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Table of Content

[1. Introduction 4](#_Toc40437673)

[1.1. Purpose 4](#_Toc40437674)

[1.2. Scope 4](#_Toc40437675)

[1.3. Terms, Definitions and Abbreviations 4](#_Toc40437676)

[1.4. Reference documents 5](#_Toc40437677)

[1.5. References to standards 6](#_Toc40437678)

[2. System Overview 6](#_Toc40437679)

[3. Functional and Performance Requirements 6](#_Toc40437680)

[4. Design requirements 7](#_Toc40437681)

[4.1. General requirements 7](#_Toc40437682)

[4.2. Vacuum Chamber 9](#_Toc40437683)

[4.3. Vacuum pipe 10](#_Toc40437684)

[4.4. Sealing and sealing surface 11](#_Toc40437685)

[4.5. Vacuum fittings 12](#_Toc40437686)

[4.6. Interfaces 13](#_Toc40437687)

[5. Manufacturing Requirements 13](#_Toc40437688)

[6. Cleaning requirements 15](#_Toc40437689)

[7. Delivery requirements 17](#_Toc40437690)

[7.1. General requirements 17](#_Toc40437691)

[7.2. Packaging for transport – Ensuring Cleanliness 17](#_Toc40437692)

[8. Safety requirements 18](#_Toc40437693)

[9. Quality requirements 19](#_Toc40437694)

[9.1. General Quality Requirements 19](#_Toc40437695)

[9.2. Documentation and data control 20](#_Toc40437696)

[9.3. Nonconformity Control System 21](#_Toc40437697)

[10. Verification requirements for the Supplier 21](#_Toc40437698)

[10.1. General requirements 21](#_Toc40437699)

[10.2. Verification documentation 22](#_Toc40437700)

[10.2.1. General requirements 22](#_Toc40437701)

[10.2.2. Verification reports (VRs) 22](#_Toc40437702)

[10.2.3. Verification Control Document (VCD) 23](#_Toc40437703)

[10.3. Phasing of the delivery 23](#_Toc40437704)

[10.3.1. Qualification of Design 24](#_Toc40437705)

[10.3.2. Manufacturing 24](#_Toc40437706)

[10.3.3. Acceptance 25](#_Toc40437707)

# Introduction

## Purpose

This Requirements Specification Document (RSD) describes the requirements and constraints for the design, manufacturing and delivery of the multipurpose vacuum chamber and vacuum components. This leads to the identification of interfaces with the ELI laser systems and ELI building facility. The RSD also acts as the parent document for the technical requirements that need to be addressed in lower-level design description documents (section 1.4.).

## Scope

The RSD contains all of the top level functional, design, performance, delivery, safety, quality and verification requirements for the following product (tender code TP20\_054): **Multipurpose vacuum chamber (MVC)** **and vacuum components**.

The MVC assembly consists mainly of vacuum vessel decoupled additionally pipe DN800 and fittings, which are also parts of this RSD and the appropriate procurement. A breadboard is decoupled from the vacuum vessel by use of edge welded bellows and is not a part of this tender. Supplier is responsible for manufacturing, assembling, testing, cleaning, delivery and final verification of the MVC and vacuum components specified in further sections. This **MVC** is registered in the PBS software under the following PBS code: *E.E2.BETA.BT.3.1*.

## Terms, Definitions and Abbreviations

For the purpose of this document, the following abbreviated terms apply:

| **Abbreviation** | **Meaning** |
| --- | --- |
| A | Analysis (as a Verification method) |
| AR | Analysis Report |
| BT | Beam Transport |
| CA | Contracting Authority (Institute of Physics AV CR, v. v. i.) |
| CDR | Critical Design Review |
| CDRR | CDR Report |
| CVC | Central Vacuum Control |
| E2 | Experimental Hall 2 |
| ELI | Extreme Light Infrastructure  |
| ESD | Electrostatic Discharge |
| EUV | Extreme Ultraviolet |
| FEA | Finite Element Analysis |
| FEM | Finite Element Method |
| FFKM | Perfluoroelastomer  |
| FKM | Fluoroelastomer polymer |
| FPM | Fluorelastomer Polymer |
| FTR | Factory Test Report |
| I | Inspection (as a Verification method) |
| MVC | Multipurpose Vacuum Chamber |
| NCR | Nonconformity Report |
| NDT | Non-Destructive Testing |
| NVR | Non-Volatile Residue |
| R | Review of design or documentation (as a Verification method) |
| RCS | Reference Coordinate System |
| RMS | Reference Mechanical System |
| RSD | Requirements Specification Document |
| T | Test (as a Verification method) |
| TMP | Turbo Molecular Pump |
| ULO | Ultra-Low Outgassing |
| UHV | Ultra-High Vacuum |
| VCD | Verification Control Document |
| VR | Verification reports |

For the purpose of this document, the following definitions apply:

* Positioning: placing of a component without high precision (no special equipment needed);
* Adjustment: Placing of a component with using special equipment (e.g. screws, actuators) to achieve high precision.

