SKA PRODUCT ASSURANCE & SAFETY PLAN

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ORGANISATION DETAILS

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TABLE OF CONTENTS

LIST OF FIGURES

1 INTRODUCTION

This plan defines the Product Assurance approach to be taken by the Office of the SKA Organisation. It is a model for those Plans that are to be implemented for the SKA by all the Consortia and their subcontractors. The Plan is based on the European Cooperation for Space Standardisation (ECSS) documents, tailored to the needs of the programme.

1.1 Product Assurance Objectives

The objectives of the Product Assurance programme are: -

a. To ensure each item of equipment that is designed, manufactured, tested and delivered meets the specification requirements for the SKA.
b. To ensure inclusion of reliability criteria in the design of the SKA
c. To identify and integrate quality engineering into manufacture and test so that the inherent design reliability is not compromised or degraded.
d. To ensure early detection of actual or potential deficiencies, system incompatibilities, or conditions that could result in unsatisfactory system performance and to provide timely and effective corrective and preventative action of all such conditions.
e. To ensure flowed-down requirements are clearly identified and understood so that they are consistent with the overall programme requirements and that they are achieved through a programme of assessment, joint review, close monitoring and feedback.
f. To ensure availability of documented evidence of conformance to drawings, specifications and test requirements.
g. To identify approved design baselines and to control departures from the baseline in an identified, well-defined and authorised manner.
h. To report regularly on progress and key events in the Product Assurance Programme.
i. To identify critical areas that may affect the successful completion of the programme and to ensure that appropriate measures are incorporated to control and monitor critical areas.
j. To certify the safety of the equipment and its operations.

1.2 Product Assurance Management

The SKA Office will appoint an SKA Product Assurance Manager, whose role is to manage and coordinate the overall Product Assurance function of the Consortium work. Each Consortium Project Manager will appoint a Consortium Product Assurance Manager / Engineer (CPAM) for this Project who will be responsible for all aspects of the Product Assurance tasks performed by that Consortium during the programme. In the execution of the Product Assurance programme, Engineers who are specialist in the various functional disciplines of Product Assurance will assist each PA Manager. Furthermore, subcontractors of Consortia will appoint a Quality Representative / Engineer with responsibilities to ensure effective Management of their Product Assurance Programme.

1.3 Scope

This Product Assurance Plan shall apply to any activity and / or item relating to prototypes and deliverables (hardware or design documentation), or to demonstrate design traceability of the deliverable hardware or design. In some instances, this may include Development phases if they are

used to qualify some aspect of the design and if the same aspect is not subsequently re¬verified on deliverables. The parts of this plan applicable to Support Equipment (SE) are specified in section 7.

Each Consortium shall write a specific Product Assurance / Quality Plan for their respective activity; considering this plan, calling upon the required applicable and reference documents appropriately. The Consortium's Plan shall detail the Product Assurance programme specifically or implement this PA plan (and declare any differences / deviations via a PA compliance matrix) for their particular activity for the SKA.

1.4 Rights of Access

SKA Office PA representatives will be afforded all reasonable rights of access to areas where Manufacture, Assembly, Integration and Test of the hardware are undertaken. Similar rights of access will be negotiated and included in all major sub-contract orders and suppliers.

1.5 Documentation Precedence

In case of conflict, the following documents will take precedence in the order given:

Consortium Agreements
This SKA Product Assurance plan
Consortium PA Plans
Any ECSS standard called up by this plan

1.6 Review and Amendment

The contents of this plan are subject to review to ensure its continued effectiveness and applicability to specified requirements.

1.7 Organisation

The Product Assurance organisation for the SKA is graphically represented in Figure 1; the aim is to ensure accurate and consistent flow of requirements throughout the various levels of responsibility.

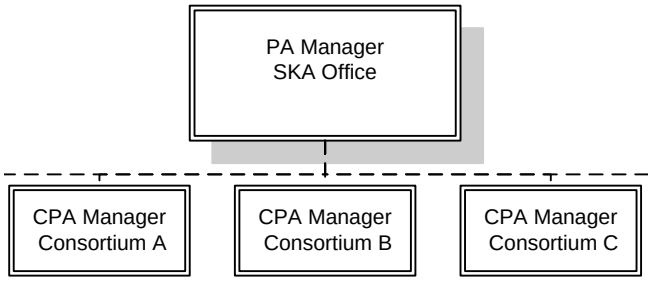

Figure 1: SKA PA Organisation**.**

1.8 Applicable Documents

The following documentation forms part of the PA Plan to the extent specified herein. Unless an issue is quoted for a document, the current issue is deemed to apply. When an issue is given, that issue and no other must be used.

[AD1] SKA PMP
[AD2] SKA SEMP

[AD3] SKA Change Management Procedure SKA-TEL.SE.CDM-SKO-PR-001
[AD4] SKA RFI Management Plan
[AD5] SKA Document Management Plan SKA-OFF.MGT.DMT-SKO-MP-001

1.9 Reference Documents

The following documents may be used to assist the Project and the Consortia when undertaking Product Assurance tasks in the SKA Programme. Unless an issue is quoted for a document, the current issue is deemed to apply. When an issue is quoted, that issue and no other must be used.

