ASTRI Mini-Array
Product Assurance Plan

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DOCUMENT HISTORY		
Issue	**Date**	**Modification**
1.0	22/01/2021	First release
1.1	05/07/2021	3.1.1: removal of the reference to the safety (WP 6000) 8.5.1 and Fig.1: insertion of the RFD management

1 Introduction

1.1 Overview

The ASTRI Mini-Array (MA) is a project of the Italian National Institute for Astrophysics (INAF) to construct and operate an observatory to study astronomical sources emitting at very high energy in the TeV spectral band. The ASTRI MA will consist of an array of nine innovative Imaging Atmospheric Cherenkov Telescopes (IACTs). These telescopes are used to image light traces generated by cosmic-ray particles in the atmosphere onto an array of photon detectors. The light collected by the telescope covers a wavelength range from 300 nm to 600 nm, with the highest intensity being around 400 nm.

The MA telescopes will be an evolution of the two-mirror ASTRI Horn [RD1] telescope, successfully tested since 2014 at the Serra La Nave Astronomical Station of the INAF Observatory of Catania. Each telescope will be equipped with the new version of the ASTRI Silicon Photo-Multiplier (SiPM) Cherenkov Camera. The main science goals of the ASTRI MA, that encompass both galactic and extragalactic science, are described in [RD2].

The nine telescopes will be installed at the Teide Astronomical Observatory, operated by the Instituto de Astrofisica de Canarias (IAC), on Mount Teide (~2400 m a.s.l.) in Tenerife (Canary Islands, Spain). The ASTRI MA will be operated by INAF on the basis of a host agreement with IAC.

A description of the organization of the ASTRI project and of the system is present in AD1, AD3 and AD4.

1.2 Purpose

This Product Assurance Plan (PAP) describes rules and procedures to be followed by the ASTRI project to assure the performance and reliability of the MA.

This PAP will provide assurance that:

- The MA in all its parts is compliant with the specifications
- The risks are identified, assessed and controlled
- The traceability and quality of deliverables are accessible at all times
- Non-conformances are identified and addressed

This PAP is:

- Written and updated by the Product Assurance Manager (PAM)
- Approved by the ASTRI project office
- Implemented by the Work Package (WP) coordinators with the help of the PAM

1.3 Scope

This document is applicable to all the phases of the project, i.e. the design phase, the construction phase of the telescopes, of the observing site and of all the required infrastructures, the test and scientific validation of the ASTRI MA and the decommissioning operations.

1.4 Content

This document is organised as follows:

1) Section 3 provides an overview of the Product Assurance programme for the ASTRI MA Project.
2) Section 4 provides the general Quality Assurance requirements, which are applicable to both the internal and external suppliers of the ASTRI Project and regards both hardware and software items.
3) Section 5 provides the specific Quality Assurance requirements for the acceptance of the deliverable items, which apply only to external suppliers of the ASTRI Project and regards both hardware and software items.
4) Section 6 describes the Quality Assurance programme specific for hardware items, which is applicable to both the internal and external suppliers of the ASTRI Project
5) Section 7 provides an overview of the Quality Assurance programme specific for software items, which is described in a specific document and is applicable to both the internal and external suppliers of the ASTRI Project
6) Section 8 describes the management of the non conformances; it is applicable to both the internal and external suppliers of the ASTRI Project and regards both hardware and software items.
7) Section 9 provides an overview of the approach to the RAMS analysis, which is described in a specific document.

1.5 Definitions and Conventions

1.5.1 Abbreviations and acronyms

AIT	Assembly Integration and Testing
AIV	Assembly Integration and Verification
AR	Acceptance Review
ARB	Acceptance Review Board
ASAP	As soon as possible
ASTRI	Astrofisica con Specchi a Tecnologia Replicante Italiana
CDR	Critical Design Review
COTS	Commercial Off The Shelf
DMS	Data Management System
ECR	Engineering Change Request
FMECA	Failure Mode Effects and Criticality Analysis
HW	Hardware, i.e .mechanical, electrical, electronic, and electromechanical items
IAC	Instituto de Astrofísica de Canarias
IACTs	Imaging Atmospheric Cherenkov Telescopes
INAF	Istituto Nazionale di AstroFisica
MA	Mini-Array

MTBF	Mean Time Between Failures
NCR	Non-Conformity Report
PA	Product Assurance
PAM	Product Assurance Manager
PBS	Product Breakdown Structure
PDR	Preliminary Design Review
PFMEA	Process Failure Mode Effects Analysis
PRR	Production Readiness Review
PM	Project Manager
PMP	Project Management Plan
PO	Project Office
QA	Quality Assurance
RAMS	Reliability, Availability, Maintainability, and Safety
RFD	Request for Deviation
RFW	Request for Waiver
SiPM	Silicon Photo-Multiplier
SE	System Engineer
SDT	Software Development Team
SOW	Statement Of the Work
SPAP	Software Product Assurance Plan
SW	Software
TRB	Test Review Board
TRR	Test Readiness Review
TRV	Test Readiness Verification
TBC	To Be Confirmed
TBD	To Be Defined
WP	Work Package

2 Applicable and reference documents

2.1 Applicable Documents

[AD1] ASTRI Project Management Plan – ASTRI-INAF-PLA-1000-001 I1.9

[AD2] ASTRI Data & Documentation Management Plan - ASTRI-INAF-PLA-1000-003 I1.2

[AD3] ASTRI Product Breakdown Structure – ASTRI-INAF-DES-2000-001 I1.8

[AD4] ASTRI Mini-Array System Architecture - ASTRI-INAF-DES-2000-002

[AD5] ASTRI MA Top Level Software Architecture - ASTRI-DES-2100-001 I2.3

[AD6] ASTRI MA guidelines for the test documents, ASTRI-INAF-PRO-3000-001 I.1

[AD7] ASTRI MA Common Technical Standards List - ASTRI-INAF-SPE-2000-003 I1.1

2.2 Reference Documents

[RD1] Pareschi G., et al., for the ASTRI Collaboration and the CTA Consortium, “The ASTRI SST-2M prototype and mini-array for the Cherenkov Telescope Array (CTA),” Proc. SPIE 9906, id. 99065T (2016)

[RD2] Science objectives of the ASTRI MA

[RD3] General guidelines for the ASTRI AIV documentation, ASTRI-IR-IASFMI-3400-050 I.1 (2014)

[RD4] ECSS-Q-ST-80C Rev.1 (15 February 2017)

3 Product Assurance programme

3.1 Product Assurance programme planning

3.1.1 Product Assurance organization and responsibilities

According to the ASTRI Project Management Plan ([AD1]), all the Product Assurance (PA) activities described in this PA Plan will be managed by the PA Office. This office will be coordinated by the PA Manager (PAM) and will be composed of the PA responsibles for the telescope mechanical structure (WP 7100), optics (WP 7200), camera (WP 7300), and SW (WP 9000). The PAM shall report to the PM the status of the PA activities and shall have organizational authority to establish and implement the applicable PA programme.

3.1.2 Internal and external suppliers

The internal suppliers of the ASTRI Project are the specific ASTRI WPs identified in the ASTRI WBS [AD1].

The external suppliers are the industrial partners which are involved into the ASTRI Project through specific commercial contracts, awarded by the Italian National Institute of Astrophysics (INAF) on the basis of public tenders. As regards the external suppliers, ASTRI is a purchaser.

3.1.3 Product Assurance interfaces

The PA responsible of each ASTRI WP shall interface with the relevant internal and external suppliers regarding all the PA matters.

3.1.4 Product Assurance plan

Each supplier, either internal or external, shall prepare, maintain and implement a plan of the PA activities in agreement with the ASTRI PA requirements.

3.2 Product Assurance programme implementation

3.2.1 Product Assurance management

The PAM shall ensure that the inputs to perform the PA activities are consistent and complete, and available in line with the project schedule, and that the outputs produced by the PA activities are consistent and complete, and delivered in line with the project schedule. Moreover, the PAM shall ensure that all the tasks described in this PA Plan are performed in line with the project schedule.

The PAM shall control the quality of products provided by the internal or external suppliers by issuing applicable PA requirements and ensuring their implementation. The PAM shall ensure that a qualification programme is defined, approved, implemented and maintained by the relevant organization.

The PAM shall approve the product acceptance during the Acceptance or Delivery Review.

3.2.2 PA reporting

The internal and external suppliers shall report on the status and progress of the PA programme implementation. The PA report shall include at least the following items for

the reporting period:

- Progress and accomplishment of each major PA task, including resolved and new problems, future planning of major activities and events
- Status of PA reviews, Audits and Mandatory Inspection Points (MIPs), Waiver requests, Non-conformances (minor and major), Critical items (including mitigation action plan status), Qualification status, EEE component status, Material and processes status, Alerts status.

The PA progress report may be part of the project progress report.