## Reference documents

|  |  |
| --- | --- |
| **Number of document** | **Title of document** |
| RD-01 | 00271018-A\_RD-01\_3D Model and Drawings\_TP20\_054 |
| RD-02 | 00211646-D\_Cleanlines and Contamination Control in Vacuum system |
| RD-03 | 00142371-B\_Design Safety Engineering Standards/Guidelines |
| RD-04 | 00115311-C\_Alignment Marks System |
| RD-05 | 00270669-A\_5.1\_ES\_VCD\_Multipurpose vacuum chamber for E2\_TP20\_054 |

Detailed list of drawings including within **RD-01** archive:

| **DRAWING NUMBER / REV.** | **DRAWING/ FILE NAME** | **FILE FORMAT** |
| --- | --- | --- |
| 00256584/02 | Main assembly\_A0 | PDF |
| 00256626/03 | Vacuum vessel\_A0  | PDF |
| 00271330/00 | TUBE DN800 MPC | PDF |
| 00271328/00 | FLANGE\_ISO-F\_DN800 | PDF |

## References to standards

If this document includes references to standards or standardized/standardizing technical documents the CA permits equal solutions to be offered by the Supplier. The CA will not reject a Supplier’s bid, upon the Supplier proves that the supplies, services or works offered meet the requirements described, including references to standards or technical documents.

# System Overview

Multipurpose chamber with vacuum components is an additional assembly for needs of required laser adjustments of the already existing BT L3. The MVC, together with vacuum components, provides sealed, clean and dry environment of pumped-down volume with the particular level of vacuum (specified further in the requirements). This volume is enclosed by the vacuum chamber and pipe. The volume is pumped-down with the roughing pump and subsequently with TMPs. Primary pumps (backing and roughing pump), vacuum valves, gauges and TMPs are not included in this contract, and thus Supplier is not responsible for their delivery.

The laser beam L3 is propagated further to the final experiment in E2 hall by use of mirrors and other optomechanical components (placed inside the chamber). Mirrors and other optomechanical components are not included in this contract, and thus Supplier is not responsible for their delivery.

The rest of this document outlines in detail all of the requirements to be met by the Supplier in the completion of the MVC assembly.

# Functional and Performance Requirements

REQ-029551/A

All components shall work in the following operational conditions:

* Temperature (standard during operation): 21 °C. In the case of climate control system failure, the MVC needs to remain safe at (21 ± 10) °C;
* Relative humidity: 40 – 80 %;
* Internal pressure: 1∙10-6 mbar;
* External pressure: 1 atm (1.01325 bar);
* ISO 7 cleanroom compatibility according to ČSN EN ISO 14644 (equivalent to ISO 14644) is mandatory for all surfaces outside of the vacuum surfaces.

Verification method: R – review, T - test

# Design requirements

The general requirements specified herein in section 4.1 refer to all components of the MVC and the next sub-sections 4.2-4.6 of the design requirements provide requirements of each of the main components which make up the MVC. These components are:

* Vacuum vessel;
* Additional pipe DN800;
* Sealing and fittings.

## General requirements

REQ-029553/A

The final design of the MVC shall be developed by the Supplier using the ELI Beamlines conceptual design as a starting point (see **RD-01**; section 1.4).

*NOTE: Any technical drawing that is part of this RSD provides information about dimensions and shall not be considered as manufacturing drawing. The Supplier is responsible for the final design.*

Verification method: R - review

REQ-029554/A

Vacuum assembly and all components exposed to vacuum shall be designed for vacuum level 1∙10-6 mbar.

Verification method: R – review

REQ-029555/A

The final manufacturing drawings shall be approved by the Contracting Authority (CA) before the commencement of manufacturing (see REQ-029670/A).

Verification method: R – review

REQ-029556/A

Any dimensional or design modifications that may arise as part of detailed manufacturing design shall be consulted with and approved by the CA.

Verification method: R – review

REQ-029557/A

As part of the preparation of manufacturing drawings, the Supplier shall perform FEM analysis of vacuum vessel deformations and pipe deformations due to atmospheric pressure differential and show that the design is consistent with REQ-029561/A and REQ-029551/A.

*NOTE: Load cases, which shall be minimally addressed are:*

* *FEA Stress analysis of Vacuum load;*
* *FEA Stress analysis of Vacuum load and temperature control failure.*

Verification method: R - review, A – analysis

REQ-029558/A

The Supplier shall provide final information regarding the weight of all delivered components.

Verification method: R - review

REQ-029559/A

The vacuum vessel, and all parts heavier than 15 kg shall be supplied with lifting eyes to aid safe installation.

*NOTE: The only Exception is vacuum pipe DN800.*

Verification method: R - review, I – inspection

REQ-029560/A

All vacuum components shall be made of Stainless steel 1.4301 and 1.4307, weldable with standard UHV vacuum welding procedures and being non-porous and free of cavities or gas inclusions.

Verification method: R - review, I - inspection

REQ-029561/A

Maximal deformations of the vessel’s walls under vacuum shall be lower than 1 mm in comparison to the vented status.