[RD1] Glossary of Terms ECSS-P-001A
[RD2] Quality Assurance ECSS-Q-20B
[RD3] Dependability ECSS-Q-30A
[RD4] Safety ECSS-Q-40B
[RD5] Non-conformance Control System ECSS-Q-20-09B
[RD6] Electrical, Electronic and Electromechanical (EEE) Components ECSS-Q-60A
[RD7] Control of Limited Shelf-life Materials ECSS-Q-70-22
[RD8] Failure Modes, Effects and Criticality Analysis (FMECA) ECSS-Q-30-02A
[RD9] Configuration Management ECSS-M-40A
[RD10] Fault Tree Analysis ECSS-Q-40-12A
[RD11] EEE Parts Failure Rates MIL-HDBK-217F
[RD12] Handbook of Reliability Prediction Procedures for Mechanical Equipment Naval Surface Warfare Center, CARDEROCKDIV, NSWC-07
[RD13] De-rating Requirement Application Rules for Electronic Components PSS-01-301
[RD14] General Product Safety directive 92/59/EEC
[RD15] Liability for Defective Products directive 85/374/EEC
[RD16] CE Marking directive 93/68/EEC
[RD17] Electromagnetic Compatibility directive 89/336/EEC

1.10 Acronyms and Abbreviations

ABCL As-Built Configuration List
ADP Acceptance Data Pack
ASIC Application Specific Integrated Circuit
CDR Critical Design Review
CE European Conformity
CIDL Configuration Item Data List
CIL Critical Item List
CoC Certificate of Conformity
CPAM Consortium Product Assurance Manager
CPM Consortium Project Manager
DCL Declared Component List
DPA Destructive Physical Analysis
DRB Delivery Review Board
ECSS European Cooperation on Space Standardisation
EEE Electrical, Electronic and Electromechanical
EIDP End Item Data Package
EMC Electro Magnetic Compatibility
EU European Union
FMECA Failure Modes, Effects and Criticality Analysis

FPGA Field Programmable Gate Array
FTA Fault Tree Analysis
IRB Internal Review Board
LAT Lot Acceptance Test
MIMIC Monolithic Microwave Integrated Circuit
MIP Mandatory Inspection Point
MPPB Materials, Parts and Processes Board
MRR Manufacturing Readiness Review
NCR Non-conformance Report
NRB Non-conformance Review Board
OTS Off-The-Shelf equipment
PA Product Assurance
PDR Preliminary Design Review
PMP Parts Material and Processes
PPL Preferred Parts List
RFA Request for Approval
RFD Request for Deviation
RFW Request for Waiver
SAR Safety Assessment Reports
SE Support Equipment
SKA Square Kilometre Array
SOW Statement of Work
SRR System Requirements Review
TRB Test Review Board
TRR Test Readiness Review
WCA Worst Case Analysis

2 PRODUCT ASSURANCE

The major functions of Product Assurance are:

a. To be responsible for and co-ordinate all Quality related matters during all phases of the programme between the Consortia and the SKA Office.
b. To ensure that the tasks and commitments defined in this plan are performed to the required standard and to the satisfaction of the SKA Board.

2.1 Product Assurance Tasks

Examples of tasks performed to achieve Product Assurance are given below and those that relate to the System level are consolidated by the SKA Office.

a. Audits / Surveillance of sub-contractors / suppliers and in-house.
b. Evaluation of sub-contractor proposals.
c. Identifying resources required for Quality tasks.
d. Preparing Quality requirements for sub-contracts.
e. The verification of the qualification status of parts, materials processes and equipment.
f. Ensuring that a programme of activity directed towards ensuring reliability and sustainability is initiated, maintained and utilised throughout the programme in accordance with this Plan and other Project requirements.
g. Participation in all Design Reviews.
h. Ensuring Compliance with applicable legislation, along with the relevant Site Country regulations for Product Safety

i. The management of Non-Conformance Reports (NCRs).
j. Demonstrating and reporting the build standard of equipment and reconciling this standard with the approved design.
k. Reviewing, Reporting and Interfacing with major subcontractors.
l. The identification of areas of risk including critical items and associated risk mitigation actions. Conducting Mandatory Inspection Points (MIPs) on sub-contractors, where required.
m. Product Assurance Reviews (such as NCR / NRB)
n. Participating in Test Readiness Review boards, see section 2.3.8.
o. Participating in Test Review Boards, see section 2.3.9.
p. Participating in Delivery Review Boards, see section 2.3.10.

2.2 PA Reporting

The SKA Office and Consortium Project Managers will provide regular account of the status of the Product Assurance tasks through progress reports. These reports will be regularly submitted to the Project Managers prior to the Project or PA progress meetings [AD1]. The following topics will be addressed, as appropriate, for each report:

a. Accomplishment of tasks since last report
b. Changes in organisation and staffing (if any) which impact Product Assurance
c. Status of specifications / procedures which relate to or require PA involvement
d. Critical Items Management
e. Existing / potential PA problems and proposed solutions
f. Major test stages / problems
g. Status and tracking of Non-conformances, Waivers and Warnings / Alerts.
h. Report the outcome of audits that have taken place (Internal / External) and those planned for the next period.
i. Reporting on Sub-contractor and supplier performance
j. Notification of issues relating to Materials, Mechanical Parts, Processes, Components, Dependability or Safety.

2.3 Reviews

2.3.1 (System) Requirements Review (SRR)

The SRR examines the compatibility of the system architecture and the allocation of performance-level requirements to products and sub-assemblies, examines the compatibility of the system interface specifications between the components of the system and releases the formal SKA System Requirement Specification and the external interface specifications.

The SRR is conducted at the end of the definition. The review will typically be conducted after the conclusion of the requirement analysis and validation activities.

Documents to be reviewed during the SRR will include:

- Finalised requirement specification (including the cross verification matrix indicating the kind of tests to be performed for each of the requirements).
- First draft of the architectural design description document
- Updated block diagram of the relevant system
- First draft interface control documents (internal and external)
- First draft verification plan/procedure

- Updated risk register and related mitigation strategies
- Updated requirements traceability matrix/database
- Strategy and plans for proceeding to the next phase
- Updated Cost, schedule, engineering resource and RAM estimates
- Logistical and software documents (To be defined)
- First draft health and safety plan

The output of this review is a well-defined status at the project level at which it is being performed.

