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MAORY Product and Quality Assurance Plan

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Prepared by:	Simonetta Chinellato	Sthwartha Clinal 2710	2022-11-25
Approved by:	Ugo Di Giammatteo	My Di hint	2022-11-25
Released by:	Ugo Di Giammatteo	Myr Di hi	2022-11-25
	Name	Signature	Date











Authors

Name	Affiliation
Simonetta Chinellato	INAF OAPD
Enrico Giro	INAF OAPD
Rosanna Sordo	INAF OAPD

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1. Introduction

1.1 Purpose

The document describes the Product Assurance Plan (PAP) to be applied during all design, manufacture, assembly, integration, test, transport and installation phases of the MAORY instrument. It describes the resources, tasks, responsibilities, methods and procedures to be adopted by all members of the consortium:

INAF - Istituto Nazionale di Astrofisica

IPAG - Institut de Planétologie et d'Astrophysique de Grenoble IPAG

NUI - National University of Ireland, Galway

This PAP, in accordance with ESO's Quality policy, follows the guidelines expressed in AD2, AD5, AD6 and AD7.

1.2 Scope

The intention of this document is to get a comparable structure of PA activities within MAORY Consortium. The Product Assurance Plan shall be applied to the Consortium, i.e. to all sub-systems, and to all subcontractors.

1.3 Definitions, Acronyms and Abbreviations

ADP	Acceptance Data Package
ARR	Acceptance Readiness Review
BoM	Bill of Materials
ССВ	Configuration Control Board
CI	Configuration Item
CIL	Critical Item List
CIDL	Configuration Item Data list
СМ	Configuration Management
CMP	Configuration Management Plan
CoC	Certificate of Conformity
DCN	Document Change Notice
DNO	Discrepancy note
EEE	Electrical, Electronic or Electromechanical
ECN	Engineering Change Notice

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ECO	Engineering Change Order	
ECP	Engineering Change Proposal	
ECR	Engineering Change Request	
FAI	First Article Inspection	
FDR	Final Design Review	
FMECA	Failure Mode Effects and Criticality Analysis	
ICD	Interface Control Document	
IRR	Integration Readiness Review	
ISMP	Instrument Software Management Plan	
MAIT	Manufacturing, Assembly, Integration, Test	
MIPs	Mandatory Inspection Points	
MRB	Manufacturing Record Book	
MRR	Manufacturing Readiness Review	
NC	Non Conformance/non Conformity	
NCR	Non Conformance Report	
MAORY	Multi-conjugate Adaptive Optics Relay	
PA	Product Assurance	
PAE	Provisional Acceptance Europe	
PCC	Project Configuration Control	
PDR	Preliminary Design Review	
PI	Principal Investigator	
PM	Program Manager	
QA	Quality Assurance	
RFD	Request for Deviation	
RFW	Request for Waiver	
SoW	Statement of Work	
SPC	Statistical Process Control	
SPF	Single Point Failure	
SRR	Shipment Readiness Review	
TRR	Test Readiness Review.	
TST	Tracking Software Tool	



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2. Related Documents

2.1 Applicable Documents

The following Applicable Documents (AD), of the exact version shown herein, form part of the present document to the extent specified herein. In the event of conflict between applicable documents and the content of the present document, the content of the present document shall be taken as superseding. In Any case refer to AD10 section 2.3 for disentangle conflicts and order of precedence in related requirements.

- AD1 MAORY Management Plan E-MAO-000-INA-PLA-001_4
- AD2 MAORY (E-ELT MCAO) Statement of Work ESO-257875 Version 1
- AD3 ESO-254547_2 Common Requirements for E-ELT Instruments
- AD4 Configuration Management Process Requirements for E-ELT Contracts ESO-193324,

Version 2

AD5 Product and Quality Assurance Manual for E-ELT Work Packages

E-MAN-ESO-156-0139 Iss.4

- AD6 PA & QA Management Process Requirements for E-ELT Programme ESO-223661 Version 1
- AD7 Document Requirement Definition for E-ELT Work Packages ESO-213265 version 1
- AD8 Instruction for Delivering Failure Mode, Effects and Criticality Analysis (FMECA) ESO-272195 version 1
- AD9 Safety Conformity Assessment Procedures SAF-INS-ESO-00000-3444

2.2 Reference Documents

The following Reference Documents (RD), of the exact version shown herein, are listed as background references only. They are not to be considered as a binding complement to the present document, but contain useful information.

- RD1 Compliance matrix E-MAO-000-INA-CMX-001_1
- RD2 MAORY Bill of Materials E-MAO-MC0-INA-BOM-001_1
- RD3 MAORY Reliability Analysis E-MAO-000-INA-ANR-002_2
- RD4 MAORY FMECA E-MAO-000-INA-ANR-001_1
- RD5 Hazard List and Analysis E-MAO-000-INA-ANR-003_1



- RD6 MAORY System Design Report E-MAO-SE0-INA-DER-001_1
- RD7 MAORY System MAIV Plan E-MAO-000-INA-PLA-010_1
- RD8 Military handbook Reliability prediction of electronic equipment MIL-HDBK-217
- RD9 Rome Laboratory Reliability Engineer's Toolkit Systems Reliability Division Rome Laboratory Air Force Materiel Command (AFMC)
- RD10 EN 9102 Quality Systems First Article Inspection
- RD11 2004/108/EC Electromagnetic Compatibility
- RD12 2006/95/EC Low Voltage Equipment
- RD13 2006/42/EC Machinery Safety
- RD14 97/23/EC Pressure Equipment
- RD15 MAORY Configuration and Data Management E-MAO-000-MPO-PLA-002_01
- RD16 MAORY Risk Management Plan E-MAO-000-INA-PLA-004_4
- RD17 Common definitions and acronyms ESO-193178 (E-SPE-ESO-313-0066) Version 6
- RD18 Document Requirement Definition and List ESO-213265 Version 1
- RD19 Instructions for Delivering Data Packages ESO-203196 Version 2
- RD20 ESO PDM Document Types and Definitions ESO-254311
- RD21 ESO Mechanical Standards ESO-192984 (GEN-SPE-ESO-50000-4645) Version 2
- RD22 Control System Development Standards ESO-193358 (E-SPE-ESO-449-0015) Version 4
- RD23 Electrical and Electronic Design Standards GEN-SPE-ESO-50000-5401 Version 4
- RD24 ESO Engineering Analysis Standard, GEN-SPE-ESO-50000-5600_iss2



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3. Product Assurance Management

The Product Assurance Plan will provide guidance as well as support for engineering activities. Based upon this plan, a common approach for the product assurance activities in MAORY, shall be established, agreed and maintained. This approach shall be in conformity to ESO guidelines (AD5).

