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| --- | --- | --- | --- |
| **Confidentiality**: | *BL - Restricted for internal use* | **TC ID/Revision**: | 00158466/B |
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# Quality Requirements for Supplier

## General Quality Requirements

|  |  |  |  |
| --- | --- | --- | --- |
| **N°** | **TC N°** | **Requirement** | **Verification by** |
| QR1-01 | REQ-022310 | A | The Supplier shall identify a Quality Manager for the project, responsible for implementing and performing management and other Quality disciplines and functions. | R - review |
| QR1-02 | REQ-022311 | A | If the Supplier delegates the quality assurance tasks to other organization it shall be done in a documented and controlled way monitored by the Supplier. | Not To Be Tracked within VCD |
| QR1-03 | REQ-022312 | A | The Supplier shall prepare, maintain and implement a Quality Plan for the product development and manufacturing to ensure that the product quality is in compliance with intended use and in conformity with requirements.*NOTE: The Client reserves the right to provide basic requirements for the Quality Plan.* | R - review |
| QR1-04 | REQ-022313 | A | The Quality Plan shall be submitted according to provisions of Annex 1. | R - review |

## Nonconformity Control System

|  |  |  |  |
| --- | --- | --- | --- |
| **N°** | **TC N°** | **Requirement** | **Verification by** |
| QR1-05 | REQ-022314 | A | The Supplier shall establish and maintain a nonconformity control system compatible with ČSN EN ISO 9001 (equivalent to EN ISO 9001). | Not To Be Tracked within VCD |

## Documentation and data control

|  |  |  |  |
| --- | --- | --- | --- |
| **N°** | **TC N°** | **Requirement** | **Verification by** |
| QR1-06 | REQ-022315 | A | The Supplier shall supply the following relevant manufacturing documents:* Full technical documentation (including manufacturing drawings)
* Breakdown list as built
* Handling, installation and maintenance manuals
* All approved “requests for deviation/waiver” (see REQ-022314; QR1-05).
 | I – inspection |
| QR1-07 | REQ-022316 | A | All documentation shall be supplied in both hardcopy and PDF/A. | I – inspection |
| QR1-08 | REQ-022317 | A | The Supplier shall provide the following types of technical documentation:* Final 3D model (if available)
* Final 2D drawings.
 | R - review |
| QR1-09 | REQ-022318 | A | The Supplier shall use the following data formats:* \*.JPG, \*.PNG, \*.PDF/A, \*.HTML
* CAD 2D: \*.dwg
* CAD 3D: \*.stp; \*.ste; \*.step, \*.x\_t; \*.x\_b, or other 3D CAD formats agreed with the Client
* Text processors \*.doc, \*.docx, OpenDocument Format
* Spreadsheet processors \*.xls, \*.xlsx, OpenDocument Format
* Presentations \*.ppt, \*.pptx; OpenDocument Format.
 | Not To Be Tracked within VCD |

# Verification Requirements for Supplier

1.

## General requirements

|  |  |  |  |
| --- | --- | --- | --- |
| **N°** | **TC N°** | **Requirement**  | **Verification by** |
| QR2-01 | REQ-022319 | A | The verification process shall be managed by the Supplier and shall proceed according to the Verification Plan (VP), see provisions of Annex 1. The verification process shall include the following activities:1. **Verification planning** (see section 2.3 below)2. **Verification execution and reporting** (see section 2.4 below)3. **Verification control and close-out** (see sections 2.5 and 2.6 below). | Not To Be Tracked within VCD |
| QR2-02 | REQ-022320 | A | The Supplier shall assign clear responsibility for the implementation of the verification process including the activities defined in QR2-01 (REQ-022319). | R - review |

