

**Request for Additional Information
Revalidation Review
Docket No. 71-3090
Model No. LEUPA**

GENERAL INFORMATION

G-1.¹ Revise Section 1.1.4, "Definitions," of Document No. 0908-LE00-3BEIN-023-A, "Safety Report," to include a brief description with the main materials of construction, sub-components, and safety function of the following components of the Model No. LEUPA:

- a. container of inner cans,
- b. containment system,
- c. external cover,
- d. inner can,
- e. inner cover,
- f. intermediate cover,
- g. thermal insulation,
- h. neutron absorber,
- i. elastomeric gaskets, and
- j. stainless steel-graphite spiral gasket.

The applicant provides high-level definitions of items a. and c. to f., but no definitions of items b. and g. to j. These components seem to comprise the main components of the Model No. LEUPA that the applicant is relying on for the safe transport of radioactive material. Therefore, these components should be clearly defined in the application.

The staff needs this information to evaluate the adequacy of the design of the Model No. LEUPA package.

This information is needed to confirm compliance with paragraph 807 of the TS R 1.

ANSWER:

The definitions requested are added below.

B: Fragment of document 0908-LE01-3BEIN-011 - CALCULATION REPORT

1. *The Container of interior containers is located in the LEUPA packaging, fixed and guided by side guides. Figure 1 contains a scheme of the container of interior containers.*
2. *This calculation is to verify the width of the pressure containment (following ASME III NB, section 3320) and the interior flat cover (using a finite elements model, code ANSYS).*

¹ In general, the nomenclature used for identifying the RAIs is as follows: Topics: G – General Information; Co – Containment; Cr – Criticality; Sh – Shielding; and St – Structural.

Figure 1: Container of interior containers

**Security-Related Information Figure
Withheld Under 10 CFR 2.390.**

Table 1: Design data

| Data | Value |
|--------------------------|--|
| Internal Design Pressure | 700 kPa [maximum required under AR 10.16.1, covering the 96.3 kPa (101.325 kPa – 5 kPa) stated in 0908-LE00-EBEIN-001-A] |
| Hydraulic Test Pressure | 875 kPa |
| Design Temperature | 70 °C |
| Mass of the Content | 50 kg |
| X-ray | 100% |

Materials

1. *The container shall be made of type ASTM A312 TP316L stainless steel pipes and Standard ANSI 16.5 #150 5" flanges, one welding neck-type and another blind-type.*

Table: Properties of stainless steel ASTM A312 TP304L

| Description | ASTM A312 TP304L (seamless) |
|---------------------------|--|
| Modulus of elasticity | 192708 MPa |
| Tensile Strength | 70000 psi (482.6 MPa) |
| Yield Strength | 25000 psi (172.3 MPa) |
| Admissible Stress at 93°C | 16700 psi (92.4 MPa) |
| Stress Intensity | 16700 psi (92.4 MPa) |
| Density | 7825 kg/m ³ |

G: Fragment of document 0908-LE00-3BEIN-023 - SAFETY REPORT

Description of Package

12. *The thermal insulator to be used is under the brand name Kaolite 1600, a cementitious composite on vermiculite powder to be mixed with water, and which can be used at 1600 °F (871 °C); it can be applied either by gravity filter or by pressure.*
13. *Its mechanical properties depend on drying conditions.*

H: Fragment of document 0908-LE01-3BEIN-024 - CRITICALITY ANALYSIS

5.2 Packaging

5.2.1 Enclosure System

1. *Linked to the container there is a cylindrical stainless steel double wall component. The space between walls (17 mm approximately) is filled with casted high purity cadmium. The flanged cover of the container also has a double wall inside which cadmium is filtered, so that the load of fissile substances is surrounded almost completely by the neutron absorbent material.*
2. *This assembly forms a compact undeformable central cell.*

Table 2: Materials used in criticality evaluations

| Material | Aprox. Mass [kg] | Density [g/cm ³] | Element | % Weight |
|---------------|------------------|------------------------------|--------------------------------|----------|
| Metal Uranium | 50.0 | 18.9 | U ²³⁵ | 19.8 |
| | | | U ²³⁸ | 80.1 |
| Poliethylene | 0.4 | — | H | 14.4 |
| | | | C | 85.6 |
| Kaolite 1600 | 85 | 0.405 (without water) | Al ₂ O ₃ | 11.0 |
| | | | SiO ₂ | 33.0 |
| | | | Fe ₂ O ₃ | 7.9 |
| | | | TiO ₂ | 1.4 |
| | | | CaO | 30.0 |
| | | | MgO | 12.1 |
| | | | Na ₂ O | 4.6 |
| AISI 304 L | 244 | 7.9 | Fe | 65.47 |
| | | | Cr | 17.0 |
| | | | Ni | 12.0 |
| | | | Mo | 2.5 |
| | | | Mn | 2.0 |
| | | | Si | 1.0 |
| | | | C | 0.03 |
| Cadmium | 58 | 8.65 | Cd | 100.0 |

I: Fragment of document 0908-LE00-3BEIN-023 - SAFETY REPORT

1.2 Description of Package

8. *The removable intermediate cover is joined to the rest of the package by means of six (6) M12 screws with an elastomeric gasket between both parts.*
9. *Outside the removable intermediate cover there is another cover made of a stainless steel circular plate, also fixed to the rest of the package by six (6) M12 screws. Between both parts there is also a 5 mm thick elastomeric gasket to avoid the entering of dirt and humidity.*

J: The spiral connection is RWI DN 5", below is a description of size and standard characteristics.