3.2.3 Documentation and data control

The documentation and data management shall be performed according to the ASTRI Documentation and Data Management Plan [AD2].

The PAM shall ensure that the applicable issues of all documents and data are available at all locations where activities required for the implementation of the PA programme are performed.

The PAM shall ensure that invalid or obsolete documents and data are removed from all points of issue or use or assured against unintended use.

The Documentation Manager shall ensure that obsolete documents and data retained for legal or knowledge preservation purposes are identified as such. These documents shall be maintained in the ASTRI MA Data Management System (DMS).

The PAM, in collaboration with the PM, shall identify the project documents requiring approval, including those requiring approval by PA.

3.2.4 PA contribution to configuration management

The PAM shall ensure that:

1) the as-designed status is defined and released prior to manufacturing;
2) the as-built documentation is properly defined, identified and maintained in order to reflect approved modifications;
3) items delivered comply with the as-built documentation.

3.2.5 Non-conformance control

The PAM shall establish and maintain a non-conformance control system, as described in Section 8 of this document.

4 General Quality Assurance requirements

The content of this section applies to both the internal and external suppliers of the ASTRI Project and regards both hardware and software items.

4.1 QA requirements for design and verification

4.1.1 Design rules

Any product shall be designed such that it can be produced with the specified level of quality, its performances and characteristics can be reproduced over different models and serial production, it can be inspected and tested under representative conditions (for production, AIV and operational environment), and it can be operated in accordance with programme constraints and requirements, throughout its whole life cycle (including handling, storage, transportation, integration and operations).

4.1.2 Critical Items identification

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.

4.1.3 Deviations and Waivers

In some cases it might be necessary and perhaps feasible to supply a non-conforming product. In such cases, a Request For Waiver (RFW) or a Request For Deviation (RFD) shall be issued by the supplier (either internal or external) in order to collect the authorisation of the ASTRI PO.

4.1.3.1 Deviation

A deviation occurs when the product does not meet the requirements or specifications before it has been produced (for example, a failure in the design has been detected), or when there is known evidence in advance that it will not meet the requirements once it has been produced (when the production process has a known problem) but for some reason the production must continue (for example, due to schedule constrains).

4.1.3.2 Waiver

A request for waiver is a request for authorization to accept an item which, during manufacturing or after final inspection, is found to depart from specified requirements but nevertheless is considered suitable for use as it is.

4.1.4 Verification rules

The requirement verification shall be performed progressively, as each stage of the project is completed, and shall provide the organized base of data upon which qualification and acceptance is incrementally declared.

The top-down requirement allocations and bottom-up requirement verifications shall be complete and consistent.

A system for tracking requirements and verification of results shall be established and maintained during the whole project life cycle.

The verification methods shall be adequate and consistent with the type and criticality of the requirements.

Depending on the level and the product, five different verification methods can be envisaged:

- Test (T). The requirement shall be verified by a dedicated test. This is the preferable option. A Test Report shall be requested to pass the verification step.
- Analysis (A). The requirement shall be verified by a dedicated analysis. If, for any reason, a requirement cannot be verified by test, an analysis is requested as alternative. An Analysis Report shall be requested to pass the verification step.
- Review of Design (ROD). The requirement shall be verified by reviewing the design by a board of experts. A reference to a Minute of Meeting (MOM) of the board shall be requested to consider the verification passed.
- Inspection (I). The requirement shall be verified by inspecting the hardware. A Technical Report shall be requested to consider the verification process passed.
- Certification (C). The requirement shall be certified by a third part. Usually this method is applied to those components that are procured from an external supplier.

Appropriate reference to the verification documentation shall be recorded and updated at project reviews up to final acceptance.

4.1.5 Verification matrix

As result of the verification strategy, a verification matrix showing all requirements and their selected verification methods shall follow the progress in the project development in all its phases from design to the acceptance.

4.1.6 Design reviews

The major design reviews shall be the Preliminary Design Review (PDR) and the Critical Design Review (CDR). Both reviews shall be conducted in accordance with project requirements and written procedures.

Design reviews shall assess that:

- Quality requirements and criteria for design, feasibility, standardization of parts and interfaces (if possible), repeatability, testability and operability are adequately considered in design documentation.
- Methods and data required for procurement, manufacturing, inspection and test are available and validated.
- Risks of not achieving requirements are highlighted and adequately controlled.

4.1.7 Documentation control

The following documents shall be recorded and stored by the quality representatives of each WP:

- Technical Specifications

- Technical Design reports
- Detailed designs
- Manufacturing dossier
- Inventory list
- Interface Control Documents
- AIT/AIV plan
- Test plans
- Test procedures
- Test results in form of a Test Report
- Control plans
- Control and inspection results during and after production
- Logbooks
- Non-conformance reports and corrective action plans
- User manual
- Installation and maintenance manual

In addition, a resume of the performed activities should be sent regularly to the ASTRI PO.

The Raw Data obtained from tests, controls, and inspections shall be recorded and stored in the ASTRI MA DMS.

Each quality representative, in collaboration with the Documentation Manager, shall audit regularly that:

- The documents of the ASTRI project are controlled.
- Only the last approved version is available to the internal and external suppliers of the ASTRI project.
- The document references, histories, and approval status are correct and consistent.
- The documents are stored in the right place.

All documents shall be kept for at least the duration of the project.

4.2 QA requirements for Assembly, Integration, and Tests (AIT)

4.2.1 Assembly, Integration, and Test control

Each subsystem shall foresee a detailed Assembly, Integration and Test (AIT) plan. The test plan shall state the type of the test, the test approach, the configuration of the assembly under test and the pass/fail criteria [RD3]. A test report shall describe the obtained results.

An AIT/AIV responsible shall follow these processes assuring an updated version of the document.

For each test the AIT plan has to discuss in detail the following items:

- Test objectives
- Test description
- Hardware and Software configuration
- Test pre-requirements
- Test equipment
- Required manpower
- Test responsible
- Safety precautions
- Acceptance/rejection criteria
- Cleanliness and environmental conditions of integration/test facility

Tests and assembly operations shall be reported in a logbook containing the most important data (applicable procedures, responsible of the operation, date, cleanliness, environment, etc.). This logbook shall be made available for verification to the ASTRI PO.

4.2.2 Test facilities, equipment, and tools

The supplier shall ensure that test facilities, equipment, and tools conform to specified requirements.

4.2.3 Test documentation

4.2.3.1 Test procedures

The supplier shall ensure that tests are performed in accordance with documented step-by-step procedures, where acceptance criteria are indicated [AD6]. For each step the following items shall be reported:

- sequential ID number of the performed action
- summary description of the performed action
- name of parameter to be checked
- expected parameter value
- measured parameter value
- action result (PASSED/FAILED)
- additional notes

The supplier QA organization shall review and approve test procedures.

4.2.3.2 Test reports

The supplier shall ensure that all tests are comprehensively documented in test reports, and that they include, as a minimum:

1) reference to the applicable test procedure, and description of the deviations from it during the actual testing,
2) test data records and evaluation, and
3) summary of test results.

The supplier QA responsible shall review and approve test reports.

4.2.4 Test reviews

The supplier shall ensure that Test Readiness Verification (TRVs) and Test Review Boards (TRBs) are performed, respectively, before and after the test itself.

Before the execution of any test, the supplier shall verify the test readiness. To this aim, it shall verify:

- the conformance between the as-built configuration status of the test sample and the design baseline;
- status of non-conformances / failures, requests for waivers, requests for deviations and open work;
- the availability and the approval status of the test procedures;
- calibration status of the test facility;
- responsibilities during the test.

The supplier shall inform in advance the ASTRI PO of the test execution and invite a PO representative to attend it. The ASTRI PAM, in collaboration with the QA responsible for the external supplier (if any), shall 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 8

After the test a Test Review Board (TRB) shall be convened to assure that:

- All the procedure steps have been properly followed
- Required data records are complete and parameters are within the requirements;
- Non conformances and failures are traced;
- Deviations in executing procedures are authorized and traced.

The ASTRI PAM, in collaboration with the WP QA responsible and the QA responsible of the external supplier (if any), shall be represented in the formal boards established for the TRBs.

At the end, the responsible of the test shall prepare a test report containing description of how the procedure has been executed, if authorized deviations are present, the test results and if it presents eventual failures and non-conformances [RD3].

4.3 QA requirements for procurement

4.3.1 Selection of procurement sources

The internal and external suppliers (hereafter purchasers) are responsible not only for the quality of their own products but also for the quality of the products procured by them. The selection of manufacturers and suppliers shall be driven by proven ability in procurement of materials, parts, and components needed by the project. They must guarantee their capability concerning the quality control and traceability.

It is responsibility of each purchaser to define criteria for evaluating and selecting its suppliers from a quality point of view, and to apply this PA Plan also to its suppliers.