## Verification Documentation

|  |  |  |  |
| --- | --- | --- | --- |
| **N°** | **TC N°** | **Requirement**  | **Verification by** |
| QR2-03 | REQ-022335 | A | The Supplier shall establish and maintain the system of verification process documentation. | Not To Be Tracked within VCD |
| QR2-04 | REQ-022336 | A | Verification documentation shall consist of following basic types of documents:* **VP, Verification Plan** (see section 2.3)
* **Verification Reports** including: CDR Report, Tests, Inspection and Analyses reports (see section 2.4)
* **VCD, Verification Control Document** (see section 2.5).
 | Not To Be Tracked within VCD |
| QR2-05 | REQ-022337 | A | The verification report shall be submitted to the Client for the review as agreed with the Client after corresponding verification activity completion, within the time frame agreed with the Client.*NOTE: Verification activity can be design review and analysis during the CIS development, test and inspection of the final System.* | R - review |

## Verification Planning

|  |  |  |  |
| --- | --- | --- | --- |
| **N°** | **TC N°** | **Requirement**  | **Verification by** |
| QR2-06 | REQ-022321 | A | The Supplier shall define the verification approach in a Verification Plan (VP) for approval by the Client prior to implementation. | Not To Be Tracked within VCD |
| QR2-07 | REQ-022322 | A | The Verification Plan (VP) shall describe **HOW** and **WHEN** each of the technical requirements will be verified:*NOTE 1: The Client reserves the right to provide binding guidelines for establishing the VP, within 15 working days from the Commencement Day of the contract.**NOTE 2: Guidelines for VP preparation can be provided by the Client.* | R – review |

## Verification execution

|  |  |  |  |
| --- | --- | --- | --- |
| **N°** | **TC N°** | **Requirement**  | **Verification by** |
| QR2-08 | REQ-022323 | A | The verification execution process shall consist of following stages according to the phasing of the contract execution:* **Critical design review (CDR**);
* **Verification of all components of the CIS system** (testing and inspection at Supplier’s site)**;**
* **Acceptance by the Client at customer site**.

*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: Verification of all elements of the CIS system is executed at the end of each corresponding manufacturing phase by inspection and tests. The purpose of this verification is checking the product readiness for shipment to the Client.**NOTE 3: In the acceptance stage the verification shall demonstrate that the product meets the specifications (see Annex 2 of the Contract) and that it is free of fabrication defects and is ready for the intended operational use.* | Not To Be Tracked within VCD |
| QR2-09 | REQ-022324 | A | Acceptance shall be carried out on final hardware and software.*NOTE 1: Output of this verification stage is Verified System.**NOTE 2: The results of acceptance stage shall be recorded by the Client within VCD (see section 2.6).* | Not To Be Tracked within VCD |
| QR2-10 | REQ-022325 | A | Verification shall be accomplished by the Supplier through one or several of the following methods:1. **Review of design**; Verification by Review (**R**) shall consist of using official project documentation (e.g. design and technical documentation, numerical analysis reports, engineering drawings, manuals and operation documentation) that unambiguously shows that the requirement is met.2. **Inspection**; Verification by Inspection (**I**) shall consist of visual examination of the manufactured and/or assembled product.3. **Test** (including functional demonstration); Verification by Test (**T**) shall consist of quantitatively measuring performance of the product and of its functions in a defined operating regime.4. **Analysis**; Verification by Analysis (**A**) shall consist of performing numerical or empirical performance evaluation of the product using a technique defined in the VP (see QR2-06; REQ-022321). | Not To Be Tracked within VCD |
| QR2-11 | REQ-022326 | A | The results of a review of design shall be documented in the Critical Design Review Report (**CDRR**) and tracked in the VCD.*NOTE: The Client can provide to the Supplier the template of CDRR.* | R – review |
| QR2-12 | REQ-022330 | A | The results of a review of analysis shall be documented in the appropriate Analysis Report (**AR**) and tracked in the VCD. | R – review |
| QR2-13 | REQ-022327 | A | The results of the inspection shall be documented in the appropriate Inspection Report (**IR**) and tracked in the VCD. | R – review |
| QR2-14 | REQ-022328 | A | The results of the test shall be documented in the appropriate Test Report (**TR**) and tracked in the VCD. | R – review |
| QR2-15 | REQ-022329 | A | The parts of the VCD related to the Design of the CIS system shall be accepted by the Client before manufacturing of the System starts. | Not To Be Tracked within VCD |

## Verification Control Document (VCD)

The Verification Control Document (VCD) lists the requirements to be verified with the selected methods at the defined levels. The VCD is a living document and provides traceability during contract phases (design, manufacturing, testing and deployment) how each requirement is planned to be verified and is actually verified.

