICATE OF COMPLIANCE
FOR RADIOACTIVE MATERIAL PACKAGES**

1. a. CERTIFICATE NUMBER	b. REVISION NUMBER	c. DOCKET NUMBER	d. PACKAGE IDENTIFICATION NUMBER	PAGE	PAGES
9320	6	71-9320	USA/9320/B(U)-96	1	OF 3

2. PREAMBLE

- a. This certificate is issued to certify that the package (packaging and contents) described in Item 5 below meets the applicable safety standards set forth in Title 10, Code of Federal Regulations, Part 71, "Packaging and Transportation of Radioactive Material."
- b. This certificate does not relieve the consignor from compliance with any requirement of the regulations of the U.S. Department of Transportation or other applicable regulatory agencies, including the government of any country through or into which the package will be transported.

3. THIS CERTIFICATE IS ISSUED ON THE BASIS OF A SAFETY ANALYSIS REPORT OF THE PACKAGE DESIGN OR APPLICATION

- | | |
|---|---|
| a. ISSUED TO (<i>Name and Address</i>)
EnergySolutions
740 Osborn Road
Barnwell, SC 29812 | b. TITLE AND IDENTIFICATION OF REPORT OR APPLICATION
MIDUS Transportation Package Safety
Analysis Report, Revision 7, dated March 2022. |
|---|---|

4. CONDITIONS

This certificate is conditional upon fulfilling the requirements of 10 CFR Part 71, as applicable, and the conditions specified below.

5.

(a) Packaging

(1) Model No.: MIDUS

(2) Description

A depleted-uranium shielded package for the transport of medical isotopes. The package has two primary components: (1) an inner cask assembly that provides containment of the radioactive material and radiation shielding, and (2) an overpack that provides impact and thermal protection.

The cask assembly consists of the cask body, closure lid, shield plug, and shield lid. The cask body is a monolithic, machined 2.5-millimeter (mm) thick stainless steel containment vessel, surrounded by approximately 62 mm of depleted uranium gamma shielding, and a 4-mm thick stainless steel outer shell. The containment system closure lid is a 19-mm thick stainless steel plate which is attached to the cask body by 8, M10 × 1.5 × 30 socket head cap screws. The containment system is sealed by two concentric ethylene propylene O-rings, and the lid is equipped with a leak test port. A stainless steel clad depleted uranium shield plug in the cask cavity and a shield lid that is installed over the closure lid provide shielding at the top end of the package. The overpack base and lid are constructed of thin stainless steel shells filled with rigid polyurethane foam. The overpack lid is attached to the base by eight recessed alloy steel bolts. The overpack lid is equipped with four stainless steel lugs for lifting and tie-down, and the overpack base has a bottom flange with four lugs that may also be used for tie-down.

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5.(a) (2) Description (Continued)

The approximate dimensions and weight of the package are:

Overall package outer diameter	520 mm
Overall package height	551 mm
Cask assembly diameter	225 mm
Cask assembly height	347 mm
Cask cavity inner diameter	85 mm
Cask cavity inner height	134 mm
Maximum package weight	330 kg

(3) Drawings

The packaging is constructed and assembled in accordance with EnergySolutions Drawing Nos.:

TYC01-1601, Sheets 1 and 2, Rev. 2	"General Arrangement of Packaging and Contents"
TYC01-1602, Sheets 1 through 4, Rev. 2	"General Arrangement of Cask Assembly"
TYC01-1603, Sheets 1 through 3, Rev. 1	"General Arrangement of Overpack Assembly"
TYC01-1604, Sheets 1 through 3, Rev. 3	"Containment System"
TYC01-1605, Sheets 1 and 2, Rev. 2	"Closure Devices"
TYC01-1606, Sheets 1 through 3, Rev. 2	"Gamma Shielding"
TYC01-1607, Sheets 1 and 2, Rev. 0	"Heat Transfer Features"
TYC01-1608, Sheet 1, Rev. 0	"Energy Absorbing Features"
TYC01-1609, Sheets 1 and 2, Rev. 0	"Lifting and Tie-Down Devices"

(b) Contents

(1) Type and form of material

- (i) Molybdenum-99 (^{99}Mo) with its daughter products as sodium molybdate (NaNO_3 1M / NaOH 0.2M) in liquid form.