4.3.2 Quality Agreement with Suppliers

A quality agreement with the selected external suppliers should be included in all procurement contracts. The only exception is for commercial products off the shelf (COTS), for which documentation and configuration management will be subject to manufacturer definition.

The quality agreement establishes:

- The quality requirements applicable to the supplier.
- The need of a supplier's quality plan and control plan.
- The tests, inspection and controls before, during and after production which the supplier has to implement.
- The list of special characteristics to be controlled by the supplier, including method and frequency.
- The calibration documentation, showing the status of test equipment used for controlling critical characteristics.
- The file format which should be used for exchanging technical drawings between the purchaser and the supplier.
- The warranty conditions.
- The procedure for solving non-conformances (see Section 8)
- The packaging requirements.
- The requirements for product identification, marking and labelling
- A signed Capability Commitment, where the supplier confirms to be capable of meeting all requirements and of supplying the requested quantity and quality on schedule.
- The documentation which the supplier shall attach to each delivery, for example:
  - As-built configuration with product number, revision index, production date and serial numbers of components and sub-components.
  - Test results, inspection logs.
  - Material certificates.
- Other supplier documentation: maintenance manual, spare parts lists, RAMS data, operation manuals, transport and handling instructions.

4.3.3 ASTRI MA contracts

Each ASTRI MA contract shall include a Statement-of-Work (SoW) and Applicable and Reference documents.

The ASTRI MA contracts shall include all the technical requirements applicable to the purchasing contract.

This PA Plan is applicable to all the ASTRI MA contracts.

4.3.4 Record and list of procurement sources

The QA responsible of the purchaser shall establish and maintain records of the procurement sources.

The industrial partners shall submit to ASTRI PAM, upon request, the list of procurement sources.

4.3.5 Surveillance of procurement sources

The purchaser shall exercise surveillance over all the activities carried out by its suppliers.

The surveillance programme shall address audits, reviews, mandatory inspection points, as well as direct supervision at the suppliers' facilities and source inspection. An example of review is the Production Readiness Review (PRR).

4.3.6 Documentation for Procurement

All the documentation related to procurements shall follow PA rules and shall report the requirements for quality control, the traceability and the appropriate standard. Conformance documentation shall be requested and act as an entry point into the manufacturer's traceability system.

It is responsibility of the QA responsible to verify that all inspections, tests, and witnessing of critical processes are performed and that the necessary documentation is provided.

The documentation related to quality that the supplier shall prepare is:

- Production layout and process flow diagram
- Process FMEA
- Control plan (and control charts if applicable)
- Process capability study (if necessary, only for special products: high amount, high complexity, schedule relevant)
- Check lists for incoming inspection
- Check lists for final inspection before delivery
- Material certificates
- Certificate of conformance
- As-Built Configuration List
- As-Designed Configuration List
- Detailed Assembly Drawings and Part Lists
- Test plan for checking the packaging of products that require special transportation conditions
- Non-Conformance Reports
- Requests for deviation/waiver (if a non-conforming product needs to be delivered)
- Acceptance Test Report, including test data sheets with acceptance signature;
- Documentation Status list (if necessary)

- Packing List.

The documentation related to quality assurance in the procurement process that the purchaser shall prepare is the following one:

- Quality agreement with suppliers
- Audit of suppliers (audit questionnaire and audit report)

The traceability system of the procured items is based on log books. Operations logged are:

- Manufacturing (manufacturing record)
- Tests and Inspections
- Integration
- If the case, non-conformance detection

5 QA requirements for acceptance

The content of this section applies only to external suppliers of the ASTRI Project, and regards both hardware and software items.

5.1 Acceptance process

The supplier shall establish and apply a formal acceptance process for all deliverable items, at any contractual level, to ensure that conformance of the items to be delivered is fully assessed and documented.

The Acceptance Review (AR) is the milestone for the acceptance of the deliverable items.

5.2 Acceptance Data Package

The supplier shall provide an Acceptance Data Package (ADP) for each deliverable item. The ADP shall be composed of all documents regarding the deliverable item (as listed in Sections 4.1.7 and 4.3.6) and shall include a 'Summary Report' of the overall test campaign performed. This Summary shall provide:

- the list of the performed tests
- the list of the produced NCRs
- an overall evaluation of the test results
- a declaration about the item compliance to applicable specifications

This Summary Report shall be considered as the 'Identity Card' of the tested item, which shall be associated to the item itself during all its operational life.

Handling, cleaning, packaging, marking, labelling, storing and transport procedures will be part of the ADP.

The ADP shall constitute the basis for formal acceptance reviews.

The ADPs shall be maintained and integrated into higher level ADPs during subsystem or system integration and testing.

5.3 Acceptance review board

The supplier shall ensure that an Acceptance Review Board (ARB) is convened prior to the delivery of any item to ASTRI.

The ARB shall be composed, at least, of the following members:

1) Representatives of the ASTRI PO:
   a) Project manager, or authorized representative, as chairman;
   b) PA manager, or authorized representative;
   c) System Engineer, or authorized representative.
   d) WP leader
   e) AIV Manager
2) Submitting supplier's representatives:
   a) Project manager, or authorized representative;
   b) PA manager, or authorized representative;
   c) System Engineer, or authorized representative.

The ARB shall be responsible for authorising the delivery of the items under acceptance, and certifying in writing that:

1) the items conform to the contractual requirements and to an approved design configuration;
2) the items are free from material and workmanship deficiencies;
3) all non-conformances are closed-out, or corresponding plans, compatible with the delivery, are accepted;
4) the relevant ADP is complete and accurate.

Delivery shall only be authorized by the unanimous agreement of the ARB members.

If the AR is declared positive, the product is accepted and it is certified to be compliant with the applicable requisites and guidelines.

For the acceptance a certificate of conformance shall be made available and signed by the supplier.

6 Quality Assurance programme for Hardware

The content of this section is applicable to both the internal and external suppliers of the ASTRI Project. It describes the Quality Assurance programme specific for hardware items, which include mechanical, electrical, electronic, and electromechanical items.

6.1 Product Identification

Product identification is fundamental for proper control of the system configuration and for future maintenance activities and product upgrades. All parts and components produced or purchased shall be clearly identified with a product number and a serial number. This information shall be engraved or placed in such a way that it cannot be removed or deleted accidentally. At each delivery the identification data of the delivered items shall be recorded and stored in a proper document. For electronic components with firmware, there shall be the possibility to know the firmware used version by means of a specific command. The firmware should be password protected in order to avoid accidental or unauthorised changes.

6.2 Traceability

The supplier shall be capable to trace data, personnel and equipment related to procurement, manufacturing, inspection, test, assembly, integration and operations activities.

The supplier shall be capable to trace backward the locations of materials, parts, sub-assemblies, and to trace forward the locations of materials from raw stock.

The supplier shall establish controls to ensure that:

1) identification numbers are assigned in a systematic manner,
2) identification numbers of scrapped or destroyed items are not used again,
3) identification numbers, once allocated, are not changed, unless the change is authorized by the customer.

6.3 Metrology and calibration

The supplier shall control, calibrate, and maintain inspection, measuring, and test equipment at prescribed intervals, or prior to use.

The supplier shall maintain calibration records for inspection, measuring, and test equipment, and shall make them available to the ASTRI PAM upon request.

The supplier shall use equipment in a manner which ensures that measurement uncertainty is known and is consistent with the specified measurement capability.

The supplier shall include in the calculations of all measurements the total error in the measurement process attributable to the cumulative error from the calibration chain, measuring equipment, and those contributed by personnel, procedures, and the environment.

The supplier shall select inspection, measuring, and test equipment in conformance with the required measurement accuracy and precision.

The supplier shall establish, document, and maintain calibration procedures, including details of equipment type, identification number, location, frequency of checks, check

method, acceptance criteria, and the action to be taken when results exceed the specified accuracy.

The supplier shall ensure that the environmental conditions are suitable for the calibrations, inspections, measurements, and tests being carried out.

6.4 Storage

The supplier shall place in secure storage areas incoming materials, intermediate items needing temporary storage, and end items before shipping. These areas shall guarantee the storage conditions applicable to the involved items. Each storage area shall be identified and labelled for its intended use.

The supplier shall maintain control over acceptance into and withdrawal from storage areas.

The supplier shall maintain records to ensure that all stored items are within the usable life limits, controlled and retested, and to provide traceability within the storage or segregated area.

The supplier shall maintain records of the expiry dates of those materials and chemicals used in production that need to be strictly observed.

6.5 Material Certificate

A material certificate proves that the quality and properties of the material correspond to the specifications and standards provided by INAF [AD7]. It can either just confirm the compliance with an international norm or it can contain the results of a chemical analysis and/or physical test made by a certified laboratory together with a statement that the required specifications are met. All electrical items shall be CE marked.