The following product assurance disciplines are considered:

- Quality assurance
- Procurement
- Reliability, Availability, Maintainability, Safety (RAMS)
- Configuration management

The procedures are outlined in the following sections.

The PA approach is based on:

- qualified, certified, trained and experienced personnel;
- qualified and certified high precision tools;
- verified procedures;
- workmanship inspections, qualification and acceptance tests;
- documented design and implementation;
- analysis and design reviews.

3.1 Organization

To be sure that all the needed activities of the Product Assurance Plan will be implemented and objectives successfully achieved, dedicated PA personnel will be present in the involved institutes of the consortium.

In particular, the PA activities will be coordinated in the Consortium by a Consortium PA manager who will be responsible for developing Product Assurance Plans appropriate to the needs of the project.

For each consortium institute, a local PA Manager will be responsible for executing Product Assurance Plans.

All PA related matters will be interfaced with ESO PA manager by the Consortium PA manager. His main task will be:

- Prepare the PAP for the consortium contribution to the project
- Ensure that deliverable documents are prepared
- Coordinate PA activities with ESO product assurance personnel
- Report status of PA activities
- Assure the effectiveness of the internal communications on QA matters inside the consortium

Main PA local activities carried out by local PA Managers:

• Monitor in House product assurance system



- Ensure deliverable documents are prepared
- Monitor contractor(s)

Analysis

Hazard Analysis

Bill Of Material

• Report status of PA activities

INAF

INAF

The PA activities for the subsystem managed at system level are under the responsibility of the Consortium PA manager.

	Document Title and Responsibility	Institution	Document Owner	Document reviewed	Document approved
	PA/QA plan	INAF	QAM	PM	РМ
	Reliability	INAF	RAM Manager	SE	PM

Table 1: Responsibility and document table as distributed inside the PA/QA team

Safety Manager

Procurement Manager

Table 2: People and their responsibility in the PA/QA related documents of previous table

SE/QAM

QAM

ΡM

ΡM

Name	Responsibility
Simonetta Chinellato	PA/QA Manager Safety Manager RAM Engineer
Enrico Giro	RAM Manager Safety Engineer
Rosanna Sordo	RAM Engineer Safety Engineer Contact with SE
Domenico D'Auria	RAM Engineer

3.2 ESO participation in activities

The consortium PA organization assures to ESO, by appointment, the access to the facilities in which MAORY will be integrated. Also all the relevant documentation of the project will be made available to ESO.

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ESO representatives will be able to access all test results, documentation reviews, hardware examination, audits and inspections relevant to the project.

3.3 Reviews

PA activities and their status will be part of all major project reviews. If necessary before starting each Manufacturing, Assembly, Integration and Test/Verification (MAIT/V) activity, facilities and tools reviews could be organised to assure the PA plan is implemented in the correct way.

Also QA activities will be subjected to management review from the PDR up to PAE. Input for the review will be:

- audits;
- customer feedback;
- process performance and product conformity;
- status of preventive and corrective actions;
- follow-up actions from previous management reviews;
- changes that could affect the Quality Management system;
- recommendations for improvements.

The results of these reviews will include decisions and actions to improve the effectiveness of the quality system, the product related to Customer requirements and the necessary resources needed for these activities.

3.4 Audits

Audits might be planned and the output of these audits is documented evidence of the activities aiming to verify compliance to requirements, the established procedures, instructions, drawings and other applicable documents.

If needed, the PA Manager might request audits toward sub-tier suppliers, implementing an audit programme defining criteria, scope, frequency and methods. Records of the audits shall be kept.

The PA manager will support any audits required by ESO. The PA manager will support the MAORY Project Manager in any necessary audit of consortium partners and subcontractors. If a formal audit is requested by ESO (at least 5 days in advance), the PA manager will organise it and assure full access to premises and relevant documentation. In the event of issues as non-conformances, the PA manager will be responsible for the proper and prompt management that lead to the resolution of the NCs.



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3.5 Progress reports

Regular reports on progress and status of PA related matters will be part of the project reporting. In particular information on the following items will be provided:

- Major PA task status;
- Hazard analysis;
- List of Non Conformances;
- Reliability analysis;
- Status on Request for Approval;
- Status on Requests for Waiver;
- Overview of major events in the forthcoming period;
- Status of PA related documentation.

3.6 Documentation Configuration and Data Management

MAORY Configuration and Data Management Plan (RD15) describes in detail this item applying ESO requirements reported in [AD4].

All PA related documentation will be managed with a suitable software to permit sharing between all the actors of the consortium and ESO. PA documentation will be stored on a server with access limited to the personnel involved on the project inside MAORY database.

3.7 Contractor and Supplier Surveillance

Contract reviews will include examination of PA related matters. Subcontractors PA activities will be managed by a local PA manager with the following duties:

- Preparation of PAP;
- Monitoring of in-house product assurance system;
- QA certifications of materials and devices
- Ensuring deliverable documentation prepared;
- Coordination of activities with a local PA Manager of the consortium

Where work will be performed at a subcontractor establishment which has no formal inhouse Quality Assurance system, a scheme will be set up specifically to enable the requirements of this plan to be implemented. If the supplier is certified (ISO 9001:2008), it shall provide, upon request, the Quality Manual for consultation.

3.8 Issues tracking and report

During all the phases of the project, all issues have to be identified, tracked and logged to ensure that they are addressed.



The Tracking Software Tool (TST) JIRA has been selected by ESO to log the issues and follow during their life-cycle. An adequate training in the use of JIRA will be organized by ESO.



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4. **Quality Assurance**

The Local PA manager will be responsible for the implementation of QA Requirements and their flowdown at the institute, subcontractors and suppliers. The following items will be part of the QA activities:

- Critical Items identification and control;
- Procurement Controls;
- Manufacturing and assembly control;
- Integration and Test control;
- Handling, Storage, Packaging, Marking and Labelling;
- Cleanliness and contamination control;
- Accidents /incidents;
- Non-conformance Control;
- Acceptance and delivery

If any requirement proposed by ESO cannot be applied, this has to be considered for exclusion with a request for Waiver or Deviation. A procedure for these requests will be established by the Customer.

Where the Suppliers and/or subcontractors are not in a position to fulfil any requirement(s) of AD6, they shall supplement their deficiencies.

4.1 Critical items identifications and control

To address critical items and follow their resolution a Critical List Item (CIL) on reliability, safety, procurements, material and processes will be prepared and maintained. For each item of the list, criticality shall be evaluated and a way to remove or control it shall be proposed. Critical Items will be considered following these criteria:

- New technology;
- Single Point Failure that could produce unacceptable down time of the instrument for corrective maintenance;
- Non-standard processes.