The liquid may be contained within product bottles, consisting of stainless steel flasks with stainless steel caps, with or without elastomeric seals. Various stainless steel components may be used as dunnage. The total volume of the payload hardware may not exceed 125 ml (as indicated by a maximum mass of 1.0 kg).

- (ii) Molybdenum-99 with its daughter products as solid, metallic molybdenum.

The metal will be contained within a sealed aluminum target can and placed in an aluminum carrier. The total mass of the payload shall not exceed 1.0 kg, including the target cans and carrier.

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5.(b) (2) Maximum quantity of material per package

Maximum activity	4,400 Ci ⁹⁹ Mo
Maximum specific activity	60 Ci/ml ⁹⁹ Mo
Liquid product volume	0 to 150 ml
Maximum mass of material	1.0 kg

6. In addition to the requirements of Subpart G of 10 CFR Part 71:

- (a) The package shall be prepared for shipment and operated in accordance with the Package Operations in Section 7.0 of the application. Optional polymeric dunnage may be placed in the space between the cask assembly and the overpack.
- (b) The package must meet the Acceptance Tests and Maintenance Program in Section 8.0 of the application.

7. The package authorized by this certificate is hereby approved for use under the general license provisions of 10 CFR 71.17.

8. Revision No. 5 of the certificate may be used until April 30, 2023.

9. Expiration date: November 30, 2026.

REFERENCES

MIDUS Transportation Package Safety Analysis Report (Document No: TYC01-1600), Revision 7, dated March 23, 2022.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

**Yoira K. Diaz-
Sanabria**

Digitally signed by Yoira K. Diaz-
Sanabria

Date: 2022.04.21 15:38:34 -04'00'

Yoira Diaz-Sanabria, Chief
Storage and Transportation Licensing Branch
Division of Fuel Management
Office of Nuclear Material Safety
and Safeguards

Date: April 21, 2022



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
WASHINGTON, D.C. 20555-0001

**SAFETY EVALUATION REPORT
Docket No. 71-9320
Model No. MIDUS
Certificate of Compliance No. 9320
Revision No. 6**

SUMMARY

By letter dated March 23, 2022 (Agencywide Documents Access and Management System Accession No ML22083A117), EnergySolutions (or the applicant) requested an amendment to Certificate of Compliance (CoC) No. 9320 for the MIDUS packaging.

The applicant identified opportunities for improvement of the leak rate test procedures within the MIDUS package Safety Analysis Report (SAR) by removing prescriptive language that does not provide any flexibility to follow the latest techniques in leak rate testing. The applicant did not change any acceptance criteria or reduce leak rate testing commitments for this package and the proposed changes, while consistent with all applicable requirements and guidance documents, do provide flexibility during performance of these leak rate tests.

The staff reviewed the application and determined that the changes do not affect the ability of the package to meet the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 71. The certificate has been updated to Revision No. 6.

EVALUATION

The applicant provided the following background for the request:

During the development and qualification of procedures for periodic/maintenance and pre-shipment leakage rate testing for MIDUS packaging per latest NRC Regulatory Guide 7.4, "Leakage Tests on Packages for Shipment of Radioactive Material," (endorsing ANSI N14.5-2014), opportunities for improvement of leakage rate test procedures within the MIDUS package application were identified. Prescriptive language in the current SAR revision for leakage rate tests does not provide any flexibility to follow the current/latest techniques in leakage rate testing. Therefore, a revision of the MIDUS package application became critical for EnergySolutions and MIDUS packaging users (domestically and internationally).

According to the applicant, the requested changes "do not change any acceptance criteria or reduce leakage rate testing commitments. In fact, proposed changes are consistent with applicable latest requirements/guidance documents while providing needed flexibility during performance of these leakage rate tests." The requested changes do not alter the confinement boundary or affect the containment performance of the package.

The applicant edited for consistency several sections of the application and clarified requirements for testing applicability: leaktight criteria are defined as equivalent to 1×10^{-7} ref-

Enclosure

cm³/s (air) as required by ANSI N14.5-2014. The applicant committed to ANSI N14.5-2014 throughout the application. A new reference (written practice for NDT – SNT-TC-1A-2006 edition or later) was added and the requirements for packagings fabricated before or after January 1, 2022, were revised.

1 Containment Boundary

There have been no changes to the containment boundary of the package; therefore, the staff's previous findings still apply.