The suppliers should be requested to attach a material certificate to each delivered batch of critical or relevant parts (for example for the steel of the telescope structure, special fixation screws, concrete of telescope foundations, etc.). The supplier should have, and forward to the quality representative of the purchaser if requested, a copy of the material certificate corresponding to raw material it used for the produced parts.

6.6 Receiving inspection

6.6.1 Receiving inspection planning

In case of incoming items, the involved QA responsible shall perform inspections of all incoming supplies in accordance with established procedures and instructions, to ensure that quality level is properly determined. He/she shall ensure that all incoming supplies, including documentation and packaging, whether delivered on his/her own premises or elsewhere, conform to the requirements of the procurement documents.

The QA responsible shall create an incoming inspection check list describing how to carry out the inspection, the characteristics to be controlled, the sampling frequency, the pass/fail criteria, the necessary tools, the person who carries out the inspection, and how to proceed when the product shows a non-conformance (see Section 8). The checklist should be filled in for each incoming inspection and forwarded to the head of production for revision and acceptance of the batch or the product before storing it in the warehouse or bringing it to the production line. The data of each incoming

inspection is part of the quality records and shall be kept until the final decommissioning of the observatory for traceability purposes. When the number of pieces is high and an incoming inspection of all parts is not feasible, the quality representative may choose a sampling method.

Receiving inspectors shall have available the procurement documents, specifications, drawings and any other document relevant to incoming supplies as required in the procurement documents.

6.6.2 Receiving inspection activities

Receiving inspection activities shall include:

- verification that the packaging meets the requirements and is not damaged
- verification that the environmental sensors and the shock and tilt indicators (if any) are not damaged
- visual inspection of the delivered items, in order to assess that product looks OK at a first glance (no loose parts, dents, cracks, etc.)
- verification that the product corresponds to the type, model and characteristics that had been ordered
- verification of correct identification and, where appropriate, configuration identification for conformance to the ordering data,
- verification that the quantity of pieces, batch number and serial numbers match with the packing list and with the purchase order.
- verification that the required documentation is attached to the delivery (packing list, as-built configuration, level of engineering, handling and safety instructions, conformance certifications, documentation on tests, etc.).
- identification of the inspection status and physical separation of the supplies in the receiving inspection area according to the following categories:
  (a) items for which the receiving inspection has not been completed;
  (b) conforming items;
  (c) non-conforming items.
- prevention of unauthorized use of uninspected and non-conforming items,
- identification of the items to be released for production with conformance status and traceability data to be recorded in manufacturing documents

In case any of the inspected parameters shows a non-conformance, the entire batch shall be put immediately in quarantine and clearly labelled to prevent that it arrives to the assembly/production line (see Section 8). The next step is to launch a non-conformance report describing the problem and to inform the responsible of the involved WP, in order to decide if the batch can be accepted after a full inspection of all parts, can be reworked, or if it must be rejected and sent back to the supplier (see Section 8).

6.6.3 Receiving inspection records

The ASTRI PAM or, in case of an external supplier, the supplier QA responsible shall maintain receiving inspection records to ensure the traceability and the availability of historical data, to monitor supplier performance and quality trends.

6.7 Qualification testing

To obtain authorization to initiate qualification tests, the supplier shall demonstrate that:

1) the qualification model is fully representative of the deliverable item and all differences have been analysed to evaluate their effect on the qualification status
2) inspection and test requirements are expressed in an unambiguous and quantified manner, including: test procedure; test conditions; test standards (if any); applicable test levels, durations and tolerances; accuracy in measurement
3) the qualification test procedures and facilities are defined and available

The applied test procedure shall state the type of the test, the test approach, the configuration of the assembly under test and the pass/fail criteria [RD3].

A test report shall describe the obtained results.

6.8 Product manufacturing

During the production phase of the HW items the goal of the quality activities is to deliver products that are free of defects. For achieving this, it is necessary to procure defect-free raw materials and components, to have stable production processes, adequate controls along the production chain and trained personnel for operating the processes.

A production layout, work flow and manufacturing Process Failure Mode Effects Analysis (PFMEA) should be created before the beginning of the production phase. This allows the definition of the controls that are necessary at each step of the production and to document them in form of control plans.

6.8.1 Identification of Special Characteristics

Special characteristics are particularly important product characteristics or process parameters which require additional measures in order to assure their compliance. They can affect fit, form, function, performance, subsequent processing, safety or compliance with government regulations.

The product suppliers and the QA representative shall identify, define, and document the special characteristics of the product and of the production process, based on the design FMEA and PFMEA analysis. Special characteristics should be clearly identified in the technical drawings, the control plan, and the work instructions.

A waiver or deviation cannot be requested for a special characteristic that departs from the required value. Products whose special characteristics are nonconforming should never be approved nor delivered to ASTRI.

6.8.2 Planning of manufacturing, assembly and integration activities and associated documents

The product supplier shall document the planning of manufacturing, assembly and integration operations and of inspections in the manufacturing plan or flow chart for the product, including the sequence of operations and associated inspections and tests. All steps reported in the manufacturing flow chart shall be described and numbered.

The planning shall include the reference to the procedures by which the various activities are performed and (if necessary) the required cleanliness levels and temperature and humidity requirements of the facilities.

The supplier shall issue and maintain manufacturing, assembly, and integration documents in accordance with established and released procedures.

The QA organization of the supplier shall review and approve such documents, and any modifications thereof.

The supplier shall provide detailed support documents and instructions, such as drawings, procedure and instruction sheets, to enable operations to be correctly performed.

6.8.3 Control of processes

The supplier shall monitor all processes used for manufacturing, assembly and integration, and enforce all applicable process requirements.

The supplier shall ensure that all manufacturing processes are covered by documented process specifications or standards.

The supplier shall describe in a specific document the procedure adopted to perform the process control.

Control plans shall be kept updated and shall be audited by the quality representative/officer.

6.8.4 Special processes

The supplier shall establish and implement procedures and controls for special processes, to ensure that:

1) Special processes are validated for the intended application.
2) Personnel who perform or inspect special processes are trained and certified
3) Materials, equipment, computer systems and software, and procedures involved in the performance of the special process are validated and monitored.

6.8.5 Process FMEA (PFMEA)

The supplier shall prepare a Process FMEA (PFMEA) which analyses the steps of the production process, in order to identify and evaluate the potential failures that can occur and prioritise the action items for alleviating the risk. The PFMEA shall undergo as many analysis loops as necessary until the risks are solved or minimized by means of a re-design of the production process and additional controls and error-proof methods.

6.8.6 Preparation of the Control Plan

A control plan shall be prepared, according to the production flow and FMEAs results.

The need of a control plan should be included as a requirement and the quality representative of the customer should check that the supplier has implemented it properly.

The control plan should include the following sections:

1) Information Table, which includes information of the part number, drawing number, supplier or contributor, contact information, approval dates, etc.
2) Process, which reports the list of those production steps in which a control or inspection activity takes place, together with the equipment, tool or machine needed to complete the step itself
3) Quality Characteristics of Product and Process, which reports the identifying number and the description of the characteristic being inspected or controlled
4) Control Methods, which reports:
   a) the specification and tolerance for each characteristic;
   b) the measurement method to collect the data;
   c) the sampling plan;
   d) the responsible in charge of making the controls;
   e) the reference number to a reaction plan flow-chart, that tells what to do in the event of an out-of-control or out-of-specification condition.

6.8.7 Production Readiness Reviews

Before starting production of the first deliverable item, a Production Readiness Review (PRR) should take place for making sure that the criticalities have been solved, the inspections and control plans are in place and the production process is capable of producing the required quality and quantity on schedule.

The manufacturing readiness review shall evaluate the following aspects:

1) status of product definition and requirements, differences with the status of the qualification model, and impacts of these differences;
2) status of manufacturing, assembly, inspection and test documentation, differences with the status of the qualification model, and impacts of these differences;
3) status of manufacturing processes;
4) implementation status of dispositions for risk reduction, as defined by risk assessment, into the manufacturing, assembly, integration, inspection and test procedures;
5) availability of personnel and of specified materials and parts, production, measuring and inspection equipment, and calibration status, when relevant;
6) cleanliness of facilities, with respect to the specified cleanliness levels;
7) facility temperature and humidity with respect to requirements.

6.8.8 Workmanship standards

The supplier shall employ workmanship standards throughout all phases of manufacturing, assembly and integration, to ensure acceptable and consistent workmanship quality levels.

Workmanship standards shall identify acceptance or rejection criteria.

Tools shall be checked for accuracy during the production life at adequate intervals.

6.8.9 Cleanliness and contamination control

6.8.9.1 Cleanliness control

The supplier shall establish controls for cleanliness of manufacturing, integration, and test facilities, and the limitation of sources of contamination.