4.2 **Procurement Controls**

4.2.1 **Procurement sources**

The selection of suppliers has to be driven by their proven ability and experience in projects with relevance with components of the required specifications.

Contractors with assessed capability with regard to quality control and traceability, such as ISO 9001 or equivalent, will be selected for manufacturing or carrying out processes on parts or assemblies. In this case it shall maintain a Quality Management System (QMS) suitable to the products and services provided, and the requirements of ISO 9001:2008 shall apply. Moreover all the certifications related to this standard shall be provided, in particular a valid ISO 9001:2008 Certificate or updated, Social Accountability (SA)8000,

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ISO14001, etc. An organisational structure has to be established to ensure these requirements produce an active role in the QMS in particular addressing the managerial process of quality planning, quality control and quality improvement. The responsibilities and authorities of this structure has to be communicated to the consortium.

It is preferable that suppliers have an ISO 90001 QMS, if this is not the case however, under request from the PA Manger they shall provide evidence that the production and service provision proceeds under controlled conditions, thus assuring that manufacturing and procurement processes are under adequate control and monitoring.

Evaluations of the suppliers have to be recorded and a register of the evaluated sub-tier suppliers is maintained (approved, conditional, disapproved related to product and process). This register has to be periodically updated and actions have to be defined towards sub-tier suppliers that do not meet quality requirements. This will permit the control of risks related to supplier selections.

Infrastructure needs to achieve conformity of product requirements must be guaranteed by the suppliers selected.

4.2.2 Procurement Process

The procurement process starts with the selection of the suppliers. This selection must account both the capabilities of the organisations to fulfill what stated in section 4.2.1 and the technical capabilities to deliver a product respecting requirements. The assignment of the contract to the supplier is based on a Statement of Work (SoW) listing the working agreement of the parts. From the QA point of view these points has to be adequately covered:

- Scope of the work
- Project objectives
- Schedule
- Responsibilities
- Risks
- Tasks
- Deliverables
- reviews and audits
- QMS if applicable
- requirements
- Manufacturing and Production Plan if applicable
- Statistical Process Control plan if applicable
- process qualifications and FAI if the case
- Standards, metrology and calibration
- qualification of the personnel
- Test and acceptance criteria

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- Certificate of Conformity (CoC)
- Acceptance Data Package
- shipping and storage procedure
- if verification is foreseen at the supplier, verification arrangements and method of the product release have to be specified.

During the contract the MAORY PA manager in coordination with the customer PA manager will follow the necessary tracking of these activities assuring records and communications inside the consortium and toward ESO, in particular on product requirements, status of the contract and non conformances issues (see Section 4.10). The control applied to suppliers will be dependent on the effect of the product on the final configuration.

Reviews have to be programmed and organized as proposed by AD3 Appendix B, if this is the case and depending on the complexity of the contract. At consortium level reviews are programmed as reported in AD2 (SoW).

In case of verification of quality requiring access to suppliers, this requirement has to be specified in the SoW and agreed.

In case a design is part of the procurement all the requirements respected in the design produced by MAORY consortium has to be fulfilled in the same way.

4.2.3 **Procurement documents**

All the documentation related to procurements will follow PA rules described in this plan and will report the requirements for quality control, the traceability and the appropriate standard. Conformance documentation will be requested and act as a point of entry into the manufacturer's traceability system. If the contractor procures materials, it will be written into the contract that only stress-released materials will be used and obtained from stockists assessed by a recognised organisation to ensure traceability. Items manufactured in-house will be subject to the same controls. In particular a documented procedure has to be established by the supplier to control identification, storage, protection, retrieval, retention and disposition of records of all the items procured. These records shall remain legible, readily identifiable and retrievable. Moreover they shall be available for review in accordance with Contract or regulatory requirements.

It is the responsibility of the local PA manager to verify that all inspections and tests and witnessing of critical processes are performed and that the necessary documentation is provided.

In case of "off the shelf" products, documentation and configuration management will be subject to manufacturer definition.

Refer to Sect. 4.12.1 for a detailed list of documentation needed at procurement.

4.2.4 Certificate of Conformity

Among the documentation particular attention has to be devoted to Certificate of Conformity (CoC), that shall contain, as a minimum:

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- Supplier Organization's name and address;
- Item number(s) and item name(s);
- PO/Contract number and Customer's name;
- Quantity;
- All drawings, parts lists, revision levels and amendments, models;
- A certification statement that the Customer requirements are met.
- As a minimum, an authorized QA signature and date;
- The references used by the Supplier Organization to provide traceability of their Quality records.

In the CoC, or attached as certifications, the following informations (where applicable) will be provided:

- Material type, lot number, manufacturer and specification number and revision level;
- Heat treat facility, lot number, process name, quench method, specification number and revision level;
- Any other Special Process performed, by facilities, specification names, specification numbers and revision levels

If raw materials are purchased, a copy of the original Manufacturer Test Reports will be provided by the Supplier.

If Special Process or testing are performed, the proper documentation will be provided, including testing facility, special process reference, test results, reference to the specification, standard or method used to validate the process.

4.2.5 Incoming Inspection

All incoming material will be inspected on arrival and will be verified that all the needed documentation is present. In particular these activities will be carried out with the responsibility of the local PA manager:

- Check and review of the conformance certifications and documentation on tests and inspections
- Visual inspections of incoming material
- Review of Witness and sample tests for Critical Items

4.3 Manufacturing

The local PA manager shall follow activities related to manufacturing processes. Particular attention will be devoted to:

- Critical parameters;
- Workmanship;
- Completeness in the manufacturing and assembly individual steps;
- Witness samples if needed (critical items)

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4.3.1 Surveillance of Manufacturing / Integration, Mandatory Inspection Points

System Engineer and QA manager will carry out a review of the manufacturing operations to individuate activities requiring special inspection. These activities shall be scheduled in order to avoid that due to subsequent works these cannot be possible in the following phases of the project.

4.3.2 Metrology and Calibration for production, AIV and evidence of conformity

In the MAIT plan all the tools and calibrated instrumentation needed for related activities must be listed. For these tools identification, location and calibrations must be recorded and traceable, and recalibration must be scheduled with respect to the need of stability of such instruments. Calibrations must follow International or National Measurement Standards. In case no standards are foreseen, the basis for the calibration or verification must be recorded in a Calibration Document/Logbook related to the tool or equipment and calibrated instruments have to be safeguarded by uncontrolled adjustments, damage and deterioration during handling, maintenance and storage.

In case of non conformance to calibration requirements the previous measurements must be assessed and recorded for their validity. In this case appropriate action on the equipment and on the product has to be taken if necessary.