The sizes and materials are in a red box.

Styles RW, RWI Dimensions 1/4" to 24" Flanges

ASME B16.20 Gaskets for ASME B16.5 Flanges

Security-Related Information Figure
Withheld Under 10 CFR 2.390.

* ASME B16.20 does not include dimensions for NPS 1/4, 3-1/2 or 4-1/2, or Class 400 flanges up to NPS 3 and Class 900 flanges up to NPS 2-1/2. Dimensions in inches.

Notes:

1. Inner rings are recommended for all graphite filled gaskets, required for all PTFE filled gaskets, and for NPS 24 and larger in Class 900, NPS 12 and larger in Class 1500, and NPS 4 and larger in Class 2500.
2. The gasket outside diameter tolerance for NPS 1/2 through NPS 8 is ± 0.03 "; for NPS 10 through NPS 24, $+0.06$ ", -0.03 ".
3. The gasket inside diameter tolerance for NPS 1/2 through NPS 8 is ± 0.016 "; for NPS 10 through NPS 24, ± 0.03 ".
4. The centering ring outside diameter tolerance is ± 0.03 ".
5. There are no Class 400 flanges in NPS 1/2 through NPS 3 (use Class 600), Class 900 flanges in NPS 1/2 through NPS 2-1/2 (use Class 1500), or Class 2500 flanges NPS 14 and larger.

Spiral Wound Specifications

Temperature Limits for Common Metals

Security-Related Information Figure
Withheld Under 10 CFR 2.390.

Temperature Limits for Filler Material

Security-Related Information Figure
Withheld Under 10 CFR 2.390.

- G-2.** Provide the translated versions of all the documents related to the application for the revalidation of the Model No. LEUPA package. (All documents should be entirely translated to the English language).

The staff noticed that some documents submitted as part of the application for the revalidation of the Model No. LEUPA contained information and text in Spanish without the proper translation. Some examples of these documents are as follows:

| Drawing Identification No. | Drawing Brief Description |
|----------------------------------|----------------------------------|
| <i>00A 0908-LE02-3ASIN-005-A</i> | Plates For Test |
| <i>00E 0908-LE01-3ASIN-010-C</i> | Packaging Of Main Body |
| <i>00F 0908-LE02-3ASIN-012-A</i> | Quick Release Hook For Drop Test |

| | |
|----------------------------------|---|
| 00B 0908-LE01-3ASIN-017-B | Packaging – Main Body Warning Plate |
| 00C 0908-LE01-3ASIN-018-B | Packaging – Main Body Nameplate |
| 00D 0908-LE01-3ASIN-019-C | Packaging – Main Body Design And Manufacture Plate |

Note: This list is not all inclusive. This request for additional information applies to all the documents submitted as part of the Model No. LEUPA application.

The staff needs this information to evaluate the adequacy of the design of the Model No. LEUPA package.

This information is needed to confirm compliance with paragraphs 807(b) and (c) of the TS R 1.

ANSWER:

The drawings and documents with the amended translations are being sent.

- G-3.** Revise the English translation of the application to include the identification number and corresponding revision of the documents translated to English referenced in the application for the Model No. LEUPA.

In some instances, documents submitted as part of this application referenced the Spanish version of documents or drawings instead of the translated version of the documents.

For example, Section 3.2 of the safety report, “Description and Properties of Packaging Materials,” includes the following statement:

“1. See Doc. 0908-LE01-3BSIN-013 – MANUFACTURE SPECIFICATION according with attached document.”

Document No. 0908-LE01-3BSIN-013 corresponds to the Spanish version of the “Manufacture Specification.” Document No. 0908-LE01-3BEIN-013-A corresponds to the English version for the “Manufacture Specification.” Therefore, the English translation of the application should reference Document No. 0908-LE01-3BEIN-013-A, which corresponds to the English translation of Document No. 0908-LE01-3BSIN-013. The table below includes some examples.

| Document Title and ID No. | Section No. | Reference Spanish Identification No. | Reference English Identification No. | Reference Title (Translation) |
|--|---------------------|---|---|--------------------------------------|
| <i>Safety Report..., 0908-LE00-</i> | 3.2, 1.; 3.3, 1. | 0908-LE01-3BSIN-013-D | 0908-LE01-3BEIN-013-A | Manufacture Specification |

| Document Title and ID No. | Section No. | Reference Spanish Identification No. | Reference English Identification No. | Reference Title (Translation) |
|--|-------------|--------------------------------------|--------------------------------------|---------------------------------|
| 3BEIN-023-A, Revision A | 3.6.1; 9. | 0908-LE01-3BSIN-012 – E | 0908-LE01-3BEIN-012 – A | Verification Of Lifting Points |
| | 3.6.1; 10. | 0908-LE01-3BSIN-025-B | LE01-3BEIN-025-A | Clamping Analysis For Transport |

Note: This list is not all inclusive. This request for additional information applies to all the documents submitted as part of the Model No. LEUPA application.