Verification method: A – analysis

REQ-029562/A

A material certificate according to ČSN EN 10204-2.2/3.1 (equivalent to EN 10204-2.2/3.1) shall be provided for all purchased vacuum materials and parts (e.g. for the chambers, hydroformed bellows, pipes, flanges, etc.) and shall be part of the documentation.

Verification method: R – review

REQ-029563/A

The vacuum vessel and the pipe shall be supplied with a full set of blanking flanges and O-rings.

Verification method: R – review, I - inspection

REQ-029565/A

The MVC shall be delivered with four alignment reference holes with dimensions shown in Figure 1. The location of these reference points would be confirmed by CA with supplier during final design.

*NOTE: Flat contact surface of 28 mm diameter shall be available around the hole.*

Verification method: R – review, I - inspection



**Figure 1:** Reference hole: Diameter 6H7 hole, 28 mm contact surface, 15 mm depth

REQ-029566/A

All vacuum surfaces shall be finished according to general UHV guidelines and subsequently electropolished (or similar) to a surface roughness Ra ≤ 0.8 µm.

Verification method: R – review, I - inspection

REQ-029567/A

The surface finish on any other surfaces (than surface specified in REQ-029566/A or REQ-029592/A) shall be uniform Ballotini (blasting with glass beads).

*NOTE: Other finish technologies* *are possible if agreed with the CA.*

Verification method: R – review, I - inspection

REQ-029569/A

The outer (non-vacuum) surface finish of components shall comply with the requirements of cleanrooms of class 7 according to ČSN EN ISO 14644 (equivalent to ISO 14644).

Verification method: R – review, T - test

REQ-029570/A

Precautions shall be taken in design and assembly of all vacuum components to avoid trapped volumes in vacuum spaces which could result in virtual leaks and these spaces shall be suitably vented.

Verification method: R – review

REQ-029571/A

Vacuum components shall be equipped with inlet and outlet flanges according to the listed standards:

* ISO 1609:1986 - Vacuum technology - Flange dimension;
* ISO 2861:2013 - Vacuum technology - Dimensions of clamped - type quick-release couplings).

Verification method: R – review, I - inspection

REQ-029572/A

Tolerances of all parts shall be, at minimum, according to ČSN ISO 2768-mK (equivalent to ISO 2768-mK).

Verification method: R – review

## Vacuum Chamber

See drawings: 00256626\_03\_Vacuum vessel\_A0.pdf

REQ-029576/A

The vacuum chamber shall allow for fixing into base. The Flatness of four fixing feets shall be 0,4 within a common tolerance zone.

*NOTE: The Supplier is not responsible for delivery of the base for vacuum chamber. The detailed 3D model and drawing of the base will be given to the Supplier after the contract signature.*

Verification method: R – review

REQ-029577/A

The Supplier shall define the Reference Coordinate System (**RCS**) of the Chamber which shall allow positioning of the Chamber in Contracting Authority’s experimental hall according to Reference Mechanical System of the hall (**RMS**).

Verification method: R - review

REQ-029578/A

The **RCS** and its relation to the **RMS** shall be set up jointly by the Supplier and the CA during the design phase (see REQ-029670/A).

Verification method: R - review

REQ-029579/A

The Supplier shall adhere to the following standard (or equivalent) with regards to the stress level of the vacuum chamber: “AD2000 Regelwerk”.

Verification method: R – review, A – analysis

REQ-029582/A

Vacuum vessel shall allow for the installation of components from the top via detachably joined cupola.

Verification method: R – review

## Vacuum pipe

See drawing: 00271330\_00\_TUBE\_DN800\_MPC.pdf

REQ-029584/A

One port of pipe shall have slots holes for connecting reducer such, that reducer rotation can be adjusted.

Verification method: R – review, I - inspection

REQ-029585/A

All openings of the pipe shall be closed by stainless steel or aluminium blank flanges.

Verification method: R – review, I - inspection

REQ-029586/A

Maximum deformations of pipe walls under vacuum shall be in accordance with above-mentioned safety standards including the “AD2000 Regelwerk”, with leak tightness and overall system performance described above. Wall thickness shall be > 5 mm.

Verification method: R - review

REQ-029580/A

Stainless steel pipes with longitudinal welding seam shall be fabricated from tubes according to ČSN EN 10217-7 (equivalent to EN 10217-7) TC2 (Test Class 2) and W2 delivery conditions. In addition, pipe shall be fabricated according to ČSN EN ISO 1127 (equivalent to EN ISO 1127) with D2/T3 tolerance and with certificate according to ČSN EN 10204 - 3.1 (equivalent to EN ISO 10204), material: 1.4301 or higher quality.

*NOTE 1: The pipe shall be finally ground with an UHV compatible process to Ra ≤ 0.8 μm followed by electropolishing to Ra ≤ 0.8 μm.*

*NOTE 2: Visual inspection for weld discontinuities, porosity and inclusions will be conducted by the CA. In case of doubts that the welds meet the requirements, the CA will perform at its own cost the following tests:*

*• x-ray for complete penetration and fusion;*

*• microstructural examination of weld samples cross-sections.*

*NOTE 3: Stainless steel tube with longitudinal welding seam according to ČSN EN 10217-7 (equivalent to EN 10217-7), TC2 and W1 delivery conditions with subsequent grinding / electropolishing can be considered equivalent /conform to pipe with delivery condition W2 under the conditions of heat-treated sheet metal as raw material and subsequent grinding / electropolishing.*

Verification method: I - inspection, T - test

REQ-029587/A

Maximum out of roundness for the pipe shall be < 1.5 %.