2.3.2 Preliminary Design Review (PDR)

The Preliminary Design Review is held when the basic system architecture has been baselined and the major sub-systems and equipment have been defined in terms of functional partitioning and interfaces. It will present and confirm the technical baseline against the SKA System Requirements Specification.

The PDR will be conducted at the end of the preliminary design phase. The review will be performed at the conclusion of the functional analysis, verification, synthesis and design verification activities at the end of the preliminary design phase.

Documents to be reviewed during the PDR will include:

- Revised and final requirements specification
- Final architectural design description document
- Final interface control documents (internal and external)
- Final block diagram
- Acceptance test plans and procedures
- First draft integration plan
- Updated requirements traceability matrix/database
- First high level estimate of consumables, spares and test equipment
- Updated risk register and relating mitigations strategies
- Updated Cost, schedule, engineering resource and RAM estimates
- Upgrade plans
- Roll out/build plans
- Logistic Engineering Standards & Procedures
- Audit of manufacturing datapacks for designs to be carried forward
- Safety analysis
- Final health and safety plan

Together, the above set of documents must reflect the fully costed design of the item. The output of the review will be a design at the project level at which it is being performed.

2.3.3 Critical Design Review (CDR)

The purpose of the Critical Design review is to establish that the final, detailed design is sufficiently mature for release of the final deliverables to the manufacturing stage of the programme. It will review the detailed design and demonstrate that the final design meets the requirements.

The CDR will be performed at the end of the detailed design phase. The following high level activities are foreseen:

- Confirmation of the requirement specification and design description baseline
- Review of all aspects of the production process as well as the supporting documents (manufacturing datapacks).
- Review of test and verification plans/procedures
- Review of updated risk registers
- Presentation of final design data on costs, engineering resource utilisation, reliability etc.
- Review of integration and test plans

The exact details of this phase will be developed and expanded during the early Pre-Construction Phase.

2.3.4 Production Review (PR)

The production review will be performed at the end of any preliminary production phase. The main aim of this review will be to confirm that the items produced do comply to specifications and is ready to go into full scale production. In this regard test and verification results will be reviewed and manufacturing datapacks will be audited. The output from this review will be utilised in the full scale production phase to produce the items against the approved set of baseline documents.

The Production Review shall evaluate systematically the following aspects:

a. Status of product, definition and requirements, differences with the status of the final prototype, and impacts of these differences.
b. Status of manufacturing, assembly, inspection and test documentation, differences with the status of that used for the final prototypes, and impacts of these differences
c. Validation status of manufacturing processes, with particular emphasis on critical processes.
d. Availability of required production, measuring and inspection equipment, and calibration status, when relevant.

2.3.5 Test Readiness Review (TRR)

The TRR is performed in order to establish whether the specific item is ready for formal testing. This will imply that integration and integration testing are complete and evidence and proof of test results can be presented.

The aim of the review will be to verify the readiness of the equipment itself, associated test documentation, and test facilities and equipment in order to start with formal testing/verification.

As a minimum the following will be reviewed during the TRR:

a) Overview of input documents and process followed to establish baseline

b) Results of the development testing performed on the equipment

c) Acceptance Test Procedure (including qualification requirements)

d) Requirement traceability matrix/database

e) Confirmation of the configuration of the equipment to be tested

f) Readiness of equipment

g) Readiness of test equipment and simulators

h) Readiness of test facilities

i) Requirements traceability matrix/database

j) Identified risks and mitigation plans

2.3.6 Acceptance Review (AR)

The AR will be performed following the conclusion of the verification of the equipment. The aim of the review will be to confirm the completeness and the results of the verification phase. The review will take the form of a Functional Configuration Audit (FCA) and a Physical Configuration Audit (PCA).

The FCA is a formal audit intended to confirm that the equipment has achieved the performance and functional requirements; that it satisfies the characteristics specified in the relevant specifications, interface specifications, and other baseline documentation; and that test plans and procedures were complied with.

The PCA is intended to confirm the physical configuration of the equipment that was tested and to establish the “as-built” configuration.

As a minimum the following will be reviewed during the AR:

a) Overview of input documents and processes followed to establish the baseline

b) Factory/site acceptance test reports (including qualification test results)

c) Change proposal register

d) Deviations/waivers

e) Requirement traceability matrix/database

f) Manufacturing datapack

g) FCA and PCA reports

2.3.7 Mandatory Inspection Point (MIP)

After an item of deliverable equipment has been manufactured and / or integrated, a Mandatory Inspection will take place. The aim is to review the hardware manufacture file to ensure all build and pertinent traceability data is complete and comprehensive; this will form the basis for reconciling the build with the approved design baseline.

Where it is deemed necessary, MIPs will be incorporated in to the manufacturing plan. These will take place when: -

- Maximum visibility of quality is given.
- The next manufacturing step is irreversible.
- The next manufacturing step renders the location inaccessible for inspection.
- When a critical process is being performed.

A MIP shall confirm that the design has been implemented and the requirements met; this shall include any agreed design updates from those originally specified. Any deviations to the design shall be identified (e.g. NCRs, Waivers etc.) together with the appropriate authorisation. A visual examination of the hardware shall always form part of the MIP.

A MIP requires 5 working days’ notice of the inspection event to the customer; the customer will attend the inspection unless the customer provides written authorisation to proceed without their participation.

2.3.8 Test Readiness Review (TRR)

The basis for undertaking a test campaign will be in the form of a Test Plan; it will provide a basic description of tests to be undertaken, their sequence and a cross reference to the procedure that will be used when performing a particular test.