6.8.9.2 Cleanliness levels

Contamination-sensitive items shall be cleaned, controlled and maintained to the required cleanliness levels.

The required cleanliness levels for the deliverable items shall be indicated on drawings, specifications, procedures, or other documents controlling the manufacture, assembly, integration and test of the items.

6.8.9.3 Cleaning materials and methods

The supplier shall develop detailed methods for attaining the cleanliness levels specified for the hardware.

6.8.9.4 Contamination control

Contamination shall be minimized by operating in clean working areas and by proper handling, preservation, packaging and storage.

Contamination-sensitive items fabricated or processed in contamination-controlled environments shall be inspected, tested, modified or repaired in identical or cleaner environments, unless specific precautions are taken to protect the items concerned from contamination.

6.8.9.5 Cleanliness of facilities

Fabrication, assembly and integration of contamination-sensitive items shall be conducted in facilities that provide cleanliness levels compatible with the specified product cleanliness.

6.8.10 Manufacturing inspections

Inspections and tests shall be planned at the points of the manufacturing, assembly and integration flow where maximum assurance for correct processing and prevention of unrecoverable or costly non-conformances can be obtained.

Among the inspections and tests as part of the manufacturing, assembly and integration flow, Mandatory Inspection Points (MIPs) shall be planned and performed with participation of ASTRI representatives.

MIPs shall be agreed with the ASTRI PO on the basis of a list prepared by the supplier.

MIPs shall be selected in accordance with the criteria as defined below, when one or more of the following conditions apply:

- When maximum visibility of quality is given.
- When critical processes are performed.
- Where the next step of the manufacturing sequence:
  a) is irreversible, or
  b) makes the item difficult and costly to disassemble for inspection, or
  c) renders the location inaccessible for inspection.
- When the item, once installed in the next higher assembly, damages by its failure the higher assembly.
- When a potential adverse impact on the properties and integrity of the end product could occur, owing to the criticality or complexity of the manufacturing step.

A MIP shall require an invitation with the agreed notice before the event, and the participation of the ASTRI representatives, or their written agreement to proceed without their participation.

MIP information shall include as a minimum:

1) Purpose and subject of the inspections,
2) Criteria for the selection,
3) Notification period,
4) MIP identifier,
5) MIP description,
6) Reference of procedures necessary to perform the MIP,
7) MIP location in the manufacturing and inspection flow chart or the AIV flow chart.

6.8.11 Logbooks

The supplier shall prepare and maintain system, subsystem and equipment logbooks for all operations and tests performed on the item.

The logbooks shall be made available to the ASTRI PAM upon request.

6.8.12 Manufacturing, assembly and integration records

The supplier shall establish and maintain manufacturing, assembly and integration records to provide all manufacturing, assembly, integration and inspection data required for traceability.

The documentation related to quality that should be prepared for the HW production includes:

- Production layout and process flow diagram
- Process FMEA
- Control plan (and control charts if applicable)
- Process capability study in specific cases (high amount, high complexity, tight schedule)
- Checklists for incoming inspections
- Test plan for checking the packaging of very delicate products
- Possible request of deviation/waiver

The records shall be made available to the ASTRI PAM upon request.

6.9 Preparation for delivery

6.9.1 Packaging

The supplier shall ensure that packaging materials, methods, procedures, and instructions are adequate for protection of items while at the supplier's plant, during transportation, and after their arrival at destination. To this aim, quality representative will prepare a specific test plan for verifying that the packaging of especially delicate parts is adequate for the transport conditions. For critical and costly products, packaged items shall be protected against shocks, dust, water, and temperature gradients. Therefore, the use of shock and tilt indicators as well as humidity and temperature sensors could be taken into consideration, especially when a verification of the integrity of the product upon arrival to the site is technically not feasible or very

complex. In such cases, it is necessary to define a threshold of humidity, temperature or shocks/accelerations and to design an appropriate packaging. Items (for example electronic components) which can be damaged by condensed water that may appear inside the packaging during transport due to large temperature and pressure changes should be protected additionally (with humidity absorbers, waterproof sealing, etc.).

In case of procured products which are shipped directly to the installation site, the quality representative should inform the supplier about the transport and environmental conditions and should supervise that the packaging requirements are met. The packaging design should be tested by the product developers and approved by the WP manager.

6.9.2 Marking and labelling

The supplier shall ensure that appropriate marking and labelling for packaging, storage, transportation and shipping of items are performed in accordance with the applicable specifications.

6.10 Delivery

6.10.1 Shipping control

The supplier shall ensure that the items to be shipped from its plant are inspected before release and found to be complete, adequately preserved and packaged, correctly marked and accompanied by all the required documentation.

Accompanying documentation shall include the ADP and, attached to the outside of the shipping container, the handling and packing or unpacking procedure and any relevant safety procedure.

6.10.2 Transportation

The supplier shall make provisions for the prevention of damages to items during transportation.

If necessary, transportation boxes shall be equipped with shock and temperature indicators.

6.11 Installation, maintenance and decommissioning

Installation, maintenance and decommissioning have to be properly analysed and documented. An installation, maintenance, and decommissioning manual shall be released as part of the project documentation.

7 Quality Assurance programme for Software

The ASTRI MA will be operated through a complex software system described in the ASTRI MA Software Top Level Architecture document [AD5]. This Section provides an overview of the Quality Assurance programme specific for software items, which is described in a specific document and is applicable to both the internal and external suppliers of the ASTRI Project.

The objective of software quality procedures is to provide adequate confidence that all the ASTRI MA developed or procured / reused software, satisfies the quality requirements throughout the product lifetime. In particular, that the software design, controls, methods, and techniques result in a satisfactory level of quality in the delivered product.

This requires the measurement and control of the quality of:

- development processes (SW Process Quality Assurance)
- products (SW Product Quality Assurance)

To this aim, the Software Development Team (SDT) shall prepare, maintain, and apply the Software Product Assurance Plan (SPAP). It defines the software quality and product assurance requirements to be applied for the design, production, testing, storage, transport, delivery and operations of all the software products for the ASTRI MA project (from the high-level application software down to the firmware level). It is based on the principles of the standard ECSS-Q-ST-80C [RD 4].

7.1 Software Product Assurance Programme Implementation

The SDT shall clearly define the scope of the software product and describe the internal organisation listing roles, tasks and responsibilities of the SDT structure. The following topics shall be included:

1) organizational structure;
2) interfaces, either external or internal, involved in the project;
3) independence of the software product assurance function;

The SDT shall individuate a software product assurance manager in its organisation. Also, the resources to be used to perform the software product assurance function shall be briefly listed. A full description of the SDT organization shall be documented in the SPAP. The SPAP shall identify and define all the SW items not specifically treated in this document.

7.2 Software Process Quality Assurance

The software process quality assurance looks at the process used to create the final software product. The scope is to ensure that the appropriate development plan for the specific product is followed, and the required software standards described in the ASTRI MA Software Standard are applied. In particular, in this section the SDT reports the adopted mechanisms for planning, controlling, and reporting on product assurance, as well as the procedures for alerts, audits, non-conformances, and for resolving detected software problems.

The SDT SPAP shall contain the list of the documents where all other related processes are adequately documented, such as software development plan or software verification and validation plan.

The plan documentation can be updated, to reflect possible changes during the development, and reviewed at the relevant milestones.

7.2.1 Software Dependability and Safety

Software components shall be object of the dependability and safety analyses in order to identify the severity of the associated possible failures.

7.2.2 Software documentation and configuration management

Software configuration control will be performed, assuring traceability of the developed software configuration items, until final acceptance and utilization. The Product Assurance manager shall verify that the Configuration management system defined in the Management Plan [AD1] is used.

The software development team is responsible, supported by the Configuration Control manager, of all the software development configuration control activities.

Software problems shall be handled since the start of code unit tests, by reporting them following the dedicated procedure defined in the SPAP. Software Problem reports shall be issued and maintained in a dedicated database. Methods and tools to protect the supplied software, checksum type key calculation for the delivered operational software, and labelling method for the delivered media shall be defined.

7.2.3 Process metrics

Metrics shall be used to manage the development and to assess the quality of the development processes.

Process metrics shall be used by the SDT and reported to the ASTRI MA, including: number of problems detected during verification; number of problems detected during integration and validation testing and use.

7.2.4 Coding

The tools to be used in implementing and checking conformance with coding standards shall be identified in the product assurance plan before coding activities start.

The SPAP shall document this process for the specific software product.

7.2.5 Testing

Testing shall be performed in accordance with a specific strategy for each testing level (i.e. unit integration, verification against the technical specification, validation against the requirements baseline, acceptance). Each planned test shall be performed following a clear procedure and its results shall be described in a report.

In case of retesting, all test related documentation (test procedures, data and reports) shall be updated accordingly. This activity should be carried out in case a major change in the software.