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

|  |  |  |  |
| --- | --- | --- | --- |
| **N°** | **TC N°** | **Requirement**  | **Verification by** |
| QR2-16 | REQ-022338 | A | The Supplier shall provide the first version of the Verification Control Document (VCD) as a part of the D1 Deliverable. *NOTE: Binding guidelines for VCD preparation will be provided by the Client within 15 working days from the Commencement Day of the contract.* | R - review |

## Verification close out

Acceptance will be carried out on the final CIS system after delivery and installation.

In case of successful acceptance phase the Client shall provide to the Supplier signed acceptance protocol. In case of unsuccessful acceptance phase the Client shall provide to the Supplier Nonconformity Report (NCR) and process in accordance with QR1-05 (see REQ-022314) shall be applied.

|  |  |  |  |
| --- | --- | --- | --- |
| **N°** | **TC N°** | **Requirement**  | **Verification by** |
| QR2-17 | REQ-022421/A | A | Upon delivery of the CIS system components in appropriate and undamaged packaging the Client shall provide to the Supplier with Handover/takeover protocol. | Not To Be Tracked within VCD |
| QR2-18 | REQ-022332 | A | The verification process shall be considered complete for a given project phase (contractual Deliverables) when the Client approves all corresponding items in the VCD by confirming that:1. All specified requirements for a given project phase (contractual Deliverable) have successfully been verified by the Supplier and results of this verification process has been approved by the Client;
2. All detected nonconformities have been solved in accordance with QR1-05 (REQ-022314);
3. Documented evidence is recorded in the VCD.

*NOTE: In the acceptance phase, the verification of the final CIS system and required documentation will be carried out and tracked by the Client in the final version of the VCD within 4 weeks after the issuing of the latest Handover/takeover protocol (D9).* | Not To Be Tracked within VCD |

# Quality & Verification Plan

The table in Section 3.2 below summarizes the compulsory Quality and Verification activities of design, manufacturing, testing and delivery. These activities must be included in the detailed Quality and Verification Plan developed by the Supplier.

# Abbreviations

| **Abbreviation** | **Meaning** | **Note** |
| --- | --- | --- |
| **I** | Inspection | As verification methods; Further details see QR2-10 (REQ-022325). |
| **RoD** | Review of Design |
| **T** | Test |
| **A** | Analysis  |
| **FD** | Functional Demonstration  |
| **R** | Review | Relevant official project documents for a given activity shall be reviewed, and a review report issued, by a responsible person at the Client. |
| **H** | Hold point | Progress shall not be made to the next sequenced activity until the Requirements of the Hold Point Activity have been met |
| **W** | Witness point | The activity shall be witnessed in person with appropriate advance notice having been given. |
| **QR** | Quality Report | All items from the Quality Plan, see QR1-03 (REQ-022312), corresponding to the given activity, must be documented |
| **AR** | Analysis Report | Documented results of corresponding verification activities shall be submitted to the Client (see section 2.4) |
| **IR** | Inspection Report |
| **TR** | Test Report |
| **n/a** | not applicable |  |
| **CDR** | Critical Design Review | Details see in QR2-08 (REQ-022323) |
| **CDRR** | CDR Report | Details see in QR2-11 (REQ-022326) |
| **VP** | Verification Plan | Details see in section 2.3 |
| **VCD** | Verification Control Document | Details see QR2-16 (REQ-022338) |