Prior to the test campaign (for example Verification Tests), the PA responsible individual will conduct a Test Readiness Review (TRR). The purpose of the TRR is to reconcile the build standard with the design and review any non-conformances, anomalies and waivers from design during build of the equipment. A determination of the effect, to the test campaign, of any anomalies, waivers or non-conformances raised throughout the build will also be undertaken. Customer representatives will review pertinent Test Procedures in the preceding 2 weeks of the meeting so comments can be provided for incorporation in the relevant document. As a schedule aid, and during the TRR, the Test Procedures may be 'red-lined' with agreed text so that the tests may be performed without the need to formally update the procedures. However, should 'red-lining' the text be too extensive (as determined by the TRR), an update may be considered mandatory.

The TRR will also confirm the calibration and validation status of the test facilities and equipment. Project 'Open Actions' will be reviewed to ensure they have no impact or, on completion of the action, invalidate the proposed test(s). For reasons of Safety, any Hazards or Safety Measures associated with the proposed test(s) will be highlighted during the TRR to ensure appropriate measures, procedures or processes have been put in place to control the Hazard or Safety concern.
The intended outcome of the TRR is to authorise the start of formal testing in accordance with the agreed plan and procedures (whether they be updated or red-lined). Subsequently, tests will be monitored and any non-conformances, occurrences or anomalies recorded, as outlined in section 3.4.

A typical agenda for a TRR: -

- Equipment Description
- MIP Status - References & Closure
- Review of any Previous Meetings
- Test Procedure / Plan / Schedule Status
- Design vs. Build Reconciliation
- Non-Conformance / open Items & Actions
- RFD/RFW
- Test Facility Status / Test Equipment / Hardware Status
- Any other Business
- Conclusion

2.3.9 Test Review Board (TRB)

Test Review Boards will be conducted on completion of the test campaign, or any other test that is deemed necessary as a result of the TRR, and the outcome of the tests undertaken. The purpose of the TRB is to review the results obtained against the test plan and procedures, together with any associated non-conformances or anomalies and to agree their acceptance or authorise their disposition. Critical Items will be reviewed to ensure they have been addressed as and where necessary.

A typical agenda for a TRB: -

- Equipment Description

- MIP Status - References & Closure
- Review of Actions from TRR & any Previous Meetings
- Test Procedure & Changes since TRR
- Design vs. Build Reconciliation
- Non-Conformance / open Items & Actions
- RFD/RFW
- Summary of Test Results (Ref & Issue of Test Report)
- Hardware Inspection
- Any other Business
- Conclusion

2.3.10 Acceptance Review (AR)

All deliverable hardware will be subject to a Delivery Review Board (DRB) to verify satisfactory design definition, build and test data has been compiled in an Acceptance Data Pack (ADP) / End Item Data Pack (EIDP).

A typical agenda for an AR: -

- Equipment Description
- MIP Status - References & Closure
- Review of Actions from TRB & any Previous Meetings
- Test Procedure & Changes since TRR
- Design vs. Build Reconciliation
- Non-Conformance / open Items & Actions
- RFD / RFW
- Summary of Test Results (Ref & Issue of Test Report)
- Hardware Inspection / Shop traveller review
- ICD compliance
- EIDP / Log Book Review
- Any other Business
- Conclusion

The ADP/EIDP will define the build standard of the delivered item and will, therefore, be the basis for subsequent builds. The pack content shall include-

- Top documentation
  - Certificate of Conformance (CoC)
  - Minutes of TRB / DRB meeting (including sign off sheet)
- As design documentation
  - CIDL (including specification reference and CNs list)
  - RFD list + including copies of RFD
  - General assembly drawing if applicable
  - I/F drawing or ICD sheets
  - Assembly drawing
  - Pin functions / connectors
- As built documentation
  - As-Built Configuration List (ABCL)
  - RFW list + copies of RFW Major Non-conformance Reports & IRB / NRB minutes
  - Non-conformance Reports List (minor)
  - MIP reports

- Test procedure / 'As run test procedure'
- Test report / calibration
- Test house certificates
- Test equipment list / calibration data (maybe part of as run test procedure)

- Log Book
  - Inspection records
  - Kitting / traceability parts list
  - Event register (transportation...)
  - Mate / demate log
  - Hazardous item log
  - Life limited items log
  - Operated time/actuations number log

- Others
  - Open items
  - Loose items
  - User manual
  - Handling / Packaging / Storage procedure
  - Safety / handling precautions

2.4 Previously Designed Items

Hardware with previous deliverable heritage may be used for the SKA design; the Consortium will demonstrate how the hardware complies with the relevant SKA requirements, such that certain tasks need not be repeated. The Consortium will submit substantiating documentation in accordance with the respective Statement of Work; if warranted, the item will be subject to a specific review, to confirm compliance with the SKA technical and environmental requirements.

2.5 Audits

Suppliers / Sub-contractors providing goods or services to the SKA programme are subject to formal approval and, where deemed necessary, audited by the Consortium to continuously assess and assure their continued effectiveness.

2.6 Traceability and Identification

2.6.1 General

Parties that manufacture design verification, deliverable and SE hardware will maintain procedures and processes that ensure effective identification and data retrieval. This will encompass identity of goods entering the organisation (and traceability to the suppliers 'outgoing' traceability), for example in accordance with [RD2], clause 5. This allows traceability to procurement, fabrication, processing, inspection, test and operating records. Furthermore, in the event of problems associated with similar items, it provides a means for locating articles and materials as well as giving current status.