The staff needs this information to evaluate the adequacy of the design of the Model No. LEUPA package.

This information is needed to confirm compliance with paragraphs 807(b) and (c) of the TS R 1.

ANSWER:

The new documentation we are sending has references to documents with English versions.

G-4. Revise the English translation of the Competent Authority Approval Certificate to include:

a. the following statement (as required in paragraph 832(f) of the TS R 1):

“This certificate does not relieve the consignor from compliance with any requirement of the government of any country through or into which the package will be transported.”, and

b. consistent wording between the Spanish and English versions of the Competent Authority Approval Certificate.

The Competent Authority Approval Certificate submitted as part of the revalidation request of the Model No. LEUPA package includes the following wording:

English Translation

10. This certificate does not exempt the sender from complying with any requirement set forth by the Government of any country through/whereto the package is transported. -----

Spanish Version

9. El presente certificado no exime al remitente ni al transportista del cumplimiento de cualquier otro requisito impuesto por el Gobierno de cualquier país a través del cual o al cual se transporte el bulto.

The statement provided by the applicant in item No. 10 of the English translation of the Competent Authority Approval Certificate should:

- i) be in alignment with paragraph 832(f) of the TS R 1, since the word “consignor” has a contractual meaning in the context of transportation of materials or goods; and
- ii) clearly reflect the intent of the document in its original language.

This information is needed to confirm compliance with paragraph 832(f) of the TS R 1.

ANSWER:

The translation of the certificate has been modified. We are sending it, please check file “LEUPA ARN certificate + translation (original version + addenda)”.

- G-5.** Revise the English translation of the application submitted for the revalidation of the Model No. LEUPA package to include the applicable revision Nos. of the drawings and documents through out the documents related to this application.

For example, the following documents include a list of documents and/or drawings without the most recent or applicable revision No.:

- i) Section 11.2, “Added Documents,” of Document No. 0908-LE00-3BEIN-023-A, “Safety Report;”
- ii) Section 8, “Applicable Drawings,” of Document No. 0908-LE020-3BEIN-008-A , “Tests Carried Out on Specimens of the Design of Type B(U) Package to Transport Radioactive Materials – Final Report;” and
- iii) Section 11, “Appendix 1 - List of Valid Drawings,” of Document No. 0908-LE01-3BEIN-013-A, “Manufacture Specifications.”

The references to engineering drawings in the application should include the corresponding revision No. to ensure that the packaging is designed, fabricated, and tested as approved for transporting the authorized radioactive material. The same principle applies to documents that constitute the licensing basis to the Model No. LEUPA package.

The staff needs this information to evaluate the adequacy of the design of the Model No. LEUPA package.

This information is needed to confirm compliance with paragraphs 807(b) and (c) of the TS R 1.

ANSWER:

All references to documents are references to the latest versions; therefore, if a reference has no revision number, this means the reference is to the latest version.

This is the layout set forth by the company as stated in its drafting manual. The package of drawings and documents you will receive now, contain the latest revisions of each document.

G-Sh-1. Clarify and revise, as needed, in the application the description of the Primary Containment Lid/Flange.

Based on Drawing No. 0908-LE01-3ASIN-005, this component is a solid lid with a solid section of cadmium in its center on the bottom side. However, Picture 27 of the "Tests Final Report" document identifies a steel disc with a large central hole as the primary containment lid/flange. This is not consistent with the design shown in the technical drawings.