The SPAP shall document this process for the specific software product.

7.3 Software Product Quality Assurance

The SPAP shall describe how metrication of the software product quality will be performed, to verify the implementation of the relevant quality requirements. Such metrication activity will give a figure of the product quality involving requirements, design, code, and testing activities as well as software documentation quality.

The SPAP shall describe how testing and validation activities will be performed in accordance to the strategy defined for each testing level and adequately documented in related plans and procedures.

In order to verify these activities, the Test documentation shall cover all the specific aspects including the test environment, the hardware and software configuration, the exploited tools and the possible test software necessary.

Test definition shall include the expected results and in any case the criteria for pass/fail determination.

Contingency steps for the fail case shall be specified. For the requirements not covered by a test activity, verification reports shall be produced by documenting (or referring to) the verification activities performed. The defined set of metrics shall furnish also a valid assessment tool to verify whether the test coverage goal has been reached.

All the software documentation produced during design, implementation, test, and verification phases shall be subject to ASTRI MA configuration management, assuring so the development and implementation traceability and permitting to maintain the software product during the operational phase.

7.4 Software Verification, Validation and Acceptance

Verification is a software process to confirm that adequate specifications and inputs exist for any activity, and that the outputs of the activities are correct and consistent with the specifications and input. Verification tests are performed by the development team. These tests cover the requirements identified within the specification document to show that expected functions are effectively performed by the resulting product.

Validation is a software process to confirm that the functional requirements and performances are correctly and completely implemented in the final product. Validation tests are performed by the end-users (costumer) of the software products. These tests are performed independently of the specification document and may highlight missing or mis-specified requirements.

7.4.1 Software Verification

Most, but not all, software requirements are traceable to executable tests, but all requirements are verified using one or more of the five System Engineering Verification methods: review of design, inspection, demonstration, test, data analysis.

A requirement may need verification at more than one of the SW reviews. For example, a requirement may need verification for design and verification of functionality at the end when the code is complete. However, for most if not for all software codes, the Testing Verification Method shall be used to verify the requirements.

Therefore, any Software product that shall be delivered to the ASTRI MA shall include software tests that demonstrate the code is well written and meets its requirements (unit tests, component tests and acceptance tests).

The SDTs shall produce a Verification Plan of the requirements. The plan maps at which SW review a requirement is verified and indicates the steps and Verification Procedures that will be used to verify the requirement. A Verification Report shall be produced to illustrate the results of the Verification Procedures.

7.4.2 Software Validation

Requirements flow to use cases and tasks that result in software deliverables, which are tested and can be demonstrated for the product stakeholder: ASTRI MA users and operators and maintainers.

Software validation process consists of regular stakeholder involvement in each software iteration cycle, including regular demos and software validation reviews. It is expected that requirement validation (along with verification) will occur during commissioning and result in changes to the software and possibly new software requirements as users and engineers test the systems and get a better sense of how they are used.

7.4.3 Software Delivery and Acceptance

The acceptance is reached only when the software has been verified, validated, delivered, and installed and is correctly running on the ASTRI MA infrastructures and the ASTRI MA personnel has been trained.

8 Non-conformances

This Section describes the management of the non conformances; it is applicable to both the internal and external suppliers of the ASTRI Project and regards both hardware and software items.

8.1 Definition

A non-conformance (NC) is defined as a failure to meet the requirements and may be detected in the product itself or in the process used for its realization. It can be detected in internal or external audits, tests, incoming inspections, during production, after production or even after delivery to the WP to whom it is intended.

8.2 Classification

NCs can be classified as MAJOR or MINOR.

A NC is classified as MAJOR if it affects the form, fit or function of a deliverable HW/SW item, or if it can have an impact on the following areas and cases:

- safety of people or equipment,
- operational, functional or any technical requirements
- reliability, maintainability, availability, lifetime
- functional or dimensional interchangeability
- changes to or deviations from approved qualification or acceptance test procedures
- approved HW/SW Interface Control Documents

A NC is classified as MINOR if, by definition, it cannot be classified as major, i.e. it does not affect the form, fit or function of a deliverable HW/SW item and have no impact on the items listed above. Examples of minor NCs are random failures, where no risk for a lot-related reliability or quality problem exists, and minor inconsistencies in the accompanying documentation.

8.3 Responsibilities related to non-conformances

It is the responsibility of any person involved in the project who detects any service, process or product that does not meet the requirements, to report the problem immediately to the members of his/her WP and to the PA responsible for his/her WP.

In case the service, process or product affected by the detected item is provided by an external supplier, the PA responsible shall report the problem to the involved supplier.

It is the responsibility of the supplier (either internal or external) who originated the nonconformity to ensure that the causes are investigated and solved in a satisfactory manner. The supplier nominates the Non-conformance Review Board (NRB), which shall be the sole technical authority for the treatment of non-conformances. In the case of internal suppliers, the NRB shall include the PA responsible for the involved WP, the WP manager/coordinator, and at least one representative for the Engineering area. In the case of external suppliers, the responsible of the equivalent areas (PM, SE, PA) shall be involved.

8.4 Non-conformance reporting

Non-conformances shall be identified and recorded in a report (NCR), which has to be prepared and managed by the PA responsible and delivered to the ASTRI PO for review. Each NCR shall be uniquely identified with a reference code, which shall be

assigned according to the rules described in the ASTRI Documentation Management Plan [AD2]. The NCR shall report at least the following items:

- revision and date
- NC classification (major/minor)
- name or serial number of the NC item
- procedure or activity in execution when the NC is detected
- problem description
- originator of the reported problem
- test set-up
- environmental conditions at problem occurring
- configuration of the equipment under test (operating modes, connections, …)
- remedial actions adopted in order to proceed with the on-going activity
- preventive actions adopted in order to avoid the problem repetition on similar items
- corrective actions adopted in order to remover the causes(s) of the problem
- name and signature of person who has verified the effectiveness of the adopted solution

In order to close the NCR, it shall be signed by all the members of the NRB and of the ASTRI management (PA responsible, WP manager, PAM, SE, PM). In addition, in the case of external suppliers, the NCR shall be signed also by the INAF contract responsible.

The template to be used for the NCRs of the ASTRI MA is reported in Appendix A.

Remedial/Corrective actions will be planned, initiated and carried out. In case no corrective actions are practicable, a request for deviation (RFD) or waiver (RFW) must be advanced.

Subcontractors will be requested to follow the same principles.

8.5 Procedure for handling non-conformances

For reporting and solving NCs with internal or external suppliers, a non-conformance procedure shall be implemented. This non-conformance procedure shall be applicable to all approved parts, software, services, systems, subsystems and infrastructure of the ASTRI MA project.

The process model reported in Fig. 1 shows the steps for detecting, reporting, solving, and closing non-conformances regarding items provided by an internal supplier of the ASTRI MA project. An equivalent model shall be applied by external suppliers.

The objective of this procedure is to respond to the unintended delivery of non-conforming products and to prevent undesired consequences. Furthermore, the causes of all non-conformances should be investigated and a Corrective Action Plan implemented, in order to avoid whenever possible a repeat of the same non-conformance.

This procedure should be mandatory for all suppliers (internal and external) and, then, it should be included as a requirement in all procurement contracts.