The key purpose of maintaining precise records of build, materials and processes are to define what has been subjected to the formal Verification Test Programme, thus enabling repeat builds of a 'delivered' item which will have the same characteristics when subjected to the various electrical, mechanical and environmental stresses.

2.6.2 Identification

The ability to maintain full traceability may be structured to meet contract requirements as defined in [RD2], clause 5.4. In the case of critical Electrical, Electronic and Electromechanical (EEE) parts, identification and traceability will be to component level.

Records shall provide evidence that inspections and tests have been performed and shall contain complete item and process inspection data, test identification as applicable, numbers of conforming and non-conforming items, and any causes for rejection.

3 QUALITY ASSURANCE

3.1 Quality Approach

Quality will be embedded into all processes by ensuring attention to quality is the first responsibility of every Consortium.

Control of sub-contractor quality is achieved by careful selection and by approving their capability. Compliance to requirements is actively monitored by means of progress meetings, audits, and where needed, direct surveillance. Third party approval (e.g. ISO 9001 - 2000 certified) will be duly considered when selecting suppliers for the SKA.

3.2 Procurement Control

3.2.1 Procurement Documentation & Selection

- Major sub-contracts, as defined by the Consortia, will be subject to a Statement of Work (SOW) defining all aspects of design, procurement, production meetings, reviews etc. The SOW will be a configured document.
- Procurement Specifications and Purchase Orders will include Quality Assurance clauses that reflect the Consortium requirements.
- Consortium PA Managers will ensure that their suppliers are approved or, if not approved, are managed to supply goods or services to the required standards and subsequently authorised by Quality Assurance. Supplier selection may be undertaken in accordance with [RD2], clause 7. Consideration shall be given to a third party certification, as appropriate to the nature of the products or services being procured.

3.2.2 Supplier Surveillance

Supplier surveillance will generally be in accordance with [RD2], clause 7.4, specifically noting the points below: -

- The performance of suppliers will be assessed taking into account acceptability, or otherwise, of previous performance. The criticality of the goods and services being provided will be accounted for in terms of quality, schedule and cost adherence; appropriate measure will be put in place to ensure these are met.
- Surveillance may take the form of regular visits, specific inspection points or meetings to discuss problems and opportunities.
- A suppliers system for non-conformance and corrective actions will be able and available to notify the Consortium of significant (‘major’) non-conformances and record NRBs as necessary.

3.2.3 Incoming Inspection / Source Inspection

- Where identified on the Purchase Order, the customer (either the SKA Office or Consortium, as appropriate) will carry out specified incoming inspection activities; acceptance of goods will not be confirmed until satisfactory completion of this activity. Non-conformances will be reported to the supplier and action taken in accordance with non-conformance recovery actions. The SKA Office may define Project Specific Instructions for inspection and quality requirements for any goods supplied for use on the SKA programme.
- When there is intent to use sampling plans for incoming inspection of goods, they may be in accordance with [RD2], clause 5.9.
- Incoming inspection of components may be undertaken in accordance with [RD2], clause 7.5.
- Where incoming inspection is not practical, the customer may perform inspections during the manufacturing process or prior to despatch from the supplier's premises (source inspection).

These inspections will be identified in the applicable procurement documentation.

3.2.4 Goods Receiving

- In cases where preferred suppliers have consistently demonstrated a high level of process control and quality, they may be allowed to ship straight to stock with / with-out incoming inspection of the hardware. However random audits and user feedback will ensure that this situation is regularly monitored.
- Receiving inspectors will have available, at the appropriate time, the procurement documents, specifications, drawings and any other document relevant to incoming supplies.
- Goods found to be unacceptable will be reported to the supplier in accordance with non-conformance procedures (or equivalent sub-contract procedures). All unacceptable goods will be quarantined to prevent accidental use prior to disposition.
- Incoming inspection records will be maintained to ensure traceability and the availability of historical data (that may be used to monitor supplier performance and quality trends). The records will include, as a minimum: date of receipt, inspection or test procedure utilised, accomplishment of applicable results of inspections / tests, and disposition of the articles or materials.

3.2.5 Non-Conformance Information Feedback

The Consortia will ensure that sub-contractors and suppliers take prompt remedial and preventative action on non-conformances raised at the supplier's facilities by responding rapidly to any queries. Design authorities will work closely with critical suppliers to apply proactive defect prevention methods and process improvements in order to ensure the quality of the required products.

3.3 Manufacturing Controls

3.3.1 Operations

Hardware suppliers will control all manufacturing processes to ensure that characteristics and design criteria specified in technical documents are adhered to. Detailed and specific fabrication documents will be generated and used to control the fabrication and build operations. Records of inspection will be reviewed at various levels to ensure that any corrective actions are applied and lessons learned are adopted.

Hardware manufacturers will adopt the methodologies outlined in AD 3, clause for the Quality Assurance tasks associated with manufacturing control. When undertaking Critical Processes, the supplier shall establish and implement special procedures, for example in accordance with [RD2], clause 8.4.

Manufacturing logs will be maintained detailing the completion of operations by the person responsible and pertinent inspection data required for traceability; they will reflect the approved Manufacturing Plan and detail the relevant procedures and inspections that apply. A manufacturing log will be unique to the hardware being built, for example via the design designation and hardware serial number.

3.3.2 Stores Control

All suppliers will maintain appropriate controls according to the critical or safety status of parts and materials relating to SKA supply.

Articles of limited life will be clearly marked with date, test time or cycle in which its useful life will be expended. Data for such articles will be recorded and may be maintained as part of a Critical Items Data List.

The storage of hazardous materials will be subject to relevant safety control (for instance, high strength magnets will be stored in an area that is suitably labelled and warnings issued so as not to affect persons with pacemakers). In addition, items that are subject to deterioration, corrosion or contamination through exposure to air, moisture or other environmental elements are preserved by methods that ensure maximum protection consistent with life and usage.