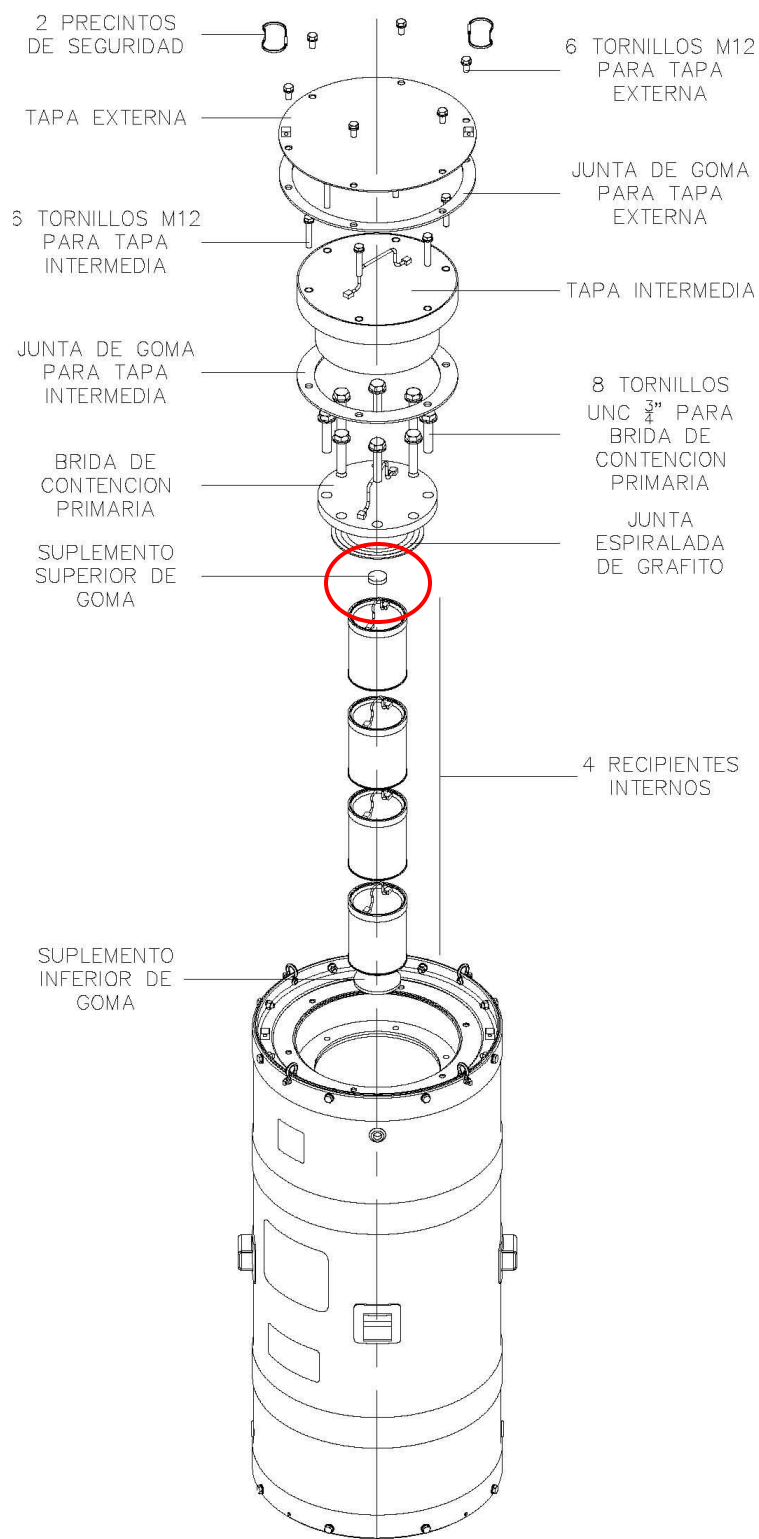
This information is needed to confirm compliance with paragraphs 807(a) and (b) of the TS R 1.

ANSWER:

Picture 27 of the "Tests final report" displays in its lower part of the main cover the rubber upper supplement; the supplement is attached to the cover.

This component conforms to drawing 0908-LE01-3AEIN-005.

The following image in the next page, displays an assembly of these components.



G-Sh-2. Clarify and revise, as needed, in the application the description of the contents" form that is currently specified as "Other."

The application should clearly describe the contents" form. In particular, the form referred to as „Other“, in the certificate of the competent authority, should be clarified. The description of the contents, including the form, should be specific so as to enable an appropriate evaluation of the package and its contents.

This information is needed to confirm compliance with paragraph 807(a) of the TSR 1.

ANSWER:

The word "Others" makes reference to all solid forms of Uranium to be transported. Since it is not possible to describe all physical forms transported, such as pellets, pieces, cylinders, etc., "others" is defined to include all forms, as long as they are made of the types of Uranium approved for transportation.

CRITICALITY SAFETY

Cr-1. Provide a benchmarking analysis of the MCNP5 program with the selected cross section library as well as the area of applicability of the selected benchmark experiments and an upper subcriticality limit (USL). The benchmarking analysis should include the following:

- a. the resulting bias and bias uncertainties, and
- b. corresponding corrections to the calculated keff values.

The applicant's criticality safety analysis does not include a discussion about the benchmarking of the MCNP5 program in order to calculate an appropriate USL for the criticality analyses.

This information is needed to confirm compliance with paragraphs 671(a), 677, 678, 679, 680, 681, and 682 of the TS R 1.

ANSWER:

We had previously made an independent calculation, which we are sending you now. Please check document 0908-LE02-3BEIN-007-A.

This independent calculation has been performed by using a different code and a different cross-section library (sequence CSAS6 in SCALE 6, which uses KENO-VI as the Monte Carlo calculation code, and the "v7-238" multigroup cross-section library, also provided with SCALE 6). Even though this is not exactly what the reviewers are requesting, we believe that this additional calculation provides independent support to the MCNP results, and helps to prove compliance with all the paragraphs of the TS-R-1 that have been mentioned.

- Cr-2.** Confirm that packages transported by air would not have moderating material, such as plastic wrap or polyethylene bags, or provide a mass limit for this material.