# List of compulsory Quality and Verification activities

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Seq.****No** | **Activity** | **Input Requirement / Specifications** | **Place** | **Quality process** | **Verification process** | **Contractor** | **ELI-BL** |
| **Input** | **Output** | **Input** | **Output** | **Quality** | **Verification** | **Quality** | **Verification** |
| **1** | **Detailed project schedule, detailed engineering design (Deliverables D1 and D2)** |
| 1.1 | Contract kick-off and planning meeting | Kick off meeting agenda | Contractor | n/a | Minutes | n/a | n/a | R | n/a | R | n/a |
| 1.2 | Design of specific components, drawings and schemes | Detailed concept design and 3D models, detailed engineering drawings for components and subsystems | Contractor or ELI-BL | Engineering drawings and schemes | Critical Design Review Report (CDRR), QR (Quality Report) | Engineering drawings and schemes | CDRRVPVCD(Annex 3 of the Contract) | n/a | RoD | H | RoD |
| 1.3 | Review of the contractor qualifications and procedures before launching fabrication | Contractor qualifications and procedures | Contractor | Contractor qualifications and procedures | Inspection report | n/a | n/a | n/a | n/a | W | I |
| 1.4 | Failure Mode and Effect Analysis (FMEA) | Detailed technical specifications (Annex 2 of the contract) | Contractor or ELI-BL | Detailed technical specifications | Analysis Report (AR) | n/a | n/a | AR/H | A | R | RoD |
| 1.5 | Vacuum control system state machine design specifications | Detailed technical specifications (Annex 2 of the contract) | Contractor or ELI-BL | Design documentation | RoD report | Design documentation | RoD report | H | RoD | R | RoD |
| 1.6 | Control system software component design and SW specifications (SRS) | Detailed technical specifications (Annex 2 of the contract) | Contractor or ELI-BL | Design documentation | RoD report | Design documentation | RoD report | H | RoD | R | RoD |

| **Seq.****No** | **Activity** | **Input Requirement / Specifications** | **Place** | **Quality process** | **Verification process** | **Contractor** | **ELI-BL** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Input** | **Output** | **Input** | **Output** | **Quality** | **Verification** | **Quality** | **Verification** |
| **2** | **Factory testing and performance verification at the Supplier (Deliverables D3, D5, D7 and D9)** |
| 2.1 | Welding coordination tasks and responsibilities | ČSN EN ISO 14731 (equivalent to EN ISO 14731) | Contractor | ČSN EN ISO 14731(equivalent to EN ISO 14731) | Certificates | n/a | n/a | H | I | R | I |
| 2.2 | Welding personnel qualifications | ČSN EN 287-1, ČSN EN ISO 9606, ČSN EN ISO 14732 or relevant (equivalents to EN 287-1, EN ISO 9606, EN ISO 14732) | Contractor | ČSN EN 287-1, ČSN EN ISO 9606, ČSN EN ISO 14732 or relevant (equivalents to EN 287-1, EN ISO 9606, EN ISO 14732) | Certificates | n/a | n/a | H | I | R | I |
| 2.3 | Inspection of the new material and components, traceability | Raw material certificates and contractor traceability procedures | Contractor | Raw material certificates and contractor traceability procedures | Certificates and procedures | n/a | n/a | H | I | R | I |
| 2.4 | Welding inspection | Production drawings (D3 Deliverable), welding procedures, welding sequence plan | Contractor | Production drawings, welding procedures, welding sequence plan | Inspection report | n/a | n/a | H | n/a | W | n/a |
| 2.5 | NDT inspection | NDT procedures | Contractor | NDT procedures | Inspection report | NDT specifications | Test / Inspection report | H | T, I | R | R, I |
| 2.5a | Visual inspection 100% EN ISO 17637 | ČSN EN ISO 5817 (equivalent to EN ISO 5817), evaluation group B | Contractor | Criteria according to ČSN EN ISO 5817 (equivalent to EN ISO 5817), evaluation group B, product to be verified | Inspection report | Criteria according to ČSN EN ISO 5817 (equivalent to EN ISO 5817), evaluation group B, product to be verified | Inspection report | H | I | W | R, II |
| 2.5b | Surface crack test /PT/ of all load bearing parts EN ISO 17637 | ČSN EN ISO 23277 (equivalent to EN ISO 23277), evaluation group 1 | Contractor | Criteria according to ČSN EN ISO 23277 (equivalent to EN ISO 23277), evaluation group 1, product to be verified | Inspection report | Test specifications | Test / Inspection report | H | T, I | W | R, I |