3.4 Inspection and Tests

General

Consortia will implement an agreed test programme with appropriate review points; these will demonstrate that contract and specification requirements are met. Maximum assurance will be given to ensure that the quality inherent in the design is maintained, by continuous monitoring by the PA responsible person. Any non-conformance will become the subject of an NCR and appropriately controlled as defined in section 3.5.

3.4.1 Inspection and Test Planning

Manufacture and Test will be defined by Manufacturing and Test plans; these plans will be Consortium approved documents. The plans will ensure the following criteria are addressed: -

- Orderly and timely inspection and testing.
- Co-ordination of inspection and testing at successive levels to ensure satisfactory stage release.
- Economical and effective use of equipment, facilities and personnel.
- Co-ordination of inspection and tests conducted by the designated Customer representative (MIPs, if required).
- Applicable drawings, processes and fabrication acceptance tests, procedures, test specifications, inspection planning etc. are available.

3.4.2 Test Specification, Test Witness and Test Reports

Design Authorities will ensure that test specifications and procedures for all formal tests are produced. All test specifications will be subject to Customer approval before their use and will include references to hazardous operations or situations; any hazard control or safety protocols will also be detailed.

On completion of the manufacturing phase, a test log will commence detailing all relevant test information. This will include, but not limited to: -

- Historical observations, including test set-up comments if necessary.
- Name, procedural number, issue and date of test.
- Deviations from procedures and open tasks
- Signature of person responsible for the entry.
- Pertinent remarks (anomaly observation, NCRs etc.) and results if necessary.

In addition, a Mate / De-mate log will accompany the hardware if deliverable connectors are used; subsequent users will accurately update the log as necessary.

Logbooks will be used freely and detail observations as they happen; it will also accompany the hardware whenever it is placed within the custody of another organisation, who will then update it accordingly. A test logbook will be unique to the hardware being tested, for example via the design designation and hardware serial number.

A Suppliers Quality Assurance function will define appropriate ways in which to ensure adherence to test procedures and that deviations or anomalies are accurately documented and treated as specified above or in accordance with section 3.5; this may include direct test witnessing by the Suppliers QA personnel or Customer representative, should it be deemed necessary at the Test Readiness Review stage.

Where safety of personnel or damage to items or associated test equipment is possible, QA personnel will be given direct authority to stop the test or will give immediate access to anyone who holds such authority.

All relevant tests will be comprehensively documented to ensure the report is sufficiently detailed to prove the specification has been achieved. The report will include, as a minimum: -

- Reference to the applicable test procedure, and descriptions of any deviations from it during actual testing
- Test data records and evaluation
- Test Equipment and software version used - also refer to section **Error! Reference source not found.**.
- Reference to any NCRs raised during the test and a summary of their resolution
- Summary of test results

Test results are accepted against the test specification and receive final approval at the relevant Test Review Board.

3.5 Non-Conformances

3.5.1 General Principles

A non-conformance is defined as an anomalous condition of hardware, software or document in which one or more characteristics do not conform to the requirements of applicable drawings and / or specifications.

Non-conformances are divided into two categories:-

Major
A non-conformance is major if it will result in the non-fulfilment of one or more of the characteristics expressed in the requirements specified by the customer. In particular characteristics relating to functional or operational performance, Interface or interchange ability requirements, form, product safety, reliability, operational life, personnel health, any failure of critical items (in particular when power has been applied), or when the NCR non-conformance results in a critical path slippage. In addition, Accidents and Incidents will be treated as major non-conformance, and flagged as 'Safety Non-Compliances'.

For EEE components, a major non-conformance will apply when the: -

- Lot / batch was rejected during manufacture, screening or testing at the manufacturers facilities, if: -
    - Use-as-is of the rejected lot / batch is proposed or,
    - It is proposed to continue processing, rework or testing although the lot / batch does not comply with the specification requirements

Major non-conformances will be notified to the next customer, and continue to the level of customer that specified the affected requirement. A major non-conformance will be subject to an Internal Review Board (IRB) that will determine the disposition and may recommend that a customer level NRB be convened.

An NRB will include, as a minimum, representatives from the PA and Engineering organisations and will be chaired by Product Assurance. All relevant PA and Engineering experts will be involved in the review, investigation and disposition of the non-conformance.

Minor
Any non-conformance that is not categorised as Major. Note: the following discrepancies at incoming inspection may be classified as minor - random failures of EEE components where no risk of lot related reliability or quality problems exist, the form, fit or function is not affected, and minor inconsistencies in the accompanying documentation.

In case of doubt, non-conformances will be classified as major. Furthermore, several different non-conformances on the same item (even if minor) will be evaluated for an underlying fault (design or otherwise); this may lead to a re-classification of the non-conformance, as major, if deemed necessary by the PA authority or customer.

The customer will be notified as soon as is feasibly possible and in the case of any non-conformances affecting interfaces or that could cause operational failure within one day. Furthermore all major non-conformances will be notified to the customer within five (5) working days and minor non-

conformance NCRs will be regularly reported via monthly progress meetings and / or reports (refer to section 2.2). However, upon request, minor NCRs will be made available to customers to view.

If, on completion and close-out of a non-conformance report, formal specification requirements cannot be met, then the body responsible may prepare and issue a request for Waiver against that requirement to the next higher contractual partner, see section 3.6.

3.5.2 Non-Conformance Control

The processing of non-conformances raised during the programme will be the responsibility of the designated PA Manager and controlled as in accordance with [RD2], section 5.6, and using [RD5] as a guide to the process.