2 Summary of Proposed Changes

The applicant has proposed changes to the text of the SAR in Chapters 4, 7, and 8, all related to the leakage rate testing of the MIDUS package, in line with the provisions of ANSI N14.5 2014. The changes proposed by the applicant are summarized, in detail, in Attachment 1 of the applicant's letter to the NRC (ESCD/NRC 22-002), dated March 23, 2022. The applicant describes the changes as being necessary to provide additional flexibility to the users of the MIDUS package, specifically in the leakage rate testing of the package.

The applicant has not proposed any changes to the design or fabrication of the MIDUS package.

2.1 Changes to SAR Chapter 4, "Containment."

The applicant modified the text in Sections 4.1, 4.2.2, 4.3.2, 4.4.1, 4.4.2, 4.4.3, 4.4.4, and 4.5 of the SAR. The changes included clarifying pre-shipment leakage rate testing options, clarifying the "leaktight" criteria for leakage testing as provided in ANSI N14.5-2014, committing to ANSI N14.5 2014, as well as some editorial corrections.

2.2 Changes to SAR Chapter 7, "Package Operations."

The applicant modified the text in Sections 7.1.1, 7.1.2, 7.1.3, 7.4, 7.4.1, and 7.5 of the SAR. These changes were primarily focused on the actual steps involved in preparing a package for transportation and included several editorial corrections, changes to provide consistency with other Sections of the SAR, highlighting the applicant's commitment to the new edition of ANSI N14.5 (2014), and speaking to specific requirements of ANSI N14.5 2014 related to the pre-shipment leakage rate testing and non-destructive testing (NDT) practices.

2.3 Changes to SAR Chapter 8, "Acceptance Tests and Maintenance Program."

The applicant modified the text in Sections 8.1.4, 8.2.2, 8.3.1, and Table 8-1 of the SAR. The applicant added specific requirements for packages fabricated before and after January 1, 2022, defined periodic and maintenance leakage rate tests in ANSI N14.5-2014, made an editorial correction to Table 8-1 of the SAR, and reiterated the applicant's commitment to the new edition of ANSI N14.5 (2014) and spoke to specific requirements of ANSI N14.5 2014 and NDT practices.

3 Review of Proposed Changes

The changes proposed by the applicant are primarily focused on introducing additional flexibility for operators of the MIDUS package in conducting leakage rate testing of the package prior to

shipment. Detailed procedures for leakage rate testing are developed by the operators of the package, and these procedures will be developed in accordance with the provisions in ANSI N14.5-2014, as committed to by the applicant in the SAR.

NRC staff does not generally review detailed procedures as part of its review of the design, fabrication, and/or operation of a transportation package; however, as part of NRC's oversight role, inspections or audits may be carried out, in this case specifically in order to review detailed procedures developed for leakage rate testing of the MIDUS package, if the staff felt it was necessary. This regulatory approach, which considers risk insights in its application, generally allows for less operational detail, such as those included in detailed procedures, to be provided in the SAR, offering additional flexibility to operators, without having an impact on the safe operation of the package.

4 Evaluation Findings

Based on the staff's review of the containment and other related sections of the application, the staff finds that the nature of the changes proposed do not have any effect on the overall safety of the MIDUS package design and the staff agrees with the applicant's conclusion that the MIDUS package continues to meet the containment requirements for normal conditions of transport and hypothetical accident conditions found in 10 CFR 71.71 and 71.73, respectively.

The staff also agrees that those proposed changes do not affect any acceptance criteria nor do they reduce leakrate testing commitments.

The staff reviewed the applicant's requested changes to the Certificate of Compliance and determined that the applicant's proposed changes to the CoC would not affect the ability of the Model No. MIDUS package to meet all the requirements of 10 CFR Part 71.

CONDITIONS

The following changes were made to the certificate of compliance:

Item No. 3(b) identifies the latest application dated March 23, 2022.

Condition No. 8 has been modified to extend the previous revision of the certificate for approximately one year.

The expiration date of the certificate (Condition No. 9) was not modified.

The References section of the certificate was updated to include the application dated March 23, 2022.

CONCLUSION

Based on the statements and representations in the application, the staff finds that these changes do not affect the ability of the package to meet the requirements of 10 CFR Part 71.

Issued with Certificate of Compliance No. 9320, Revision No. 6.