Moreover operating and storage ambient conditions have to be verified to be suitable for the calibrated tools and instruments. Processes involving monitoring and measurements procedures needed to fulfill requirements must be identified in the MAIT.

Documentations about calibrations must be kept to permit an efficient traceability of the calibration records.

Also tools and equipment, including software programs used for the automation, control and monitor must be calibrated and validated prior to be used for production. In the case of software the ability to satisfy the intended application must be confirmed.

4.3.3 Monitoring and Measurement of Processes

In principle in the case of MAORY Consortium, production pipelines requiring an internal process monitoring are not foreseen. If such a process should be individuated in the production planning, suitable monitoring procedure will be defined and applied. In particular, PA manager will define the type and the extent of monitoring or measurements to assure the conformity to product requirements, following Section 7.2.6 of AD6.

In case of Non Conformance, corrections and actions must be taken, as described in Section 4.10.

In case of Special processes refers to requirements listed in Section 7.1.1 of AD6.

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4.3.4 Monitoring and Measurement of Products

The PA manager will plan with Subtiers, at appropriate stage(s) of the production, the monitoring and measuring of the characteristics of the product to verify that product requirements are met. This plan can include sampling Inspection, if proved suitable and after Customer approval. If monitoring devices are specifically designed for the purpose, product verification shall also apply. Records of the planned verification shall be kept and they have to report the name of the responsible for the authorization to delivery to the customer.

Product verification is applied not only when an item is supplied, but also after any modification, unless otherwise agreed with the Customer.

In case of non conformance, corrections and actions must be taken, as described in Section 4.10. Corrective actions will be evaluated in a cost/benefit analysis.

4.3.5 Control of Production Process Changes

MAORY consortium will control and document any change affecting process, production equipment, tools and or software program. Only Personnel authorized can approve changes in the production processes. All the changes that require Customer and /or regulatory authority approval in accordance with SoW or regulatory requirements must be notified to ESO and accepted. Moreover the results of changes to production processes shall be assessed to confirm that the desired effect has been achieved without adverse effects to product quality conformity.

In case of intended or actual changes that may affect the conformity of the products MAORY consortium will notify ESO with a report indicating the changes for any of the following:

- Change in the Quality Manager Representative;
- Change in QMS (if applicable)
- Change in Manufacturing Line, Facility Location, Sub-tier Supplier, equipment or processes for which the product was qualified and quality control processes;
- Change in the Product Assurance Plan

Notifications must include the list of the changed procedures identified by revision level, which are the intents of the changes and the signed statement that changes do not diminish the compliance with ESO requirement.

In case of notification the effect of change on Inspection with respect to fit, form, reliability, function, conformity of the Supplier Organization products must be documented.

It is necessary the approval by ESO for amendment of this quality assurance plan.



4.4 Integration and test control

4.4.1 Assembly, Integration and test control

Assembly, Integration and Test activities (AIT) will be described in a devoted document in accordance with the SoW (AD2) and a plan has to be released to give the detail of the:

- Hardware configuration
- Tests objectives
- Tests parameters
- Test sequences
- Acceptance/rejection criteria
- Test equipment
- Facilities involved
- Hazards identified
- Cleanliness environment of integration/test facility

In particular all these phases have to be guaranteed to be performed in controlled conditions.

4.4.2 Tests and acceptance criteria

Acceptance tests have to be described in the system and subsystem AIT plans. Step by step procedures and acceptance criteria will be indicated in devoted sections. Major acceptances tests will verify:

- The conformance between as built configuration status of the test sample with the design baseline;
- All verifications (including tests) have to be done and traced against the applicable requirements to the object under verification;
- Status of NC / failures, RFW, RFD and open work;
- the availability and the approval status of the test procedures;
- calibration status of the test facility;
- responsibilities during the test.

Local quality assurance manager will monitor that all the Quality Assurance activities are followed and in particular that:

- The approved procedures are applied during the test;
- No errors arise during the execution of the procedures;
- Record and logbook of the activities are taken;
- Non Conformances are traced following rules reported in Section 4.10;

After the test, a post review is performed to assure that:

- Required data records are complete and parameters are inside requirements;
- NC and failures are traced;

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- Deviations in executing procedures are authorized and traced.
- After execution, all the procedure steps have been followed and test samples (if necessary) have been collected for qualification.

At the end the responsible of the test will prepare a test report containing description of how the procedure has been executed (if authorized deviations are present), the test results and if present eventual failures and NCRs.

4.5 Traceability and logbooks

Aim of the traceability is the identification of the product from its realization to its disposal. Each product has to be identified univocally using an appropriate labelling that ensures a bidirectional and unequivocal relationship between parts, material or products and their associated documentation or records. This relationship must be established and maintained. Moreover identification of the configuration of the product must be ensured, in order to identify differences between actual and agreed configuration.

Monitoring and measurements requirements are the means used to identify the status of the product.

Logbooks are the means to record operations on the products from its production, to AIT phase and operations of all relevant activities (see Section 4.6).

In particular they have to refer to and trace data, personnel, equipment related to procurement, fabrication, Inspection, Test, assembly, integration and operations activities. Trace has to be maintained backward to the locations of subassembly, parts and material and and forward from raw stock.

For critical items, traceability shall be verified directly by the Local Quality Manager.

4.5.1 Manufacturing Records Book

A Manufacturing Record Book (MRB) for incoming material has to be collected. This MRB must contain all documentation certifying quality control and all applicable information of an order, such as: a Certificate of Compliance, certifications and component testing.

4.5.2 Logbooks

Logbook will start with incoming inspection of the material needed to the assembly phase and must follow all the phases of AIT. Logbooks will be composed of record sheets and diaries.

The record sheets with include the following fields:

- operation chronological number;
- name of operation / test;
- applicable procedure ref. and / or report;
- responsible person/organisation and signature for entry;



- dates of operation / test
- cleanliness environment
- NCRs if present

The diary is a chronological notebook to log all activities, progress and details during the manufacturing and AIT phase. The pages will be numbered and referenced by the history record. The diary will be used freely and include comments on operations as they take place. The logbook will follow the life of its related hardware and will be part of the delivered Acceptance Data Package (ADP).

4.6 Shipping and storage procedures

Procedure for identify, handling, storage, packing/unpacking, transport and protection will follow guidelines possibly proposed by ESO and will be collected under MAORY consortium responsibility. They will be part of the ADP.

All packaged or bagged items will protect items from shock, dust, external water, condensed water and high or low temperature during transportation. Containers will be equipped with adapted shock indicators.

All packages will be identified by labelling. Handling and packing/unpacking requirements will be clearly displayed on all equipment and packaging.

All the activities described in this section can be generally classified as Preservation of the product and its constituent parts up to the intended destination, which must be identified in the SoW of each procurement contract.