The calculation for air transportation does not consider the presence of moderating materials. However, the applicant describes in the criticality analysis the use of polyethylene bags or similar material surrounding the fissile contents. Therefore, the staff requests a statement be added to the Competent Authority Certificate to convey that the presence of moderating materials for the purpose of wrapping the contents in the package for air transport of the package is not allowed. Otherwise, provide a mass limit for the amount of moderating material that is supported by a criticality safety analysis.

This information is needed to confirm compliance with paragraph 680 of the TS R 1.

ANSWER:

Almost all MCNP calculations reported in document 0908-LE01-3BEIN-024 do include a polyethylene mass representing the proposed wrapping (400 g for the whole LEUPA package). Therefore, the influence of this moderating material has been taken into account. The only case where this wrapping has not been considered in the MCNP calculations reported in document 0908-LE01-3BEIN-024, was in Section 8 (package transported by air). This case is very conservative since it assumes all fissile material is reshaped as a sphere, ignoring the absorber material (cadmium), and reflecting the sphere by water. Moreover, the independent calculations documented in 0908-LE02-3BEIN-007-A reproduce the model calculated with MCNP but this time with SCALE and, additionally, it evaluates the effect of adding the moderating material to the fissile material. Even though the effect of polyethylene on reactivity it is not negligible, the resulting keff is still low enough with a safe margin.

In short, the mass limit, supported by calculations, is 400 g of polyethylene for the whole LEUPA package.

- Cr-3.** Describe the acceptance tests conducted to verify the presence and distribution of neutron poisons during and after the fabrication of the package.

The application does not include information explaining how the applicant ensures that cadmium is present, uniform, and free from voids in order to perform its safety function.

This information is needed to confirm compliance with paragraph 501 of the TS R 1.

ANSWER:

We are sending a data sheet for the infiltration of cadmium. Please check files "Quality Control Sheet Cadmium 1" and "Quality Control Sheet Cadmium 2".

The data sheet states all values used in the specified procedure which ensures complete filling of cadmium in all established areas.

The following procedure applies to all components with cadmium, no exceptions. The procedure consists of the following steps:

- 1- Weighting component in drawing 0908-LE01-3AEIN-006-A – Main body Cadmium chamber, empty, that is to say, without the cadmium inside.
- 2- Fill out the space delimited for cadmium in drawing 0908-LE01-3AEIN-006-A – Main body Cadmium chamber, with Water. With the densities of Water and Cadmium, the cadmium mass to be used, and hence the final weight of the component 0908-LE01-3AEIN-006-A – Main body Cadmium chamber, is calculated.
- 3- Heating of component 0908-LE01-3AEIN-006 - Cadmium chamber, by contact with direct flame.
- 4- Infiltration of the cadmium melted by the holes of component 0908-LE01-3AEIN-006 – Main body Cadmium chamber POS 8, until the limit.
- 5- Weighting component 0908-LE01-3AEIN-006 – Main body Cadmium chamber with solidified cadmium and through the weight make sure the whole volume is completed.

Cr-4. Explain how the array analysis bounds a single package evaluation.

In the criticality analysis, the applicant considers an array of packages under normal conditions of transportation (NCT) and hypothetical accident conditions (HAC). However, in Section 7.1 of the criticality analysis, the applicant notes that the TS-R-1 standard requires the assurance of subcriticality for an isolated package, but the application does not include:

- i) a statement explaining that the analysis for an isolated package is bounded by the array analysis, nor
- ii) an analysis of an isolated package.

This information is needed to confirm compliance with paragraphs 677, 678, 679, and 680 of the TS R 1.

ANSWER:

The array analysis has covered different moderation and absorption conditions. In particular, those cases where absence of Cadmium is assumed, combined with different moderation conditions, are the most conservative envelope for the isolated package, given the increase in Uranium mass that all the array cases have, as compared to the isolated package. A statement in this direction will be added to the application.

Cr-5. Provide a representative sample of input files, including those considered to be most limiting, used in performing the criticality safety evaluation for the Model No. LEUPA package. This sample should include the:

- a. representative modeling samples of each geometry configuration, and
- b. modeling samples of the bounding or most reactive configurations.

The applicant did not provide a sample of input files used to perform the criticality safety evaluation. These computer input files should provide additional assurance regarding the criticality safety evaluation of the package. Since the demonstration of criticality safety of the Model No. LEUPA package relies on the calculated results, the staff needs additional assurance that the content and methodology of the computer models is adequate to ensure that the package meets the fissile material safety standards.

This information is needed to confirm compliance with paragraphs 671(a), 677, 678, 679, 680, 681, and 682 of the TS R 1.

ANSWER:

We are sending the input files. Please check inside folder “DOCS”, the folder “INPUT FILES”.

SHIELDING EVALUATION

Sh-1. Clarify and revise, as needed, the following information in the application:

- a. The method used to calculate neutron dose rates. The applicant discussed the use of MicroShield in the application section related to neutron dose rates. However, MicroShield does not have the capability to calculate neutron dose rates.

ANSWER:

This is right, MicroShield should have never been mentioned in connection with “neutron” dose rates. The dose rate values reported, obtained with MicroShield, are in all cases due to the gamma rays produced by decay of uranium and its daughters.