Verification method: R - review, I – inspection

## Sealing and sealing surface

REQ-029589/A

The Supplier shall deliver vacuum compatible sealing for all detachable vacuum connections with respect to REQ-029599/A, REQ-029600/A and REQ-029601/A.

Verification method: R - review

REQ-029590/A

Sealing used for all vacuum parts shall be made of fluorelastomer polymer (FPM) material; FKM or FFKM materials or equivalent (e.g. Viton).

*Note: The CA would perform RGA test of the cleaned O-rings prior use without any charge for ensuring cleanliness of the chamber according requirements.*

Verification method: R - review

REQ-029591/A

The hardness of the sealing O-rings shall be 60 or 70 HSC (Shore) unless agreed otherwise with the CA.

Verification method: R - review

REQ-029592/A

The roughness of sealing surfaces of all flanges shall be Ra ≤ 0.8 µm.

Verification method: R - review

REQ-029593/A

Seal faces shall be suitably protected immediately after final machining to minimise the risk of damage. This protection shall only be removed for the purposes of cleaning and inspection, prior to final assembly.

Verification method: R - review, I - inspection

REQ-029594/A

The surface finish of seal faces shall be compatible with the requirements of the ISO-K resp. ISO-F seals used.

Verification method: R - review

## Vacuum fittings

See drawing: 00271328\_00\_FLANGE\_ISO-F\_DN800.pdf

REQ-029595/A

The Supplier shall deliver fittings for all detachable vacuum connections.

Verification method: R - review, I - inspection

REQ-029596/A

The clamps and screw sets shall be of suitable design and use a material that prevents permanent deformation after multiple uses.

Verification method: R - review

REQ-029597/A

The screws and nuts shall be silver coated.

Verification method: R - review

REQ-029599/A

All ISO-K flanges shall be designed for Centering ring with the outer ring.

*NOTE: All ISO-K flanges are denoted in enclosed drawings.*

Verification method: R – review

REQ-029600/A

Unless otherwise stated, all ISO-F flanges shall be designed for O-ring without a groove (flat flange).

*NOTE 1: All such flanges are denoted in enclosed drawings.*

*NOTE 2: ISO-F flanges that are required to be designed for O-ring with groove are specified in the further requirement.*

Verification method: R – review

REQ-029601/A

All ISO-F flanges that are the exception to the requirement REQ-029600/A shall be designed for O-ring with groove (grooved flange). There must be indent enabling O-ring removal without damaging it. *NOTE: All such flanges are denoted in enclosed drawings.*

Verification method: R – review

REQ-029602/A

O-ring groove design shall be dovetail (trapezoidal) with respect to the elimination of trapped volumes.

Verification method: R – review

## Interfaces

REQ-029604/A

The Supplier shall design interfaces for all of the connections given in the **RD-01** (see section 1.4).

*NOTE:   All interfaces shall be in accordance with the ISO 1609:1986 and ISO 2861:2013 standards.*

Verification method: R – review

REQ-029605/A

Assessment of the safety aspects related to the MVC shall be performed by the Supplier.

Verification method: R – review, A – analysis

# Manufacturing Requirements

REQ-029607/A

If the components geometry permits, the seams shall be welded vacuum-sided to avoid outgassing sources.

Verification method: R – review, I - inspection

REQ-029608/A

Vacuum sealing welds made externally shall have full penetration leaving a smooth surface on the vacuum side and shall meet acceptance criteria EN ISO 5817, class B.

Verification method: R – review, I - inspection

REQ-029606/A

Sealing - vacuum welds size shall be appropriate size to stand the load and avoid any possible appearance of lack of fusion or other weld discontinuity after final vacuum surface finish.

*NOTE: Weld design shall be approved by the CA before start of production as part of check of manufacturing documentation (see section 10.3.1).*

Verification method: R – review, I - inspection

REQ-029609/A

Vacuum-compatible welding of components shall be performed as shown in Figure 2.

Verification method: R – review, I - inspection



**Figure 2:** Welded joints compatible with vacuum

REQ-029610/A

The parts to be welded shall be thoroughly cleaned and degreased.

Verification method: R – review, I - inspection

REQ-029611/A

Inert shielding gases shall be used during welding to minimize oxidation.

Verification method: R – review

REQ-029612/A

Only qualified welders according to EN ISO 9606-1 or EN 287-1 or EN ISO 14 732 shall execute the welding.

Verification method: R – review (qualification certificates to be supplied to the CA)

REQ-029613/A

Qualified welding supervision according to EN ISO 14 731 and qualified welding procedures shall be present and used for manufacturing.