| **Seq.****No** | **Activity** | **Input Requirement / Specifications** | **Place** | **Quality process** | **Verification process** | **Contractor** | **ELI-BL** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Input** | **Output** | **Input** | **Output** | **Quality** | **Verification** | **Quality** | **Verification** |
| 2.6 | Vacuum control system offline testing of sequences and failure mode handling | Vacuum control system state machine design specification | Contractor | Vacuum control system state machine design specification | Quality report | Test specifications | Test report | H | T | W | R, I |
| 2.7 | Machine Safety and Personnel Safety Interlock systems simulated interface functional testing | Control system design specifications | Contractor | Vacuum control system state machine design specification | Quality report | Test specifications | Test report | H | T | W | R, I |
| 2.8 | Optomechanical motion control systems basic functional demonstration | Motion control system design specification | Contractor | Motion control system design specification | Quality repot | FD specifications | Inspection report | H | FD, I | W | I, I |
| 2.9 | Inspection of the finished chamber structure including surface and dimensional control | Production drawings Detailed Technical Specifications (Annex 2 of the Contract) | Contractor | Production drawings, Detailed Technical Specifications | Inspection and dimensional control report | Production drawings, Detailed Technical Specifications | Inspection and dimensional control report | H | T, I | W | R, I |
| 2.10 | Inspection of the cleaned CIS chambers and vacuum tests | Manufacturing requirements including the cleaning procedureVacuum test requirements  | Contractor | Manufacturing requirements including cleaning procedureVacuum test requirements  | Inspection and Test reports | Manufacturing requirements including cleaning procedureVacuum test requirements  | Inspection and Test reports | H | T, I | W | R, I |
| 2.11 | Inspection of the CIS optical support chassis assembly and vacuum qualification | Production drawingsCleaning procedure | Contractor | Production drawings, cleaning procedure | Inspection and dimensional control report | Production drawings, cleaning procedure | Inspection and dimensional control report | H | T, I | W | R, I |
| 2.12 | Acceptance of each of the CIS chambers with optical support chassis assembled and vacuum tested | Production drawingsDetailed technical specifications (Annex 2 of the contract)Cleaning procedures | Contractor | Production drawings, Detailed technical specs (Annex 2 of the contract), Cleaning procedures | Inspection and Test report | Production drawings, Detailed technical specs (Annex 2 of the contract), Cleaning procedures | Inspection and Test report | H | T, I | W | R, I |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Seq.****No** | **Activity** | **Input Requirement / Specifications** | **Place** | **Quality process** | **Verification process** | **Contractor** | **ELI-BL** |
| **Input** | **Output** | **Input** | **Output** | **Quality** | **Verification** | **Quality** | **Verification** |
| **3** | **Delivery to ELI-Beamlines (Deliverables D4, D6, D8 and D9)** |
| 3.1 | Packaging for transport | Packaging for transport | Part listShipping specifications | Contractor | Part listShipping specifications | Shipping list | n/a | n/a | H | I | W |
| 3.2 | Shipping and reception at ELI-Beamlines | Shipping and reception specifications | ELI-BL | Shipping and reception specifications | Reception report | n/a | n/a | W | I | H | I |
| 3.3 | Unpacking and inspection | Unpacking and storage specificationsManual / specifications for installation | ELI-BL | Unpacking and storage specificationsManual / specifications for installation | Reception report | n/a | n/a | n/a | n/aI | H | I |

*Note: Regarding the referred to standard/s or standardized/ standardizing technical documents the Client allows/permits also another equal solution to be offered.*