Neutrons originate from spontaneous fission in uranium. The contribution of these neutrons to the total dose rate in contact with the LEUPA package is negligible, as compared to that due to decay gammas from uranium. For this reason, this contribution is not calculated.

- b. Dose rates reported in Sections 2.6, 3.4, and 3.5 of the “Safety Report.” The dose rates at the package surface should be larger than the dose rates at 1 meter from the package surface.

ANSWER:

The observation is correct, there was a typing error. It has been corrected in the document we are sending now.

- c. Verification that contamination levels of an empty package meet all appropriate limits. "Operation Manual," Section 7.2.9, paragraph 1, only lists one contamination limit; there are two limits. Paragraph 1 should include verification that inner contamination levels do not exceed one hundred times either limit in paragraph 507 of TS-R-1.

ANSWER:

This paragraph has been modified in the new revision we are sending of Document 0908-LE00-3BEIN-017; below is a fragment of the Document:

7.2.9 Empty Packages

1. *To be dispatched as exempted package, the plates with radioactive symbol must be covered, in such a way that they may not fall off until arrival. The following steps shall be checked:*
 - a. *The package must be kept in good conditions and tightly closed.*
 - b. *The inner contamination level cannot exceed:*
 - *400 Bq/cm² for beta and gamma emitters and low toxicity alpha emitters; and*
 - *40 Bq/cm² for all other alpha emitters.*
 - c. *The radiation level at any external part of the exempted package shall not exceed 5 µSv/h.*
 - d. *Labels that may have been on its surface while loaded with radioactive material will be discarded.*
 - e. *Place the UN No. on exempted packages.*
- d. Verification that dose rates for a loaded package meet all appropriate dose rate limits. "Operation Manual," Section 7.2.6, should include verification that all regulatory dose rate limits in TS-R-1 are met, including the limits for the package surface and the limits at the prescribed distance(s) from the package surface.

ANSWER:

This verification is contemplated in section 7.2.7 of Document 0908-LE00-3BEIN-017 - OPERATION MANUAL:

7.2.7 Transport

1. *Before each dispatch the following must be done:*
 - a. *Verify the external cleansing of the package by sweep test.*
 - b. *Complete dispatch form of each package.*
 - c. *Visually inspect the external look of each package.*
 - d. *Verify that the temporary radioactive contamination of the external surfaces does not exceed:*
 - i. *4 Bq/cm² for beta and gamma emitters and low toxicity alpha emitters.*

- ii. 0.4 Bq/cm^2 for all other alpha emitters.
 - e. Verify the Transport Index (TI). This shall be determined as the maximum radiation level in millisievert units per hour (mSv/h) at a distance of one (1) meter from the external surfaces of the package. The determined value is multiplied a hundred times and the obtained figure is the Transport Index. This figure shall be rounded up (for example 1.13 shall be 1.2), except in cases of 0.05 values or less, which can be considered as zero.
 - f. Verify that the ISC value is the one stated in the Approval Certificate of the LEUPA – RA/103/B(U)F-96.
 - g. Verify that the package is duly marked and labelled:
 - i. UN abbreviation.
 - ii. Clover symbol printed (Picture 1 Paragraph 534 – AR 10.16.1 Rev. 2).
 - iii. Labels on package, placed on two opposite sides (Picture 2 Paragraph 536, Picture 5 Paragraph 539 and N° of the United Nations AR10.16.1 Rev. 2).
 - iv. Name of dispatch.
 - v. Net mass.
 - vi. Type of package.
 - vii. Identification mark.
 - viii. Series No.
 - ix. Sender and Addressee address.
 - h. Verify the package has been sealed.
 - i. Verify all required documentation for dispatch.
 - i. Approval Certificate– ARN.
 - ii. Loading Form.
 - iii. Dispatch Form.
 - iv. Sender's certificate/statement (Paragraph 545 – AR 10.16.1 Rev. 2).
 - v. Consignment details (Paragraph 544 – AR 10.16.1 Rev. 2).
 - j. Verify that the approved and in force inspection form is with dispatch documentation.
 - k. Verify that the loading and unloading form is with dispatch documentation (see **¡Error! No se encuentra el origen de la referencia.**).
2. Once the above mentioned issues are verified, the LEUPA package is free for transport.

- e. The applicable drawings in Appendix 1 of the “Manufacture Specifications” document. The list of applicable drawings in Appendix 1 of the “Manufacture Specifications” document should include Drawing No. 0908-LE01-3ASIN-020, “Low Enriched Uranium Package (LEUPA) – Gasket Set and Rubber Supplements.”

This information is needed to confirm compliance with paragraphs 425(c), 501, 502(a), 521, 524, and 525 of the TS R 1.

ANSWER:

The package contains information on a new version of the manufacturing Specification, with inclusion in Appendix 1 of drawing No. 0908-LE01-3AEIN-020 - Set of joints rubber supplements.