3.5.3 Corrective and Preventive Action

The Consortium Project Manager will be responsible for corrective and preventive actions aimed at finding solutions to malfunctions and to the cause of the non-conformance, to avoid their recurrence, and improve Quality in a permanent manner by implementing these solutions and measuring their effectiveness.

Corrective actions are undertaken to correct the cause of discrepancies and avoid their recurrence when:

- The real cause of the occurrence is identified,
- The occurrence could have been avoided if special organisational or technical precautions had been taken upstream.

In addition to corrective actions, preventive actions are undertaken to eliminate the potential causes of unsatisfactory quality when non-conformances and anomalies are recorded. These are analysed and repetitive causes identified. The need for preventative action is assessed, investigated and undertaken where appropriate and necessary.

3.5.4 Non-Conformance Documentation

All Non-Conformance Reports will be managed, recorded and documented using [RD5] as a guide. NCR's Non-conformances will be serialised and have a systematic approach of analysis and closeout. Furthermore, NCR summary listings will be reported via the monthly progress report (refer to section 2.2).

The numbering of NCRs shall conform to [AD5].

3.6 Waivers

A waiver is the written authorisation to use or release a product that does departs from specified requirements; it is limited to the shipment of a product that has specific non-conforming characteristics for a limited quantity or time. The waiver will be submitted to the customer and escalated to the organisation responsible for specifying the affected requirement. A suitable proforma can be found in [RD5].

The numbering of waivers shall conform to [AD5].

4 CONFIGURATION AND DOCUMENT MANAGEMENT

Configuration Management and Document Control will be performed at all levels of the project. All documents that provide a technical description of the management, design and test of the Telescope & Elements are subject to configuration control, and each document will carry a discrete, unique identification.

A full list of configured documents will be made available in the form of a Configuration Item Data List (CIDL) that will identify the document issue and status; furthermore, the list will provide historical data on the documents, revision dates and change note reference number. The CIDL provided at the CDR will record the design baseline.

For the relevant hardware and software, Design Authorities will maintain a CIDL specifying the baseline design that will be updated as the design and test programme progresses. At delivery, or at the TRB, the design baseline CIDL will be presented as an As Built Configuration List (ABCL), detailing deviations from the CIDL presented at the CDR (e.g. referencing NCRs, Waivers, NRBs etc. against the relevant design aspect).

Any Deliverable design item or hardware / activity used to trace verification heritage of the Telescope design shall be subject to Configuration control. In some instances, this may include Development phases if used to qualify some aspect of the Telescope design if it is not re-verified on later hardware, i.e. Deliverables.

4.1 Change Control

The management of change to Configuration Items is mandatory for all SKA development activities and is documented in.[AD3].

5 SOFTWARE PRODUCT ASSURANCE

Software PA and Configuration Control are subject to a separate Software PA Plan (TBS).

6 PRODUCT LIABILITY AND SAFETY

The SKA Project has a duty of care to all users, through the EU General Product Safety directive (92/95/EEC) and those pertaining at the Sites and other locations where SKA assets are being operated, to ensure that its products are safe and do not cause harm; this not only applies when the products are used in their intended manner, but also under conditions of reasonably foreseeable misuse. Legislative requirements impose obligations on a Company to be legally bound by ("Criminal" or "Legal" Liability) or answerable for ("Civil") the safety of its products. These obligations are collectively known as Product Liability and apply to all hardware products; it does not cover safety in the work place (environment), which is addressed via local Occupational Health, and Safety policies and procedures. Within the European Union (EU), supply is subject to European Union Law, applied directly through Decisions and Regulations, or indirectly by directives, which are applied in the member states through National legislation. Outside the EU, similar conditions apply, which may meet or exceed EU stipulations. Although only applicable in the European Union, RD 14, RD 15, RD 16 and RD 17 can be used when formulating a Product Liability process; each Consortium, dependant on the nature of their product, shall establish an applicable list.

6.1 Scope of Product Liability for Hardware

6.1.1 All Hardware Products

All hardware products shall meet the requirements of all applicable regulations and statutes in order to achieve a minimum level of safety and legislative compliance, irrespective of the final destination, including those intended for internal use, whether new build or re-use of older equipment. The following requirements shall be met:

- Each Consortium shall detail a Product Liability & Safety approach, pertinent to their hardware and activities; it shall define how the Product Liability and Safety activities will be controlled throughout the programme. The size and content of the Product Liability and Safety plan will be appropriate to the activities and may form part of the PA Plan.
- Safety Assessments shall be conducted on all products; the results shall be retained and present in appropriate Safety Assessment Reports (SAR) and, ideally, should be generated at the start of the product(s) development. Products should not be delivered until all identified Hazards have been eliminated, or reduced to acceptable levels by the use of controls or warnings and the final issue of the SAR has been accepted by the SKA Office.
- User manuals will list all hazards and define appropriate safety warnings.
- Documents which detail the design, as-built state and assessment of each equipment/system are generated and stored in a form that permits subsequent recovery and analysis.
- Product Liability and safety aspects are reviewed in Design Reviews.
- Where necessary, operator training in safety aspects is given and records are retained.