Verification method: R – review

REQ-029614/A

The Supplier shall apply cleaning and degreased procedure. This procedure shall be submitted to the CA.

Verification method: R - review

REQ-029615/A

Tools used during manufacture shall not contaminate the vacuum surface.

Verification method: I - inspection

REQ-029616/A

All cutting fluids, greases etc. used during manufacture shall be capable of being removed entirely by subsequent cleaning operations.

Verification method: R - review, I - inspection

REQ-029617/A

Sealing surfaces shall be in particular free of scratches or dents.

Verification method: I – inspection

REQ-029618/A

Any oxidation of vacuum surfaces, especially in the range of weld joints, shall be removed such that the cleanliness requirements are met (see section 6).

Verification method: T – test, I - inspection

REQ-029619/A

Continuous vacuum sealing welds shall be completed on the vacuum side of the vessel.

*NOTE: If tack/stabilizing welding is required, it may be used on the non-vacuum side of the chamber only and* ***intermittent welds shall be used.***

Verification method: R – review, I - inspection

REQ-029620/A

The Supplier shall supply the CA with an extra set of O-rings for each O-ring.

Verification method: I - inspection

REQ-029621/A

All manufactured parts shall be free of sharp edges.

Verification method: I - inspection

REQ-029622/A

All manufactured parts shall be burr free.

Verification method: I - inspection

REQ-029675/A

The Supplier shall perform leak test of the assembly (the chamber consisting of the vacuum vessel and provide to the CA the results of this test (see REQ-029671/A).

*NOTE 1: Single leak test (spray test) shall be performed according to ČSN EN 1779, method A.3 (equivalent to EN 1779).*

*NOTE 2: Total leak test shall be performed according to ČSN EN 1779, method D.2 (equivalent to EN 1779). If this is not possible, other methods may be proposed by the Supplier.*

Verification method: T – test

REQ-029676/A

The measured single leak rate using He detector shall be less than
1∙10-9 mbar l/sec.

Verification method: T – test

REQ-029677/A

The total leak rate measured shall be better than 5∙10-4 mbar·l/sec.

Verification method: T – test

# Cleaning requirements

All vacuum surfaces and vacuum components require cleaning compatible with high-energy laser e-beam coated optics. Failure to do this will cause catastrophic damage to the highly sensitive optics housed by the MVC. Specifically, hydrocarbons are known to degrade the laser damage threshold of high-power laser optics. The cleanliness requirements detailed below are similar to ultra-high vacuum systems and the standards of EUV lithography/semiconductor industry. Only a monolayer of molecules on the surfaces inside of the vacuum is tolerable.

REQ-029623/A

All inner walls of the vacuum components shall be electro-polished.

Verification method: R - review

REQ-029624/A

The Supplier shall provide the CA with the description of the cleaning procedure for vacuum components which will be reviewed and approved by the CA.

Verification method: R – review

REQ-029625/A

All parts shall be cleaned to meet a particle cleanliness level of 200 with the best effort a particle level 300 guaranteed per MIL–STD-1246C (or equivalent standard) superseded by IEST-STD-CC1246E for particles with size > 5 μm.

Verification method: R – review, T - test

REQ-029626/A

The total non-volatile residue (NVR) testing shall be performed for all parts of the MVC. The NVR level shall be A/10 per MIL-STD1246C (or equivalent standard) superseded by IEST-STD-CC1246E, i.e. < 0.1 μg/cm2.

*NOTE: The table below shows the non-volatile residue cleanliness levels of the MIL-STD1246C.*



Verification method: R – review, T - test

REQ-029627/A

RGA tests for the MVC shall meet the same requirements as described in Table 4 of RD-02 (see section 1.4).

*NOTE: Minimally the amplitude of all peaks up to 200 amu > 44 AMU is no higher than 1/100 of the 44 AMU peak and the peak at 43 AMU is not higher than 1/10 of the 44 peak.*

Verification method: R – review, T - test

REQ-029628/A

The Supplier shall consult procedures for the particle, the NVR, and RGA cleanliness levels verification to the CA. The CA shall approve of these procedures prior to test completion and acceptance.

*NOTE: See RD-02 and RD-03 for the CA’s approved methods for clean procedures and procedures for verifying cleanliness.*

Verification method: R – review

# Delivery requirements

## General requirements

REQ-029629/A

The transportation of the MVC and vacuum components shall be conducted by the Supplier at the ELI Beamlines facility in Dolní Břežany.

Verification method: I - inspection

REQ-029630/A

The transportation procedures shall be discussed and reviewed by the CA installation’s officer.

Verification method: R – review

REQ-029631/A

The crates shall be labelled with the contents of the crate, i.e. with all part numbers of the contained components.

Verification method: I - inspection

REQ-029632/A

All parts of the MVC shall be inspected after arrival at the CA facility to ensure no damage occurred during transport.

Verification method: I - inspection

REQ-029634/A

The MVC and vacuum components shall be delivered in a protective package preventing damage and contamination and a minimum of two plies separate clean packaging (see REQ-029637/A).

Verification method: R - review, I - inspection

REQ-029635/A

All Parts shall be identified according to technical documentation.