Local quality managers will supervise that all procedures will be followed.

4.7 Cleanliness

MAORY consortium will identify activities and hardware needs of particular cleanliness conditions. In this case appropriate clean rooms certified following international standard (i.e. ISO 7 for example) will be used. As for the other calibrated tool, consortium members will control cleanliness and contamination during all MAIT phases. Personnel must be trained to work in clean rooms

4.8 Accidents/incidents

Accidents or incidents will be recorded as for a major Non-Conformance (See Section 4.10). Safety non compliance, accidents and incidents will be flagged as such in the NCR and reported explicitly at ESO.



4.9 Non-conformance procedures

4.9.1 Non conformance classification

During the delivery phases some non conformances (NC) can be individuated.

A Non Conformance can be defined as:

- Potential: NC will happen if no action is taken
- Actual: verified non-fulfilment of requirement(s)
- Suspected: there is a possibility that a condition could have caused NC (e.g. a product that possesses some of the same characteristics as a NC product)

Different actions are to be taken, according to the above definitions:

- Potential \rightarrow Preventive action
- Actual → Remedial, Recovery, Corrective, Containment Actions
- Suspected \rightarrow Corrective, Containment Actions

Preventive Action means eliminating a cause of a potential nonconformity, triggered by a discovery.

Remedial Action means the removing an actual nonconformity in a product that was previously conforming (e. g. remove a conforming product has been damaged).

Recovery means seeking out products with the same characteristics as those found nonconforming. It does not remove the cause of the nonconformity.

Corrective action describes the pattern of activities that traces the symptoms of a NC to its cause, produces solutions for preventing its recurrence, implements the change and monitors that the change has been successful.

Containment action removes an immediate cause thus allowing production to continue until product or process design change removes the root cause.

4.9.2 Non conformance severity

NC severity can be classified as MAJOR or MINOR.

MAJOR are classified those non-conformances that affect one of the following:

- Approved design requirements
- Approved test requirements and procedures
- Approved Interface Control Documents
- RAMS
- Schedule at System Level

MINOR NCs do not affect items listed above. Minor non-conformances will be handled in accordance with MAORY Consortium procedures.

Each local Quality Manager will ensure the following non-conformance (NC) processing:

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- Non-conformances will be identified and recorded (NCR) and corrective/recovery actions will be planned, initiated and carried out. In case no corrective actions are practicable a RFD/W must be advanced;
- Each major NC must be notified at the Project Office represented by the Quality Manager
- The PA Manager shall notify to ESO the NCR
- A non-conformance report shall be released to ESO into their entirety;
- Minor NCR reports are not delivered to ESO. They are managed at consortium members level with their subcontractors. These NCR reports can be reviewed upon request, on a case by case basis with sufficient advance notification.

Subcontractors will be requested to follow the same principles.

4.9.3 Non conformance reporting

If a non conformance during MAIT phases arises it will be operated under a Non Conformance Control System possibly using a software (Tracking Software Tool TST, see section 3.8) to obtain a standardized approach to identify, report, review, analyse, correct and verify the corrective actions. This system will cover all the deliverable items of MAORY.

When a NC is detected a form will be filled and a decision if to stop or to continue the ongoing activities. This disposition must be taken by the System Engineer with the help of the Quality Manager.

All NC will be logged into the Issue TST. Major NCs shall be logged within 48 (forty-eight) hours of their discovery, while Minor NCs shall be logged within 5 (five) days of their discovery.

Discrepancy must be analysed by an internal expert board, held regularly, that must determine:

- Cause of the NC. If necessary outside experts can be help in this process
- Disposition with corrective and preventive actions described by a Non Conformance Report (NCR). Typically the can be classified as:
 - "Scrap";
 - "Use as is": In this case the NC will generate a Request for Waiver (RFW) or a specification change. These shall be authorized by a "change control board".
 - o **"Repair**"
 - "Change design": In this case a Engineering Change Request (ECR) is proposed.
- After modifications re-verification has to be performed. This imply re-inspection, retest and an updating of the previous design analysis.

If the process undergoes to a "use as is" recommendation it generates a NCR and RFW following this way:

• In case of minor NC, the RFW will be examined totally internally to the consortium by a board composed by the local PA manager and the technical specialists involved in the item on which the non-conformance has occurred.

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 In case of major NC also the consortium PA manager and the Project Manager must be informed. After filling a NCR and a RFW they have to propose a corrective action to ESO. If accepted the RFW will be closed and the non conformance reference recorded on the non conformance list.
If necessary a board with ESO could be organized with the consortium represented by SE manager, Program manager and PA manager. Representatives of other organisations may also participate.

Records of the nature of the nonconformities and actions taken will be maintained.

If a non Conformity is detected after delivery, action will be taken appropriate to the effect of the Non Conformity.

4.10 Verification and Validation Procedures

4.10.1 Verification and Validation Procedures

System team of the consortium shall define verification and validation procedures during the project and at all levels of product development w.r.t. equipment, parts, components, processes, services, subsystems, as well as organisational matters as quality management, configuration management, risk management, and procurement function of suppliers.

Depending of the level and the product different methods shall be applied:

- Test
- Analyses
- Similarity (a similar component was verified already in another project with similar conditions)
- Qualification procedure
- Design review
- Inspection
- Certificate

4.10.1.1 **Processes Validation**

Process validation shall be taken into consideration for each process for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as result, deficiencies become apparent only after the product is in use or the service has been delivered. These processes shall be clearly identified in the Critical List Item (CIL). Validation aims to demonstrate the ability of these processes to achieve the

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planned results. When validated for the process must be used the term "validated process" and this status reported in the related section Special Process or equivalent in the CIL. Description of the arrangements for these processes must be established for:

- criteria for review and approval of the process (Process Qualification);
- approval of the equipment and qualification of the personnel;
- use of specific methods and procedures;
- requirements for records;
- revalidation.

If Sub-tier Suppliers are engaged in a special process they must be part of the full chain of approval and validation of the special process. This approval does not relieve MAORY consortium of the responsibility for exercising controls on the Sub-tier Suppliers to assure that the work is in accordance with specification requirements. Record of the approval must be maintained by MAORY consortium

In case of process verification and validation a representative item of the first production run must be used for the verification, documentation and tooling needed and capable for producing items that meet requirements. In case of changes in the production process the validation must be repeated in the new conditions.

To qualify a process, the First Article Inspection (FAI) must be performed following RD10 as reference. The FAI can be applied at the specific request in the contract or the SoW. In case a FAI is foreseen in a contract signed by MAORY consortium, ESO will be informed in advance to reserve the right to participate in the FAI. The result of the FAI must be drafted in a report. This report and the First Article must be reviewed and inspected by the consortium and/or ESO. For any other point not addressed here for the FAI refer to section 6.9.2 of AD6.

