



ATTN: Document Control Desk  
Director, Division of Fuel Management  
Office of Nuclear Material Safety and Safeguards  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

**Subject: Request to Amend Certificate of Compliance No. 9320, Revision 5 for the Model MIDUS Type B Shipping Package (EPID L-2022-LLA-0039)**

References: (1) Certificate of Compliance 9320, Docket No. 71-9320, Revision 5.  
(2) Letter from EnergySolutions (A. Gelfond) to NRC, Subject: Upcoming Request to Amend Certificate of Compliance No. 9320, Revision 5 for the Model MIDUS Type B Shipping Package, Letter No: ESCD/NRC 22-001, March 14, 2022 ([ML22073A266](#))

Dear Director:

EnergySolutions (ES) hereby submits an application to U.S. Nuclear Regulatory Commission (NRC) to amend Certificate of Compliance (CoC) for the MIDUS Transportation Package (Ref. 1). The application requests changes in fabrication, periodic/maintenance, and pre-shipment leakage rate testing descriptions in the SAR (Chapters 4, 7 and 8).

Background:

MIDUS Type B Shipping Packages transport medical isotope (Mo-99), which is used for diagnoses of heart disease and cancer, to study organ structure and function, and to perform other important medical applications. During 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), critical opportunities for improvement of leakage rate test procedures within the MIDUS package SAR 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, revision of the MIDUS package SAR is critical and time sensitive for EnergySolutions and MIDUS packaging users (domestically and internationally).

Requested SAR Revision:

Requested SAR changes which were already discussed with NRC staff during the initial meeting (March 14, 2022) 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. There is no effect on technical disciplines/safety analyses (structural, thermal, containment and shielding/criticality).

A summary of the specific proposed changes to the MIDUS package SAR is provided in the Attachment 1 of this letter. In addition, all changes in the SAR are marked using change bars, consisting of vertical lines drawn in the right margin. Enclosure 1 contains electronic copy of the non-public version of the revised



SAR that contains proprietary information and security-related sensitive information that should be withheld under 10 CFR 2.390. Enclosure 2 contains one electronic copy of the public version of the revised SAR in which all proprietary information and security-related sensitive information is redacted. Enclosure 3 contains an affidavit containing a full statement of the reasons that the proprietary information in the SAR should be withheld from the public, pursuant to the requirements of 10 CFR 2.390.

As stated in the letter (Ref.2), EnergySolutions is requesting expedited review and issuance of revised MIDUS CoC before April 22, 2022, due to urgency associated with placement of MIDUS packagings in service and necessity to update the Certificate of Competent Authority (issued by the U.S. Department of Transportation) along with obtaining validation of the MIDUS CoC by Authority for Nuclear Safety and Radiation Protection (ANVS) in the Netherlands.

This letter is submitted electronically via NRC Electronic Information Exchange (EIE) system with an electronic copy to be sent to Mr. Pierre Saverot.

Should you or any member of your staff have questions, please contact me at (803)587-9117.

Sincerely,

A handwritten signature in black ink, appearing to read "Aleksandr Gelfond".

Aleksandr Gelfond  
Director of Engineering/Licensing, Cask Division

Attachments:

- (1) Summary of Changes, MIDUS Transportation Package SAR, Revision 7, March 2022 (Document No. TYC01-1600)

Enclosures:

- (1) MIDUS Transportation Package Safety Analysis Report, Revision 7, March 2022 (Document No. TYC01-1600), Non-Public Version (1 electronic copy), **(Proprietary and Security-Related Information – Withhold Under 10 CFR 2.390)**.
- (2) MIDUS Transportation Package Safety Analysis Report, Revision 7, March 2022 (Document No. TYC01-1600), Public Version (1 electronic copy).
- (3) Affidavit pursuant to 10 CFR 2.390.

cc) Mr. Pierre Saverot, Project Manager, NRC  
Mr. Gerard van Noordennen, Senior VP of Regulatory Affairs, EnergySolutions