Verification method: R – review

REQ-029636/A

Maximum dimensions of used components and their non-dismountable sub-components shall be 2000 x 2000 x 1750 m.

Verification method: R – review

## Packaging for transport – Ensuring Cleanliness

List of Terms for this Section:

1. **ULO Polyethylene ("ULO")**: Ultra-Low Outgassing polyethylene bag or sheet ≥150 µm thick, with a certified NVR level of ≤ 0.14 µg/cm2 (certified ULO polyethylene or equivalent).
2. **Part Specific Label**: A cleanroom label identifying product information in accordance with contract documents.
3. **Intimate Layer**: The innermost layer of ULO and which is in direct contact with the MVC.
4. **Outer Layer**: The outermost layer of ULO used in packaging of the MVC.
5. **Label of Cleaner**: Cleanroom label with the following information: Cleaner name and location, cleaning process (es) used and date of cleaning.
6. **Cleaned Components/Assemblies:** Components/Assemblies that clean enough to satisfy cleaning requirements (i.e. components and surfaces which will be exposed to vacuum).

REQ-029637/A

Cleaned components/assemblies shall be double packaged in ULO foil and sealed.

Verification method: R – review, I - inspection

REQ-029638/A

All cleaned components/assemblies shall be dry prior to packaging.

Verification method: R – review, I - inspection

REQ-029639/A

When possible, the cleaner shall ensure that part number and, if applicable, serial numbers on the Part Specific Label match with that of the components/assemblies in that bag. Such label shall be at the inner and outer packaging ULO foil.

Verification method: R – review, I - inspection

REQ-029640/A

Assembly and packing of the MVC on the Supplier side shall take place under controlled conditions in a cleanroom class 7 environment or better according to ČSN EN ISO 14644 (equivalent to EN ISO 14644).

*NOTE: The ISO 14644 certification of the Supplier’s cleanrooms is not required.*

Verification method: R – review, I - inspection

# Safety requirements

REQ-029641/A

The Supplier shall perform hazard identification and risk assessment of the MVC as a part of the design process.

Verification method: R – review, A – analysis

REQ-029642/A

The Supplier shall be compliant with all regulations described in the Design Safety Engineering Standards/Guidelines (see RD-03 of reference documents).

Verification method: R – review

REQ-029643/A

The Supplier shall abide by all safety requirements and procedures of the CA facility.

*NOTE:* *All corresponding ELI Beamlines regulations and procedures associated with the Supplier’s obligations will be provided to the Supplier.*

Verification method: R – review

REQ-029644/A

The Supplier shall supply a Declaration of Conformity or any other equivalent document legally recognized and accepted in the Czech Republic for each product type if the appropriate legislation determines the Supplier's obligation to have a Declaration of Conformity (or the equivalent document) for the purposes of a Device sale in the Czech Republic to fulfil the requirements of 2001/95/EC directive or applicable Czech law.

Verification method: R – review

# Quality requirements

## General Quality Requirements

REQ-029645/A

The Supplier shall identify a Quality manager, which will be responsible for implementing and performing management and other Quality disciplines and functions to ensure fulfilment of all the requirements described in this RSD.

Verification method: R - review

REQ-029646/A

The Supplier shall prepare, implement and maintain a quality plan for the MVC development and manufacturing to ensure that the product quality is in compliance with intended use and in conformity with requirements.
*NOTE 1: The CA reserves the right to provide basic requirements for the Quality Plan during its preparation.*

*NOTE 2: The CA can assist with the quality plan definition.*

Verification method: R - review

REQ-029647/A

The Supplier's personnel shall be certificated according to ČSN EN ISO 9712: 2013 (equivalent to EN ISO 9712:2012), Non-destructive testing - Qualification and certification of NDT personnel.

Verification method: R - review

REQ-029648/A

If the Supplier’s Quality organization delegates quality assurance tasks to any another organization it shall be done in a documented and controlled way monitored by the Supplier.

Verification method: Not To Be Tracked within VCD

REQ-029649/A

The Supplier shall report quality plan progress to the CA as part of product assurance activities.

Verification method: Not To Be Tracked within VCD

## Documentation and data control

REQ-029650/A

The Supplier shall provide the following relevant manufacturing documents:

* Full technical documentation (including manufacturing drawings, see REQ-029553/A, REQ-029555/A and REQ-029670/A);
* Breakdown list as-built or/and material list (see REQ-029560/A, REQ-029562/A, REQ-029590/A and REQ-029606/A);
* All approved “requests for deviation/wavier” (see REQ-029575/A).

Verification method: I – inspection

REQ-029651/A

The Supplier shall provide to the CA the Product User Manual as part of the delivered MVC. The Manual shall include the instructions and descriptions regarding the following procedures:

* transport, handling, manipulation, storage and cleaning;
* step-by-step installation and alignment procedures;
* safe operation and maintenance procedures.

Verification method: R - review

REQ-029652/A

All documentation shall be supplied in the English language in both hardcopy and electronic format according to the REQ-029653/A and REQ-029654/A.