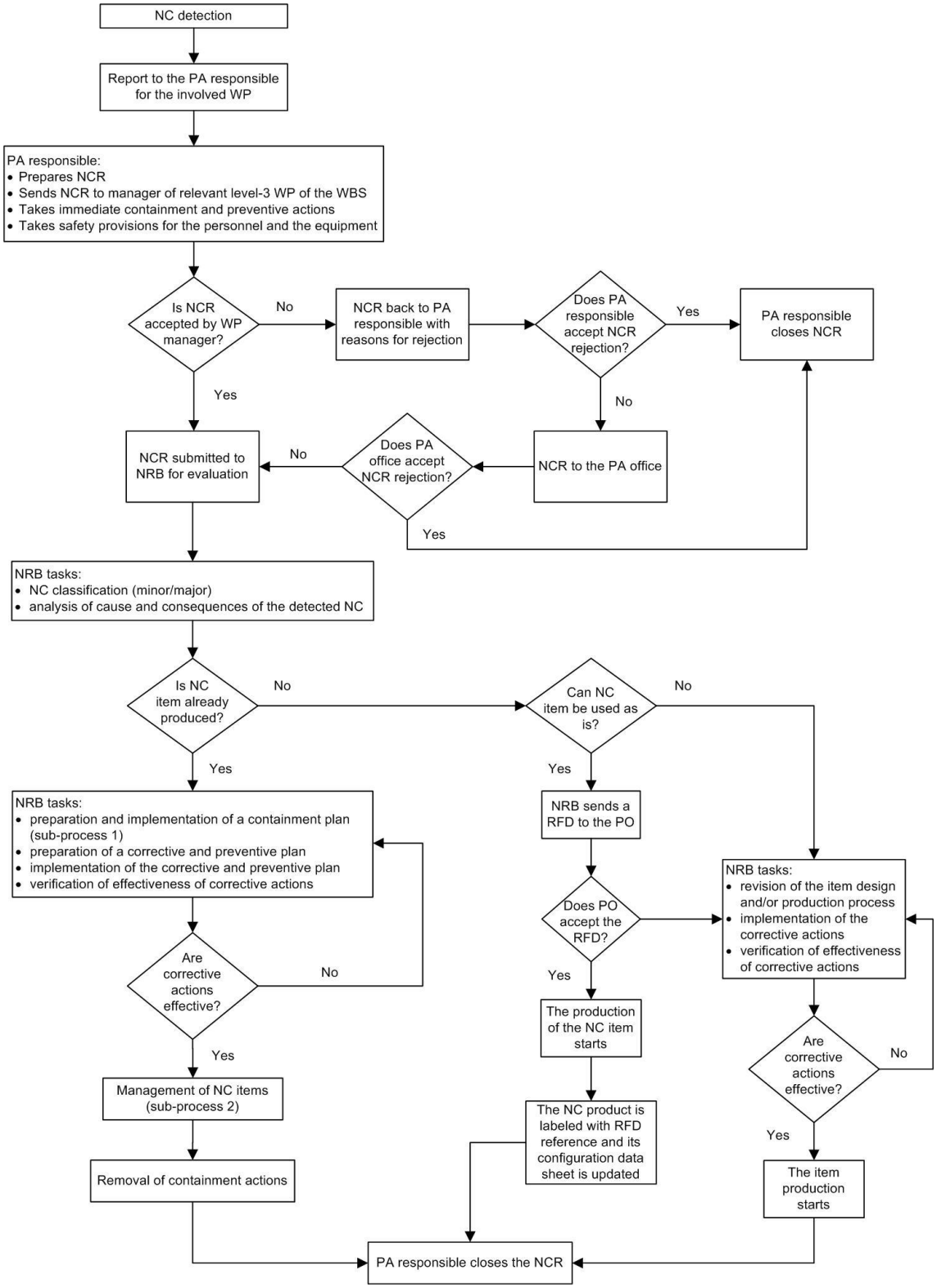

Figure 1: Flow-chart of the procedure adopted for the NC management

8.5.1 Management

Any NC detection is reported to the PA responsible, who prepares a NCR which describes in detail the detected NC. In the case of items provided by an external supplier, a NC detected by the supplier itself is managed by the supplier PA responsible; if, on the other hand, a NC is detected by an ASTRI member, it is managed by the ASTRI PA responsible. The NCR is sent to the coordinator of the level-3 WP involved in the production or procurement of the affected item (according to the ASTRI MA Project Management Plan [AD1]). The WP coordinator can send back the NCR to the PA responsible, including the reasons for the rejection. The PA responsible can either accept the reasons for the rejection and close the NCR or escalate it to the PA office, which in turn can either accept the reasons for the rejection and close the NCR or send it back to the team coordinator.

If the team coordinator accepts the NCR or receives it back from the PA office, he nominates a NRB, which is responsible to classify the detected NC and to identify its causes and consequences.

If the detected NC regards already produced items, the NRB determines the containment actions to isolate the NC items (for HW items only), the corrective actions to eliminate the causes of the NCs, and the preventive actions to avoid the occurrence of the NC on similar items. These tasks shall form an Action plan, which shall be written down in the NCR, together with the due dates and the final fate of the nonconforming product. The NCR is then stored with the status ‘Action Plan’. In order to allow a fast response, the Containment Action plan and a detailed Corrective Action plan should be written and implemented.

If, on the other hand, the detected NC regards items which are not yet produced, the NRB evaluates if they can still be used. If this is possible, the NRB prepares a RFD which is submitted to the PO: the PO can either accept the RFD, allow the item production, update the configuration data sheet of the affected products, and label them with the corresponding deviation reference, or reject the RFD. In this case, and also in case the NC items cannot be used, the NRB revises the item design and/or production process, implements the relative corrective actions and verifies their effectiveness: if they are effective the item production starts, otherwise the corrective process is iterated.

8.5.2 Containment Action Plan

The containment action plan of already produced NC items is described in Fig. 2. It shall include (to the extent that is possible in each case) the following steps:

a) After receiving of the NCR, the NRB should locate, identify and quarantine ASAP all nonconforming products and those that could be potentially affected by the same problem, based on the traceability logs and delivery documentation. Locating the NC products means to find out if they are in their own production line, in the warehouse, in transit to the AIV site, in the warehouse of the AIV site or even built in the final product.
b) All quarantined products will be clearly identified with a red label and NCR number and must be checked 100% before using them. The schedule for checking them is determined by the production needs and is independent of the action plans in the NCR. Moreover, if it is decided that in the meantime the production can continue, an

inspection of 100% of produced parts shall be implemented, until the cause of the NC has been identified and corrective actions are verified to be effective.

c) When non-conforming items are procured products, the team coordinator shall:
   - Communicate the NC to the supplier, forward it the NCR and request a list of affected and potentially affected batches. This list shall be delivered by the supplier ASAP.
   - Quarantine all affected and suspicious products in the warehouse, production line, and finished products at the both the team facilities and the AIV site facility
   - Request the supplier to check all the quarantined products
   - Request the supplier to check 100% of all products before delivering them until the cause has been identified and eradicated.

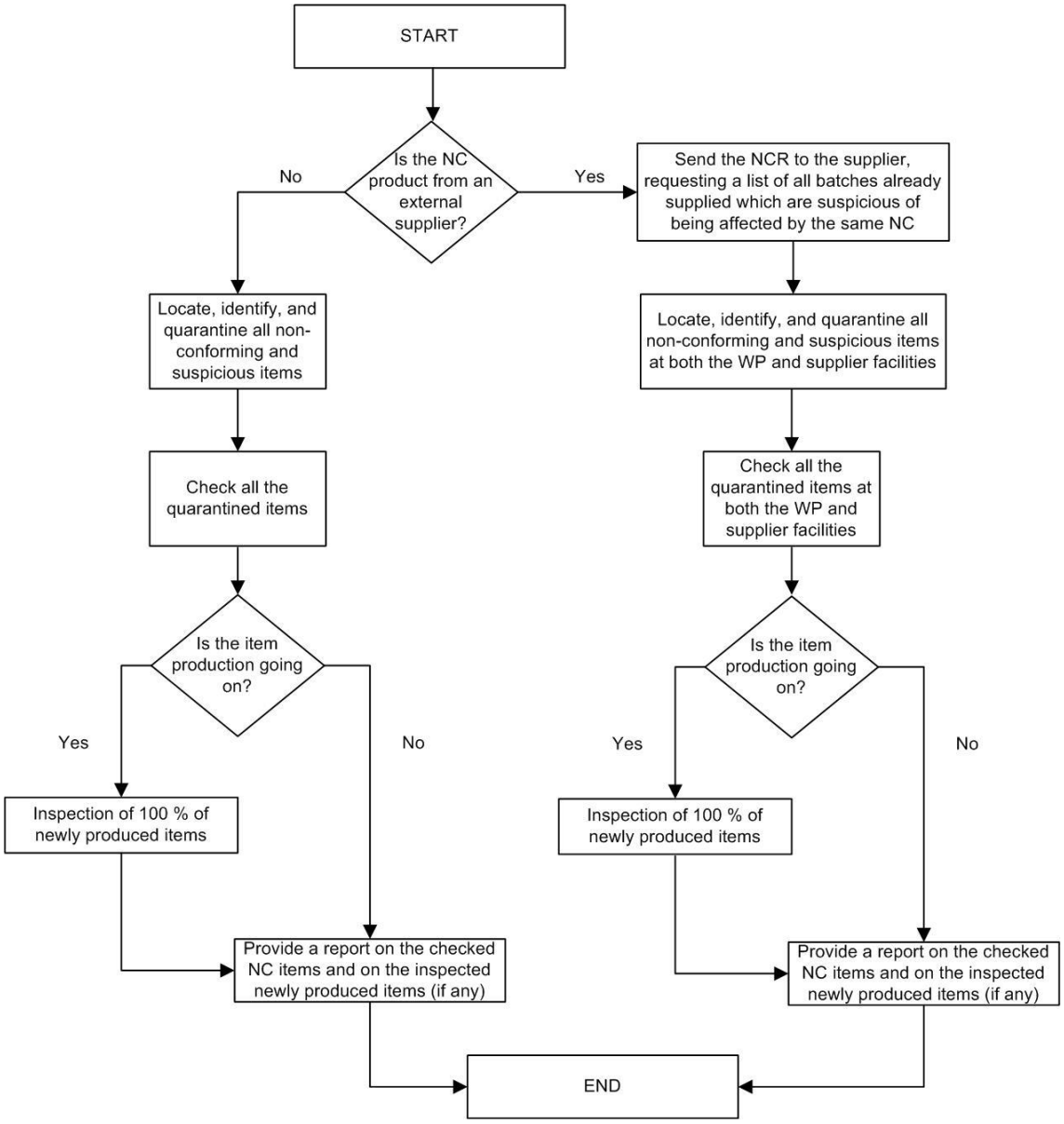

Figure 2: Flow-chart for the containment plan of the NC items (sub-process 1 of Fig. 1)

If the non-conforming procured products are already affecting final products produced and delivered by the work-package, the team coordinator should communicate the problem to the PO and send it a list of affected and suspicious batches that should be quarantined. The team coordinator might also provide additional information (photos, defect samples, special test instructions) for helping the customer to identify the affected products.