- Sh-2.** Revise the “Safety Report” to provide information, including analyses as needed, to demonstrate compliance with the TS R 1 dose rate limits for packages that have experienced the accident conditions tests and changes in dose rates due to the normal condition tests.

The application only reports a single package surface dose rate value and a single dose rate value at 1 meter from the package surface. For a Type B package, the application must show that the impacts of the tests described in TS R 1, paragraphs 719 through 724, do not result in more than a 20% increase in the maximum radiation level at the external surface of the package. This should include the results of a normal condition free drop test on the package side with the point of impact being on the part of the package identified as item No. 30 in Drawing No. 0908-LE01-3ASIN-010. The current analyses and tests should include a normal condition free drop test with this configuration. Also, the applicant must demonstrate that the package does not exceed the dose rate limits in paragraph 657 in its condition after the accident conditions tests listed in TS R 1, paragraph 657.

This information is needed to confirm compliance with paragraphs 646(b) and 657 of the TS R 1.

ANSWER:

We consider no additional dose rate calculation is needed, given the package does not suffer any significant change as a consequence of the tests mentioned in TS-R-1 paragraphs 646(b) and 657. The resulting damage is localized and mostly superficial, therefore it is not expected any relevant or measurable change in the contact dose rate.

STRUCTURAL EVALUATION

- St-1.** Provide the following information regarding the four attachments welded on the outside of the outer “shell” of the Model No. LEUPA package:
- a. design details in order to identify the function of these components of the package,
 - b. if these are structural elements, provide the purpose of these attachments,
 - c. provide the details such as the extent and nature of any damages observed on these attachments and the body of the package (at the locations of these attachments) subsequent to the required regulatory drops, and

- d. provide justification demonstrating the adequacy of their performance subsequent to the required regulatory drops.

The applicant describes these components in Document Nos. 0908-LE01-3ASIN-004A and 0908-LE01-3ASIN-010 without providing further details about their dimensions and functionality.

This information is needed to confirm compliance with paragraphs 608 and 715 of the TS R 1.

ANSWER:

These components were designed for the purpose of making handling easier in the manufacturing processes; they do not have a specific role in the transportation and restraint of the package. The restraint methods allowed are described in document 0908-LE00-3DEIN-018- TRANSPORT MANUAL. In the following image you can see the deformations suffered in the drop and crush tests.



- St-2.** Provide justification for the applicant's statement that the Model No. LEUPA package will prevent the entry of a 10-centimeter (cm) cube after being subjected to tests specified in paragraphs 719 to 724.

The applicant does not provide sufficient information in Document Nos. 0908-LE00-3BSIN-023A and 0908-LE02-3BSIN-002A to justify how the applicant meets the requirements in paragraph 675².

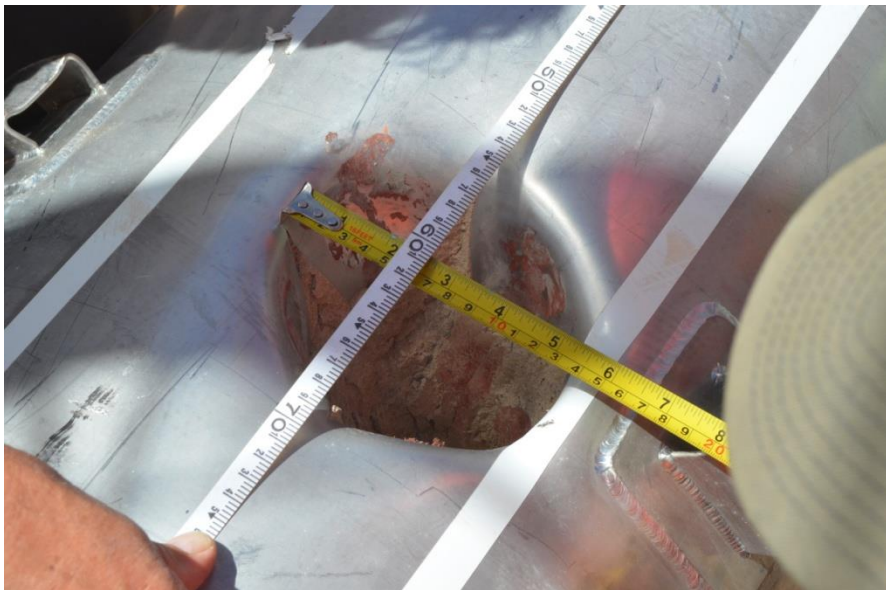
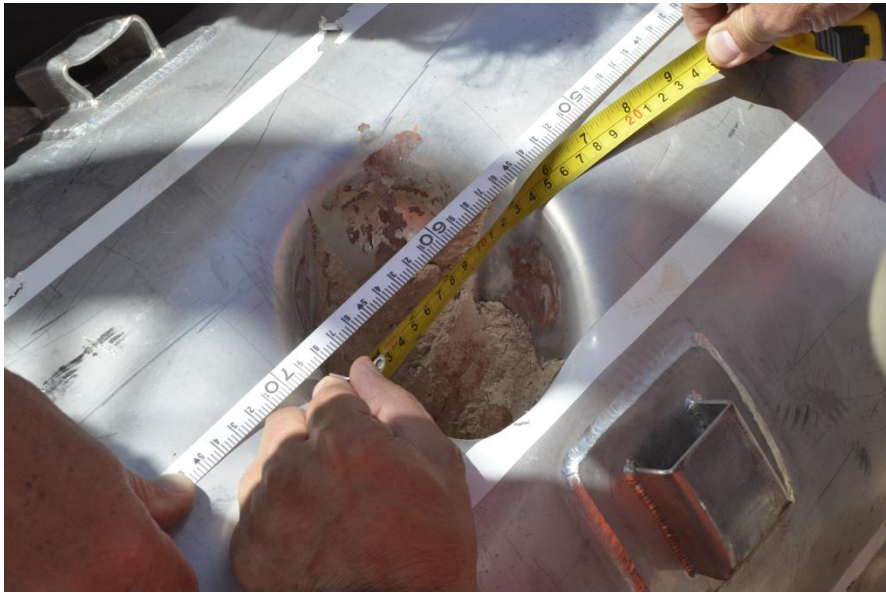
This information is needed to confirm compliance with paragraph 675 of the TS R 1.