Verification method: R - review

REQ-029653/A

The Supplier shall provide the following types of technical documentation:

1. Final 3D model in one (two preferred) of the following formats:
* Universal format: step \*.STP;
* Native data
	+ Part/Assembly files for Autodesk Inventor version 2020,
	+ Part/Assembly files for Siemens NX.
1. Final detailed manufacturing drawings in one (two preferred) of the following file formats:
* \*.dwg;
* Native data
	+ Drawing files for Autodesk Inventor version 2020,
	+ Drawing files for Siemens NX.

Verification method: R – review, I - inspection

REQ-029654/A

The Supplier shall use also the following data formats:

* \*.JPG, \*.PNG, \*.PDF, \*.HTML;
* text processors \*.doc, \*.docx; OpenDocument Format;
* spreadsheet processors \*.xls, \*.xlsx; OpenDocument Format;
* presentations \*.ppt, \*.pptx; OpenDocument Format.

Verification method: Not To Be Tracked within VCD

REQ-029655/A

The MVC shall be marked on the outside with the following information:

* Manufacturer;
* Date of manufacture;
* Manufacturer reference (e.g. serial number).

Verification method: I - inspection

## Nonconformity Control System

REQ-029575/A

The Supplier shall establish and maintain a nonconformity control system compatible with ČSN EN ISO 9001 (equivalent to EN ISO 9001).

Verification method: Not To Be Tracked within VCD

# Verification requirements for the Supplier

The verification process will be performed by the Supplier to demonstrate that the MVC meets the specified requirements of the CA.

## General requirements

REQ-029656/A

The Supplier shall assign clear responsibility for the implementation of the verification process including the following activities:

1. **Verification planning** (via VCD, see section 10.2.3);
2. **Verification execution and reporting** (see sections 10.2.2 and 10.3);
3. **Verification control and close-out** (see sections 10.2.3 and 10.3.3).

Verification method: Not To Be Tracked within VCD

REQ-029657/A

The verification process shall be accomplished by the Supplier through one or more of the following verification methods:

1. **Review**; Verification via Review **(R)** shall consist of using approved records (examples of such approved records are design documents and reports, technical descriptions, and engineering drawings, manuals and accompanying operation documentation) or evidence that unambiguously shows that the requirement is met.
2. **Inspection**; Verification via Inspection **(I)** shall consist of visual determination of physical characteristics including photographs taken by the Supplier and sent to the CA proving that the specific requirements have been met.
3. **Test** (including functional demonstration); Verification via Test (**T**) shall consist of measuring product performance and functions under realistic operating conditions. When the test objectives include the demonstration of qualitative operational performance (functional demonstration), the execution shall be observed and results recorded.
4. **Analysis**; Verification via Analysis **(A)** shall consist of performing theoretical or empirical evaluations (e.g. mathematical models, calculations, etc.).

Verification method: Not To Be Tracked within VCD

## Verification documentation

### General requirements

REQ-029658/A

The Supplier shall establish and maintain the system of verification process documentation (see REQ-029659/A and REQ-029660/A).

Verification method: Not To Be Tracked within VCD

REQ-029659/A

Verification documentation shall consist of following basic types of documents:

* **Verification reports** (see section 10.2.2);
* **VCD, Verification Control Document** (see section 10.2.3).

Verification method: Not To Be Tracked within VCD

REQ-029660/A

The verification reports shall be submitted to the CA for the review as agreed with the CA after corresponding verification activity completion, within the time frame agreed with the CA in the VCD (see section 10.2.3).

*NOTE: Verification activity can be design review and analysis during the MVC development, test and inspection after the final MVC assembly.*

Verification method: R - review

### Verification reports (VRs)

REQ-029661/A

The results of the analysis shall be documented in the corresponding **Analysis Report** (further “**AR**”) and tracked in the VCD (see section 10.2.3).

Verification method: R - review

REQ-029662/A

The results of a review of design shall be documented in the **Critical Design Review Report** (further “**CDRR**”) and tracked in the VCD (see section 10.2.3).

*NOTE 1: The CDR is intended to verify that the design meets corresponding requirements (could be accepted) and/or identify required corrective actions needed to accept the design and start manufacturing phase of the contract.*

*NOTE 2: The CA can provide to the Supplier the template of CDRR.*

Verification method: R - review

REQ-029663/A

The results of the inspection shall be tracked in the VCD.

Verification method: R - review

REQ-029664/A

The results of the tests shall be documented in the appropriate **Factory Test Report** (further “**FTR**”) and tracked in the VCD (see section 10.2.3).

Verification method: R – review

### Verification Control Document (VCD)

The Verification Control Document (**VCD**) lists the requirements to be verified with the selected methods at the defined stages of the MVC delivery (see section 10.3). The VCD is a living document which shall be used throughout the entire Contract delivery and its phases (see section 10.3). The VCDprovides traceability during delivery phases (Qualification of Design, Manufacturing, Delivery and Acceptance).

The VCD represents a formal tool of communication between the Supplier and the CA (formal record, reporting tool).

REQ-029665/A

The Supplier shall provide a **Verification Control Document** (further “**VCD**”) for the reviews as agreed with the CA.