8.5.3 Corrective Action Plan

The corrective action plan (applicable also to suppliers) includes the following steps:

a) The NRB will investigate the causes of the nonconformity and design a solution to eradicate the problem.
b) If it is decided that in the meantime the production can continue, an inspection of 100% of produced parts should be implemented.
c) The NRB implements the solution and checks its efficacy (for example, by inspecting at least 20 % of produced parts): if the corrective actions are effective, the revision of the new parts is removed and the NCR is closed, otherwise the causes of the nonconformity are investigated again and a new solution to eradicate the problem is designed.

8.5.4 Management of NC items

In Fig. 3 the flow chart to manage the NC items is reported.

If the NC item is internally produced, if possible it is reworked or repaired and delivered to the AIV site. If, on the other hand, no rework or fixing is possible, but the NC item can be used as it is, a RFW is sent to the PO. The PO can either accept the RFW, update the configuration data sheet of the affected products, label them with the corresponding waiver reference and deliver them for further integration, or reject the waiver and scrap the NC item. A NC item which cannot be used as it is is scrapped as well. It is expected that this last possibility is applicable only to HW items, since in the SW case any NC item can be repaired or reworked.

If the NC item is provided by an external supplier, the same procedure is adopted to agree with the supplier the fate of the affected items.

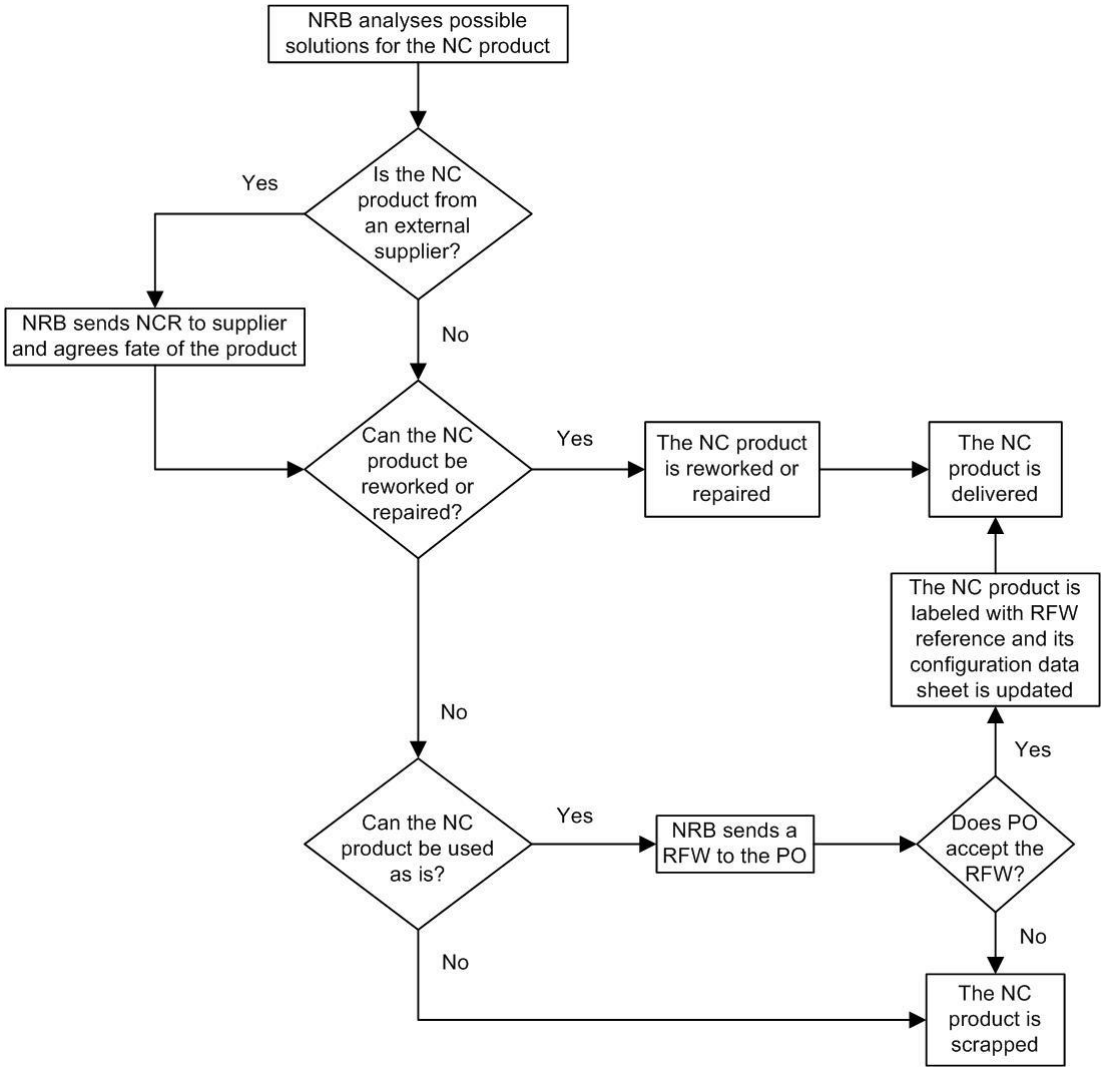

Figure 3: Flow-chart for the management of NC items (sub-process 2 of Fig. 1)

9 RAMS

During the ASTRI MA construction, a reliability analysis shall be implemented since the design phase, in order to guarantee fulfilment of the availability requirement of the instrument during its lifetime. Each subsystem shall carry out this analysis coordinated by the ASTRI MA RAM manager. A RAMS plan shall be developed and carried out for the activities related to this topic. RAMS activities shall be implemented since the starting point of the project and shall be part of the progress reports and reviews.

9.1 Reliability evaluation

A Failure Mode, Effects, and Criticality Analysis (FMECA) shall be implemented in the design and development phases of the instrument. This analysis shall be implemented divided into subsystems.

As output of FMECA analysis, Single Point Failures shall be potentially identified. A list shall be implemented with the aim to solve or mitigate their effects. If it is not possible to avoid them, a final list with probability and occurrence shall be delivered.

9.2 Maintainability

By analysis on the requirements on operation lifetime, hardware configuration and Mean Time Between Failures (MTBF) of the subcomponents, a maintainability plan shall be carried out. In particular, as product of this analysis a spare list and a maintenance (preventive and corrective) manual shall be delivered. Preventive maintenance shall assure that reliability requirements are fulfilled. Corrective maintenance shall assure that instrument downtime is within the specifications.

9.3 Safety Assurance

Aims of the safety assurance program are:

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

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

As output of the safety assurance program, a hazard analysis document shall be delivered, containing the hazard item list with the associate risk level and actions to be implemented to mitigate them.

10 Appendix A

The following template shall be used to track NCRs:

NCR No.: INAF-NCR-XXXX-YYY (see AD2) NCR type: Major/Minor	Revision: Date:
NCR Title:	
NC item (name/serial number):	
Procedure (with code) or activity in execution when NC occurs:	
Description of Non-conformance: Description of the problem and of the occurrence conditions (HW/SW configurations, environmental conditions, test set-up, …) Reported by: Requirements violated (if any):	
Cause of NC:	
Remedial Action: Description of possible solutions adopted to proceed with the on-going activity Action by: action responsible	To be completed by: due date
Action to Prevent Recurrence: Description of possible solutions adopted to avoid repetition of the same problem on similar items Action by: action responsible	To be completed by: due date
Corrective Action: Description of the solution adopted to remove the problem causes Action by: action responsible	To be completed by: due date
Verified by: who verifies the action effectiveness	name signature

NCR close-out			
Name	Position	Signature	Date
	Responsible WP Supplier		
	Responsible QA Supplier		
	PM Supplier		

	Responsible ASTRI WP		
	Responsible ASTRI sub-WP		
	PA Responsible for ASTRI WP		
	ASTRI PA Manager		
	ASTRI RUP		
	ASTRI DEC		

Table 1. Template for the Non-Conformance Reports