6.1.2 Support Equipment Products

The term “Support Equipment” is used for any products that are not destined for final use in the SKA telescopes. Typically, this includes Mechanical and Electrical Support Equipment as well as test and communications equipment. In addition to the general implementation activities provided in 10 and 10.1 above, Support Equipment are subject to the following:

- As a minimum level of safety and legislative compliance, all support equipment, irrespective of destination, are
    - Designed and assessed to meet the “essential requirements” of all applicable New Approach directives through testing, or compliance with EU harmonised standards (“EN Standards”).
    - Supported by a Declaration of Conformity with these New Approach directives, signed only by duly qualified and authorised signatories.
    - “CE” or equivalently marked, prior to despatch/putting into service, to indicate that they are compliant with applicable safety legislation, irrespective of destination.
    - Supported by a ‘User Manual’ containing appropriate safety warnings.
    - Supported by a ‘Technical File’ held in configuration control and retained for a minimum of 10 years from the last date of manufacture
- Controls are in place to ensure that only compliant equipment, suitably ‘CE’ marked, is dispatched from, or put into service within the EC.
- All new externally supplied equipment to be used within a Ground the SKA, has a CE mark or equivalent and supporting Declaration of Conformity.

6.1.3 Deliverable Hardware

The term “Deliverable” means a product whose intended final use is as part of an SKA Telescope. In addition to the general requirements of section 10.1.1, these products must be verified against the [AD4] when operated on the Site. This controls strict liability issues regarding EMC, otherwise controlled by the far less stringent **Error! Reference source not found.**. Compliance with [AD4] is necessary in any event due to radio-observatory functional requirements.

6.2 Safety Engineering

Each Design Authority will be responsible for the safety of their product. Hardware and software will be designed such that it will not cause a hazard to, in order of priority: -

- Human life, including disablement and occupational illness.
- The environment.
- Public and private property.
- Support equipment and facilities.

6.2.1 Consequence Category and Severity

Consortia will appoint Safety representatives to assure the safety of the Element design, manufacture, test and operation. Safety will be designed in to the hardware and conform to the relevant National safety regulatory body. A Safety Assessment will be undertaken to identify hazardous events and categorise them in to the following according to their most severe effects –

1 Catastrophic Hazard / Consequence
Loss of life, life threatening, permanently disabling or occupational illness.
Long-term detrimental environmental effects.

2 Critical Hazard / Consequence
Temporarily disabling, but not life threatening injury, or temporary occupational illness.
Propagation of failure to, or major damage to facilities.
Loss of, or major damage to, public or private property.
Short-term detrimental environmental effects.

3 Marginal Hazard / Consequence
Minor injury or occupational illness.
Minor damage to deliverable or associated hardware.
Minor damage to public or private property.

4 Negligible
Other, less than marginal, events.

6.2.2 Failure Tolerance

The design of the Instrument will incorporate failure tolerance whenever failure effects can lead to catastrophic or critical hazards to which the following conditions apply: -

1. No single failure, hazardous event or operator error will have a catastrophic or critical consequence, and
2. No combination of:

a. two failures,
b. two operator errors,
c. one failure and one operator error

will have catastrophic consequences

Hardware failures will not cause additional failures with hazardous effects, or propagate to cause the hazardous operation of interfacing hardware. In addition, the FMECAs produced as part of the Dependability function (section **Error! Reference source not found.**) will be used to aid and support the hazard analysis in the evaluation of the effects of failures.

6.3 Product Liability and Safety Documentation

The Consortium will maintain safety related data in accordance with the SKA project and relevant National policy to support the telescope design, build and test programme. It will take the form of a Safety documentation file in aid of producing a safety certificate. As a minimum, it will include:

- Safety Assessment and Analysis
- Hazard Analysis (taking in to account the results of the FMECA and FTA)
- Safety Non-Conformances (Accidents and Incidents)

7 SUPPORT EQUIPMENT

This PA Plan will be made applicable to SE to the extent necessary to ensure the hardware meets legislative requirements, design definition and does not propagate failures to the deliverable hardware.

7.1 SE Product Assurance

PA Reporting activity shall cover SE as well as Development, Verification and Deliverable hardware; rights of access will apply as detailed in section 1.4. All SE will be subject to the review process outlined in section 3, although the detail required should be suitable for the purpose of the equipment.

7.2 SE Quality Assurance

SE will be subject to Non-Conformance Management to the extent necessary to understand the 'as-built' condition. NCRs will be considered minor except in the instance where there is a direct impact on Deliverable Hardware interfacing (including cleanliness and functional performance) or schedule impact to deliverables; these will be considered major and include customer involvement (to the level who specified the requirement) in agreeing the disposition via a NRB. Should a customer, interfacing, or operational requirement not be met, the waiver process detailed in section 3.6 will apply.

7.3 SE Dependability

Dependability Analyses shall apply to interfacing aspects of the SE to Deliverable hardware; a FMECA and Fault Tree analysis will be undertaken on the interface detail. The analysis shall ensure that faults do not propagate through the interface and cause damage to the deliverable equipment; this shall include software. Any failure mode identified will also 'fail safe'. Parts that have a long procurement lead-times shall be considered critical items and reported through the Critical Items List; they will managed to ensure that should such a part fail during a Qualification / Deliverable test campaign, sufficient spares exist to perform a repair without significant impact to the test schedule.

7.4 SE Configuration Management

Configuration Management will apply to the extent that the design definition of the SE is understood to perform the various tasks within this section. A CIDL will be presented specifying the design at the time of the relevant review. This will be updated to an 'as-built' definition, containing relevant NCRs and Waivers against the respective design criteria. The purpose of this approach is that the hardware is sufficiently understood that should a failure occur, the cause can be determined and rectified in as short a period as possible. Furthermore, should repeat builds be necessary, then sufficient information exists to ensure the resulting hardware exhibits the same interface and functional characteristics of the original, accepted design.

7.5 SE Product Liability and Safety

All SE will meet the Product Liability requirements detailed in section 6. Safety Engineering, as shown in section 6.2, shall apply and Safety Non-Compliance Control will be performed. On delivery, the Safety Documentation specified in section 6.3 will be presented as part of the EIDP.