*NOTE 1: Guidelines for VCD preparation see in RD-05 (section 1.4).*

*NOTE 2: The form of VCD will be agreed between the CA and the Supplier based on the best commercial praxis used by the Supplier.*

Verification method: R - review

REQ-029666/A

In the VCD the Supplier shall specify **HOW** and **WHEN** each requirement is planned to be verified.

*NOTE: Since some requirements are to be verified through a review of design the VCD shall be prepared by the Supplier and agreed with the CA before starting of the Design Review.*

Verification method: R - review

REQ-029667/A

The verification approach shall be defined by the Supplier in the VCD and provided to the CA prior to implementation.

Verification method: R - review

REQ-029668/A

The Supplier will provide regular progress reports to the CA in the form of the VCD execution and, if required by the CA, a PowerPoint presentation.

Verification method: R - review

## Phasing of the delivery

This section is intended to briefly summarize basic milestones of the Contract delivery. These milestones represent gates (checkpoints) where the quality of the delivery is to be evaluated.

Delivery shall not proceed past these gates unless their satisfactory accomplishment is approved by the CA.

Delivery lifecycle shall contain at least the following phases (***quality gates***):

* **Qualification of Design;**
* **Manufacturing and Delivery;**
* **Acceptance** (performed by the CA).

### Qualification of Design

Summary of what has to be provided by the Supplier in terms of documentation (technical documentation including manufacturing drawings and design supporting documentation, verification reports including CDRR and AR) before starting the manufacturing. The goal is to verify the **manufacturing drawings and design supporting documentation**.

The output of this phase is **the** **Final Design and the agreed scope of technical documentation**.

REQ-029669/A

Before completion of the Qualification Design phase the Supplier shall provide following information that shall be agreed by the CA:

* structure and content of the **verification reports** (see section 10.2.2);
* structure and content of the **VCD** ready to be implemented (see section 10.2.3).

Verification method: R - review

REQ-029670/A

Before completion of the Qualification Design phase the Supplier and the CA shall agree on:

* Final **manufacturing drawings** provided by the Supplier (see REQ-029553/A and REQ-029555/A);
* Acceptance results of design verification submitted by the Supplier in the corresponding **CDRR** and **AR** (see REQ-029662/A and REQ-029661/A);
* Detailed procedures related to the **testing** during Manufacturing phase (see REQ-029613/A, REQ-029614/A, REQ-029624/A, REQ-029628/A, REQ-029630/A and section 10.3.2);
* Nonconformity control system (see REQ-029575/A).

Verification method: R – review

### Manufacturing

The goal is to demonstrate that the manufactured and assembled MVC meet all requirements specified herein.

This quality gate concerns primarily:

* **Inspection of the manufactured and assembled MVC**;
* **Testing at the Supplier’s site** (factory testing);
* **Cleaning, packaging and delivery**.

The output of this phase is **the readiness of the successfully verified MVC assembly to be delivered to the ELI Beamlines**.

REQ-029671/A

The results of the Manufacturing phase of verification shall be recorded by the Supplier in the appropriate FTR (see REQ-029664/A) and overall results (including review of documentation/reports and inspection of the assembled MVC) shall be recorded in the VCD (see section 10.2.3).

Verification method: R - review

REQ-029672/A

The Supplier shall provide reports with results of vacuum and cleanliness tests of the MVC (see REQ-029675/A, REQ-029676/A, REQ-029677/A, REQ-029625/A, REQ-029626/A and REQ-029627/A).

Verification method: R - review

REQ-029673/A

The final issue of the VCD shall be submitted to the CA after the approval of the last report before delivery.

Verification method: R - review

### Acceptance

The final acceptance will be carried on the complete and fully assembled MVC after delivery and successfully passing acceptance tests. Upon delivery of the MVC in the appropriate and undamaged packaging, the CA shall provide to the Supplier with a Handover/takeover protocol.

The basis for acceptance will be completed VCD summarizing the overall verification results together with relevant documentation supporting the verification (i.e. VRs, approved manufacturing drawings and 3D model, Product User Manual, etc.).

In case of successful acceptance phase, the CA will provide to the Supplier signed acceptance protocol. In case of unsuccessful acceptance, the CA will provide to the Supplier a Nonconformity Report (NCR) and the Supplier will be obliged to address the nonconformance.

REQ-029674/A

The Final Acceptance phase shall demonstrate the following:

1. Final MVC has been successfully verified by the Supplier and the results of this process have been documented properly through VRs (see section 10.2.2) and VCD (see section 10.2.3);
2. All detected nonconformities have been solved in accordance with REQ-029575/A;
3. Final MVC is free of fabrication errors and is ready for the intended operational use.

*NOTE 1: In the acceptance phase, the verification of the final MVC and required documentation will be carried out by the CA within 7 weeks after the issuing of the latest Handover/takeover protocol.*

*NOTE 2: The MVC will pass the acceptance when all specifications/requirements of the drawings/RSD are met.*

*NOTE 3: The cleanliness is an important acceptance requirement.*

Verification method: Not To Be Tracked within VCD