² Note that paragraph 675 refers to the acceptable outcome of the tests specified in paragraphs 719 to 724.

ANSWER:

The only test which produces an opening in the external hull is the penetration test. Document 0908-LE02-3BEIN-008-A - TEST FINAL REPORT shows in figures 19 and 18 the test and its results approved by the Nuclear Regulatory Authority issuing the certificate, present during the test.

Below are more pictures of the results, where we see the maximum penetration diameter is 14 cm and decreases towards the inside, which means it would not fit a 10 cm side cube.



St-3. Clarify and revise, as needed, in the application the load used for the stacking test described in Section 6.2.2 of the “Tests Final Report” document: 0908-LE02-3BSIN-008A.

Section 6.2.2, paragraph 2, indicates that a 2,399 kg load was used, while Section 6.2.2, paragraph 3, appears to indicate a 473 kg load (i.e., a load equal to the package's mass) was used. Also, on page 43 of the same report it is indicated that 2,399kg load was stacked on the specimen for 43 hours. Thus, it is unclear that the test described by the applicant in Section 6.2.2 meets the requirement in TS-R-1 paragraph 723.

This information is needed to confirm compliance with paragraph 723 of the TS R 1.

ANSWER:

The wording in section 6.2.2 is confusing, and has been corrected in the revision we are sending now.

St-4. Provide documentation to confirm that the package (e.g., the spiral gasket seal) is designed and evaluated to the following conditions:

- a. at temperatures between -40°C and 70°C,
- b. for pressures as low as those resulting from a 60 kilopascals (kPa) ambient pressure, and
- c. if there is an internal pressure that produces a pressure differential of not less than the maximum normal operating pressure plus 95 kPa.

Although the spiral gasket seals the content's inner containers, the application did not include documentation to support the performance of the containment boundary nor the spiral gasket.

This information is needed to confirm compliance with paragraphs 619, 637, and 643 of the TS R 1.

ANSWER:

Document 0908-LE01-3BEIN-011- CALCULATION REPORT studies the container for an internal pressure of 700 KPa.

The LEUPA package is not designed to work with vacuum.

The spiraled connection is designed for this temperature range. The data sheet is added in the answer to item G-1-J.

OPERATING PROCEDURES

OP-Sh-4. Revise the "Operation Manual" document to include a description of the package unloading operations.

The "Operation Manual" should include procedures for unloading the package, including receipt inspections and actions to take if the package is damaged. These kinds of operations descriptions are missing but should be provided to ensure the package is operated in accordance with its approved design.

This information is needed to confirm compliance with paragraphs 509 and 510 of the TS R 1.

ANSWER:

The new revision of document 0908-LE00-3BEIN-017- OPERATION MANUAL contains an unloading procedure.

ACCEPTANCE AND MAINTENANCE TESTS

AT-Sh-1. Provide acceptance criteria for the acceptance tests and maintenance programs/tests that include the package component specifications (material and dimension specifications) in all the provided technical drawings, as discussed below.

While the “Manufacture Specifications” document lists all of the package drawings in an appendix, the acceptance tests and criteria only refer to a few of these drawings. Some components’ material specifications and dimensions are not part of the limited number of drawings referenced in the acceptance tests as acceptance criteria. Therefore, the applicant should provide acceptance tests and criteria that address all of the package’s components in all the drawings listed in the appendix to the “Manufacture Specifications” document. The acceptance criteria should include all the specifications in all the package drawings. Furthermore, the applicant should describe the acceptance criteria in the “Inspection and Maintenance Manual” for maintenance of the package. The criteria should be like those in the “Manufacture Specifications” document.

This information is needed to confirm compliance with paragraph 501 of the TS R 1.

ANSWER:

We are sending a new revision of document 0908-LE00-3BEIN-026- INSPECTION AND MAINTENANCE MANUAL, containing an item with acceptance criteria for each component.