Moreover all qualifications and validations must be reported and records shall be traceable.

4.10.2 Verification matrix

As result of the verification strategy, a verification matrix showing all requirements and their selected verification methods will follow the progress in the project development in all its phases, from Design to the Acceptance. For the consortium level the verification matrix with its compliance refers to RD1.

4.10.3 Analysis of data

The Supplier Organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvements can be made, through the use of:

- Quality Policy (if applicable)
- Quality objectives (if applicable)
- analysis of data, using statistical methods if applicable
- preventive/corrective actions
- experience with similar products or processes

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• management review

The analysis shall include information generated as a result of monitoring and measurement and from other relevant sources, and will provide information relating to:

- conformity to product requirements
- characteristics and trends of processes and products including opportunities for preventive action
- Sub-tier Suppliers performance.

Internal and external audits shall be used as a tool to drive continual improvements, to verify the reduction of the overall nonconformities and of repeated nonconformities.

4.11 Acceptance and delivery

An Acceptance Readiness Review (ARR) will be foreseen for all hardware, software and deliverable items provided by MAORY consortium to ESO. Each deliverable will be provided to ESO with an Acceptance Data Package (ADP).

4.11.1 Acceptance Data Package

The ADP is a collection of documentation with all relevant data related to configuration, integration and test operations for the deliverable described. Collecting data for the ADP starts with the design phase of the item and follows all its lifetime before delivery during all steps (manufacturing, assembly, tests and integration). The typical documents of the ADP are:

- Certificate of Conformance;
- Compliance matrix if applicable;
- Test plan if applicable;
- As Built Configuration List;
- As Design Configuration List;
- Detailed Assembly Drawings and Part Lists
- Interface control documents;
- Major Non Conformance Reports, major RFW reports;
- Full NCR list, RFW list;
- Acceptance Test Report including test data sheets with acceptance signature;
- Documentation Status list (if necessary)
- Packing List.

4.12.2 Urgent/special delivery

In case an incoming product is released for urgent production purposes, it shall be positively identified and recorded in order to permit immediate recall and replacement in the event of nonconformities to requirements.



• 4.12.3 Service Operations Post Delivery Support

In case servicing is reported in the SoW for example for the warranty period, post delivery support shall provide as applicable the following:

- collection and analysis of in service data;
- action to be taken, including investigation and reporting, when problem are detected after delivery at the site of installation;
- control and updating of technical documentation;
- approval, control, and use of repair schemes;
- control required for off site work (e.g. organization work undertaken at the ESO facilities)

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5. RAMS

In MAORY construction since the beginning, from the Design Phase, it will be implemented a reliability analysis to guarantee fulfilment of the availability requirement of the instrument during its lifetime. Each subsystem will carry out this analysis coordinated by the consortium PA manager. RAMS activities will be implemented since the starting point of the project and will be part of the progress reports and reviews. Items in the following sections will be addressed in different documents.

5.1 Reliability evaluation

A Failure Mode Element Criticality Analysis (FMECA) will be implemented in the design and development phases of the instrument. This analysis will be implemented for all the relevant subsystems separately.

As product of FMECA analysis, Single Point Failures will be potentially identified. A list will be implemented with the aim of solving or mitigating their effects. If not possible avoiding them, a final list with probability and occurrence will be delivered.

5.2 Maintainability

By analysis on the requirements on operation lifetime, hardware configuration and MTBF of the subcomponents, a maintenance manual will be carried out. In particular as product of this analysis a Spare List and a Maintenance (preventive and corrective) Manual will be delivered. Preventive maintenance will assure that reliability requirements will be fulfilled. Corrective maintenance assures that instrument downtime will be inside specifications.

5.3 Safety Assurance

The safety assurance program aims:

- to identify hazards;
- to identify hazards for personnel;
- to assure compliance with safety requirements and rules;
- to eliminate hazards or mitigate them to an acceptable level.

The safety assurance program will cover all the phases of the project (design, manufacturing, assembly, testing, transportation and operations).

As a product of the safety assurance program, an Hazard Analysis document will be delivered containing the Hazard List items with the associated risk level and actions to be implemented to mitigate them.

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5.3.1 Applicable documents

For safety applicable documents will be ESO safety manual (AD9).

Safety with respect to all hardware activities are a local responsibility under the relevant national safety regulations.

5.3.2 Safety Data Package (SDP)

The Safety Data Package will provide MAORY of all the items related with safety. In particular:

- A description of the instrument from the point of view of the safety;
- An identification of potential hazards in mounting, integrating and operating MAORY;
- Description of the hazards and their classification using a risk scale;
- Hazard control.



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6. Risk assessment

During the overall phases of the project risk identification and management will be carried out. A document, under responsibility of the PM, will be devoted to the risk process analysis and managing (RD16).



7. Mechanical and Electrical, Electronic or Electromechanical (EEE) Parts selection and control

Where possible ESO standards will be adopted in all mechanical and EEE components. For these latter items the performance of the equipment shall not be affected by external electromagnetic interference of a specified level, whether conducted or radiated.



8. Materials Selection and Control

As a common rule, all possible precautions shall be taken to avoid problems when different metals are used together, for example galvanic couples and differential expansion. Corrosion-sensitive materials shall be avoided unless they are submitted to an appropriate surface treatment and/or coating.



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9. ESO propriety

For any relationship between ESO property (including Intellectual Properties) and its use by MAORY Consortium refer directly to Section 6.9.8 of AD6. In case of Sub-tier Suppliers all the requirements of this section will be flown down.



• Annex A: PA correspondence table

R3	Requirements Flow down	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4	Quality Assurance
R4	Requirements Flow down validity	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4	Quality Assurance
R5	Requirements Flow down fulfilling	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4	Quality Assurance
R6	request for Waiver or Deviations	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.10.3	Non conformance reporting
R7	Sw QA requirements and Configuration Control Management requirements	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	9	Configuration Management and Control
R8	Conflict between requirements	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	2.1	Applicable documents
R9	Conflict between requirements	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	2.1	Applicable documents
R10	Conflict between requirements	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	2.1	Applicable documents
R11	Correspondence Table	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	Annex A	Correspondence Table