**Summary of Changes**  
**MIDUS Transportation Package Safety Analysis Report, Revision 7**

<b>Section</b>	<b>Page(s)</b>	<b>Change</b>	<b>Purpose/Justification</b>
4.1	4-1	Revised 3 <sup>rd</sup> sentence in 5 <sup>th</sup> paragraph	Remove reference to pressure rise leak rate test due to flexibility of pre-shipment leak rate test options provided in Section 7.4.1.
4.2.2	4-5	Revised sentence for clarity and consistency	Define leaktight criteria equivalent to $1 \times 10^{-7}$ ref-cm <sup>3</sup> /s (air) as required by ANSI N14.5-2014
4.3.2	4-5	Revised sentence for clarity and consistency	Define leaktight criteria equivalent to $1 \times 10^{-7}$ ref-cm <sup>3</sup> /s (air) as required by ANSI N14.5-2014
4.4.1	4-6	Revised 1 <sup>st</sup> sentence for clarity and consistency	Define leaktight criteria equivalent to $1 \times 10^{-7}$ ref-cm <sup>3</sup> /s (air) as required by ANSI N14.5-2014
4.4.2	4-6	Revised 1 <sup>st</sup> sentence for clarity and consistency	Define leaktight criteria equivalent to $1 \times 10^{-7}$ ref-cm <sup>3</sup> /s (air) as required by ANSI N14.5-2014
4.4.3	4-6	Revised 1 <sup>st</sup> sentence for clarity and consistency	Clarify requirements for testing applicability and define leaktight criteria equivalent to $1 \times 10^{-7}$ ref-cm <sup>3</sup> /s (air) as required by ANSI N14.5-2014
4.4.4	4-6	Revised 1 <sup>st</sup> and 2 <sup>nd</sup> sentences for clarity and consistency	Editorial correction for clarity and consistency.
4.5	4-7	Revised reference [4.3]	Commitment to ANSI N14.5-2014
7.1.1 (Step 16)	7-3	Revised 1 <sup>st</sup> bullet. Deleted 2 <sup>nd</sup> bullet	Provide consistency between requirements of this step with Section 8.2.2. Delete reference to section 8.1.4 (was provided in error), add reference to Section 8.2.2.
7.1.2 Step (10)	7-4	Revised 1 <sup>st</sup> bullet	Provide consistency between requirements of this step with Section 8.2.2. Delete reference to section 8.1.4 (was provided in error), add reference to Section 8.2.2.

<b>Section</b>	<b>Page(s)</b>	<b>Change</b>	<b>Purpose/Justification</b>
7.1.3	7-4	Revised “Special Equipment Required”	Clarify requirement for pre-shipment leak rate test equipment to be consistent with Section 7.4.1.
7.1.3 Step (1)	7-4	Revised reference section	Editorial correction
7.4	7-9	Deleted 2 <sup>nd</sup> and 3 <sup>rd</sup> paragraph in this section	Editorial correction. Detailed/prescriptive requirements for type/accuracy/range and sensitivity of the test are no longer required.
7.4.1	7-9	Revised section (entirely), deleted Figure 7-2, deleted Section 7.4.2	Include requirements for pre-shipment leak rate test as per ANSI N14.5-2014.
7.5	7-10	Revised reference [7.1] and added reference [7.2].	Commitment to new edition of ANSI N14.5 (2014) /adding new reference (written practice for NDT – SNT-TC-1A-2006 edition or later).
8.1.4	8-1/8-2	Revised section	Address requirements for packagings fabricated before January 1, 2022/after January 1, 2022.
8.2.2	8-4/8-5	Revised section (entirely)	Define new periodic and maintenance leak rate testing requirements per ANSI N14.5-2014.
Table 8-1	8-9	Revised Note 1	Editorial correction due to change in referenced section.
8.3.1	8-10	Added references [8.3] and [8.4]	Commitment to new edition of ANSI N14.5 (2014) /adding new reference (written practice for NDT – SNT-TC-1A-2006 edition or later).

Enclosure 1

MIDUS Transportation Package Safety Analysis Report, Revision 7, March 2022

(Document No. TYC01-1600)

Non-Public Version

(1 electronic copy),

**(Proprietary and Security-Related Information – Withhold Under 10 CFR 2.390)**

Enclosure 2

MIDUS Transportation Package Safety Analysis Report, Revision 7, March 2022

(Document No. TYC01-1600)

Public Version

(1 electronic copy)

Enclosure 3  
Affidavit pursuant to 10 CFR 2.390  
(1 electronic copy)