R12	Correspondence Table	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	Annex A	Correspondence Table
R13	statements reporting	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	Annex A	Correspondence Table
R14	Quality Manager system	Not applicable				
R15	ISO 9001:2008 (if applicable)	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.2.1	Procurement sources
R16	Quality Manual (if applicable)	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	3.7	Contractor and Supplier Surveillance
R17	Quality Plan	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	3.7	Contractor and Supplier Surveillance
R18	Contents of the Product Assurance Plan	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	all	all
R19	Control of document requirements	MAORY Configuration and Data Management	E-MAO-000-MPO- PLA-002	2	all	all
R20	Control of document requirements	MAORY Configuration and Data Management	E-MAO-000-MPO- PLA-002	2	all	all
R21	Control of record	MAORY Configuration and Data Management	E-MAO-000-MPO- PLA-002	2		
R22	Control of record	MAORY Configuration and Data Management	E-MAO-000-MPO- PLA-002	2		
R23	Control of record	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.2.3	Procurement documents



R24	Control of record	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.2.3	Procurement documents
R25	Control of record	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.2.3	Procurement documents
R26	Management QMS	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.2.1	Procurement sources
R27	Management QMS	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.2.1	Procurement sources
R28	Management QMS	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.2.1	Procurement sources
R29	Management QMS	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.2.1	Procurement sources
R30	QA Manager duties	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	3.1	Organization
R31	QA organization	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	3.1	Organization
R32	Responsibility Assignment Matrix	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	3.1	Organization
R33	communication	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	3.1	Organization



R34	effectiveness of the QMS	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	3.1	Organization
R35	Review	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	3.3 3.5 3.7	Reviews Progress report Contract surveillance
R36	Review	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	3.3 3.5 3.7	Reviews Progress report Contract surveillance
R37	record management review	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	3.5	Progress report
R38	management review	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	3.3	Reviews
R39	management review	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	3.3	Reviews
R40	Resources	Project Management Plan	E-MAO-000-INA- PLA-001_04	4		
R41	HR competence	Project Management Plan	E-MAO-000-INA- PLA-001_04	4		
R42	HR training	Project Management Plan	E-MAO-000-INA- PLA-001_04	4		
R43	working environment and organisation	Project Management Plan	E-MAO-000-INA- PLA-001_04	4		
R44	infrastructure	Project Management Plan	E-MAO-000-INA- PLA-001_04	4		
R45	infrastructure flowdown	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.2.1	Supplier selection



R46	environment management	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.8	Cleanliness
R47	documents describing environment procedures	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.8	Cleanliness
R48	environment control procedures	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.8	Cleanliness
R49	trained personnel	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.8	Cleanliness
R50	arrangements to control contamination	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.8	Cleanliness
R51	Product Realization	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4	Quality Assurance
R52	Product Realization planning	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4	Quality Assurance
R53	Product Realization planning	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4	Quality Assurance
R54	Product realization process - Design and Development	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2		this table
R55	Project Management	Project Management Plan	E-MAO-000-INA- PLA-001_04	4	all	all
R56	Risk Management	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	6	Risk assessment



R57	Configuration Management	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	3.6	Documentation Configuration and Data Management
R58	Control of Work Transfer	System Manufacturing, Assembly, Integration and Test Plan				all
R59	Determination of Requirements related to the Product	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.11.2	Verification Matrix
R60	Review of Requirements	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.2.2 4.11.2 4.12	Procurement Process Verification Matrix Acceptance and delivery
R61	Review of Requirements timeline	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003		4.2.2	Procurement Process
R62	Review of Requirements	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003		4.2.2	Procurement Process
R63	record of the review	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003		4.2.2	Procurement Process
R64	requirements changing	MAORY Product and Quality Assurance Plan	-MAO-000-INA- PLA-003		4.2.2	Procurement Process
R65	customer communication	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003		4.2.2	Procurement Process
R66	QA-PA communications	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003		4.2.2	Procurement Process



R67	Purchased Design and requirements	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003		4.2.2	Procurement Process
R68	planning and control of the design	Project Management Plan	E-MAO-000-INA- PLA-001_04	4	11	Systems Engineering Management
R69	planning and control of the design	Project Management Plan	E-MAO-000-INA- PLA-001_04	4	11	Systems Engineering Management
R70	planning and control of the design	Project Management Plan	E-MAO-000-INA- PLA-001_04	4	5	Project Breakdown Structures Systems Engineering
						Management
R71	safety design	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	5.3	Safety Assurance
R72	Validation and Verification Plan	MAORY SYSTEM MAIV plan	E-MAO-000-INA- PLA-010	1	all	all
R73	ICD managment	MAORY System Interface Control document	E-MAO-SE0-INA- ICD- 001_01D2_MAORY -ICD			
R74	Planning updating	Project Management Plan	E-MAO-000-INA- PLA-001_04	4	11	Systems Engineering Management
R75	Input relating to product requirements	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.2.2	Procurement Process
R76	Input relating to product requirements	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.2.2	Procurement Process
R77	Requirement traceability	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.2.2	Procurement Process
R78	Design outputs	Project Management Plan	E-MAO-000-INA- PLA-001_04	4	11	Systems Engineering Management



R79	Design development	Project Management Plan	E-MAO-000-INA- PLA-001_04	4	all	all
R80	Data design features	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.12.1	Acceptance Data Package
R81	Review of design	Project Management Plan	E-MAO-000-INA- PLA-001_04	4	4.4	MAORY Project Meetings and Reviews
R82	Review I/O	Project Management Plan	E-MAO-000-INA- PLA-001_04	4	4.4.2	MAORY Project Phases and Reviews
R83	Review responsibility	Project Management Plan	E-MAO-000-INA- PLA-001_04	4	4.4	MAORY Project Meetings and Reviews
R84	Review records	Project Management Plan	E-MAO-000-INA- PLA-001_04	4	4.4	MAORY Project Meetings and Reviews
R85	Review reports	Project Management Plan	E-MAO-000-INA- PLA-001_04	4	4.4	MAORY Project Meetings and Reviews
R86	Review reports	Project Management Plan	E-MAO-000-INA- PLA-001_04	4	4.4	MAORY Project Meetings and Reviews
R87	Review reports	Project Management Plan	E-MAO-000-INA- PLA-001_04	4	4.4	MAORY Project Meetings and Reviews
R88	Reviews	Project Management Plan	E-MAO-000-INA- PLA-001_04	4	4.4	MAORY Project Meetings and Reviews
R89	Design verification	Project Management Plan	E-MAO-000-INA- PLA-001_04	4	11	System Engineering Management
R90	Design verification records	Project Management Plan	E-MAO-000-INA- PLA-001_04	4	11	System Engineering Management
R91	planning and control of the design	Project Management Plan	E-MAO-000-INA- PLA-001_04	4	5	Project Breakdown Structures
					11	Systems Engineering Management
R92	design Validation completion	Project Management Plan	E-MAO-000-INA- PLA-001_04	4	11	System Engineering Management
R93	design Validation record	Project Management Plan	E-MAO-000-INA- PLA-001_04	4	11	System Engineering Management



R94	Test plan	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.4	Integration and test control
R95	Design and Development Verification and Validation Documentation	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.11 4.12.1	Verification and Validation Procedures Acceptance
R96	Design configuration management	MAORY Configuration and Data Management	E-MAO-000-MPO- PLA-002	1	all	all
R97	Design configuration changes	MAORY Configuration and Data Management	E-MAO-000-MPO- PLA-002	1	all	all
R98	design changes review, verification and validation	Project Management Plan	E-MAO-000-INA- PLA-001_04	4	11	System Engineering Management
R99	design and development review	Project Management Plan	E-MAO-000-INA- PLA-001_04	4	11	System Engineering Management
R100	reviews of changes records	Project Management Plan	E-MAO-000-INA- PLA-001_04	4	11	System Engineering Management
R101	selection of suppliers	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.2	Procurement Controls
R102	selection criteria	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.2	Procurement Controls
R103	purchased product conformity	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.2	Procurement Controls
R104	suppliers and products control	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.2	Procurement Controls



R105	compliance of selected Sub-tier Supplier	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	3.7	Contractor and Supplier Surveillance
R106	register of sub-tiers suppliers evaluations	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.2.1	Procurement sources
R107	Documentation and traceability of purchased products	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.2.3	Procurement documents
R108	Purchasing information	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003		4.2.2	Procurement process
R109	Adequacy of specified purchase requirements	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.2.2	Procurement process
R110	Inspections and verification activities	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.2.4	Incoming inspections
R111	Verification at the sub- tier supplier's premises	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.2.2	Procurement process
R112	Verification of the quality supplies requiring access to the sub-tier Suppliers	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.2.2	Procurement process
R113	production and service provision under controlled conditions	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.2.1	Procurement sources
R114	controlled conditions	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.3	Manufacturing



R115	production planning	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.3	Manufacturing
R116	production process verification	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.11.1.1	Processes validation
R117	production process changes and verification	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.11.1.1	Processes validation
R118	FAI objective	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.11.1.1	Processes validation
R119	FAI as validation of the process production	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.11.1.1	Processes validation
R120	FAI application	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.11.1.1	Processes validation
R121	component checking for FAI	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.11.1.1	Processes validation
R122	information on the FAI	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.11.1.1	Processes validation
R123	FAI report	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.11.1.1	Processes validation
R124	FAI records	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.11.1.1	Processes validation



R125	component values	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.11.1.1	Processes validation
R126	marking of values outside tolerance	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.11.1.1	Processes validation
R127	FAI signing	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.11.1.1	Processes validation
R128	review and inspection of the FAI report and First Article	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.11.1.1	Processes validation
R129	First articles marking	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.11.1.1	Processes validation
R130	Dispositions declared in the FAI report	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.11.1.1	Processes validation
R131	Material Review Board	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.11.1.1	Processes validation
R132	FAI documentation	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.11.1.1	Processes validation
R133	Notification to the customer about deviations after the FAI	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.11.1.1	Processes validation
R134	Personnel authorized to approve changes	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.3.5	Control of Production Process Changes



R135	Acceptance of changes	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.3.5	Control of Production Process Changes
R136	Control of the changes	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.3.5	Control of Production Process Changes
R137	Assessment of results of changes	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.3.5	Control of Production Process Changes
R138	Notification of changes that may affect conformity	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.3.5	Control of Production Process Changes
R139	Approval of the customer	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.3.5	Control of Production Process Changes
R140	Notification of changes description	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.3.5	Control of Production Process Changes
R141	effect of change to Inspetion	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.3.5	Control of Production Process Changes
R142	equipment and tools for production	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.3.2	Metrology and Calibration for production and AIV
R143	storage requirements	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.7	Shipping and storage procedures
R144	Service Operations Post Delivery Support	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.12.3	Service Operations Post Delivery Support



R145	Processes validation	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.11.1.1	Processes Validation
R146	Special process classification	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.11.1.1	Processes Validation
R147	Aim of the validation of special processes	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.11.1.1	Processes Validation
R148	validated processes	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.11.1.1	Processes Validation
R149	arrangements to validate processes	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.11.1.1	Processes Validation
R150	approval for Sub-tier Suppliers engaged in special processes	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.11.1.1	Processes Validation
R151	records of approval of special processes	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.11.1.1	Processes Validation
R152	product identification	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.5	Traceability and logbooks
R153	configuration identification	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.5	Traceability and logbooks
R154	product status	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.5	Traceability and logbooks



R155	unique identification and records	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.5	Traceability and logbooks
R156	bidirectional relationship between products and related documentation	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.5	Traceability and logbooks
R157	Customer Propriety	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	9	ESO Propriety
R158	Identification, verification, protection and safeguard of Customer property	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	9	ESO Propriety
R159	reporting on damage of Customer property	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	9	ESO Propriety
R160	customer proprietary documents	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	9	ESO Propriety
R161	evidence of the purging of proprietary documents	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	9	ESO Propriety
R162	Transmission of Customer documents	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	9	ESO Propriety
R163	flowdown of customer Property requirements	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	9	ESO Propriety
R164	preservation of the conformity of the product	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.7	Shipping and storage procedures



R165	preservation definition	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.7	Shipping and storage procedures
R166	preservation of the constituent parts of the product	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.7	Shipping and storage procedures
R167	Monitoring and measurement to be undertaken and related equipment necessary to provide evidence of conformity of the product	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.3.2	Metrology and Calibration for production, AIV and evidence of conformity
R168	calibration/verification of the equipments and monitoring	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.3.2	Metrology and Calibration for production, AIV and evidence of conformity
R169	calibration and environmental conditions during measurements	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.3.2	Metrology and Calibration for production, AIV and evidence of conformity
R170	process to ensure monitoring and measurement	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.3.2	Metrology and Calibration for production, AIV and evidence of conformity
R171	use of a calibrated equipment to maintain its validity	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.3.2	Metrology and Calibration for production, AIV and evidence of conformity
R172	Assessment of measurement when equipment is found not conform	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.3.2	Metrology and Calibration for production, AIV and evidence of conformity
R173	Actions for equipment and product affected by not conformity	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.3.2	Metrology and Calibration for production, AIV and evidence of conformity
R174	Calibration / verification records	MAORY Product and Quality Assurance Plan	E-MAO-000-INA- PLA-003	2	4.3.2	Metrology and Calibration for production, AIV and evidence of conformity

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R175	software ability to satisfy the intended application of monitoring and	MAORY Product and Quality Assurance	E-MAO-000-INA- PLA-003	2	4.3.2	Metrology and Calibration for production, AIV and evidence of
	measurement	Plan				conformity