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Quality assurance requirements for ESA space systems

Prepared by:
Product Assurance and Safety Department
European Space Research and Technology Centre
Noordwijk, The Netherlands

Approved by:
The Inspector General, ESA

european space agency / agence spatiale européenne
8-10, rue Mario-Nikis, 75738 PARIS CEDEX, France

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ABSTRACT

This standard defines the Quality Assurance requirements which implement the ESA Quality Assurance policy and which are applicable to ESA space systems.

DOCUMENTATION CHANGE RECORD

Issue number and date	Sections affected	Remarks
Issue 1 April 1981	All	New document
Issue 2 February 1991	All	Document completely revised

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APPENDICES

ABBREVIATIONS AND ACRONYMS

ABCL	As-built configuration list
ADP	Acceptance data package
AIT	Assembly, integration and test
CCB	Configuration control board
CIDL	Configuration item data list
COC	Certificate of conformance
CSL	Configuration status list
RB	Delivery review board
ESA	European Space Agency
KIP	Key inspection point
LOE	Log of exceptions
MIF	Manufacturing and inspection flow chart
MIP	Mandatory inspection point
MRB	Material review board
NCR	Nonconformance report
NDI	Nondestructive inspection
QA	Quality assurance
PA	Product assurance
P/N	Part number
PTR	Post-test review
RFW	Request for waive
S/N	Serial number
SRP	Standard repair procedure
TRB	Test review board
TRR	Test-readiness review

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SECTION 1: GENERAL

1.1 SCOPE

This specification sets forth the requirements for Quality Assurance (QA) which shall be applied to ESA space systems.

1.2 APPLICABILITY

The requirements in this specification apply to all types of space systems under ESA contract, including manned and unmanned spacecraft, launchers, experiments, ground equipment, facilities, related services and procedures.

The requirements in this specification apply at the system and all lower levels during all programme phases as relevant, including design, development, qualification, fabrication, test and operations.

The requirements in this specification apply to the extent stated in the contract.

NOTE: Complementary quality assurance requirements for software are defined in ESA PSS-01-21.

1.3 APPLICABLE DOCUMENTS

The documents listed below are applicable to the extent specified herein.

ESA PSS-01-001	Glossary of product assurance and safety terms
ESA PSS-01-10	Product assurance management for ESA space systems
ESA PSS-01-11	Configuration management and control for ESA space systems
ESA PSS-01-12	ESA Contractor product assurance assessment system
ESA PSS-01-201	Contamination and cleanliness control
ESA PSS-01-202	The preservation, storage, handling, transportation of ESA spacecraft hardware

ESA PSS-01-203	Quality assurance of test houses for ESA spacecraft and associated equipment
ESA PSS-01-204	Particulate contamination control in clean rooms by particle fall-out measurement.
ESA PSS-01-21	Software product assurance requirements for ESA space systems
ESA PSS-01-30	Reliability assurance for ESA space systems
ESA PSS-01-40	System safety requirements for ESA space systems
ESA PSS-01-60	Component selection, procurement and control for ESA space systems
ESA PSS-01-70	Material and process selection and quality control for ESA space systems and associated equipment
ESA PSS-01-705	The detection of organic contamination of surfaces by infrared spectroscopy

1.4 DEFINITIONS

The definitions listed in ESA PSS-01-001 are applicable.

SECTION 2: QUALITY ASSURANCE PROGRAMME MANAGEMENT

2.1 QUALITY ASSURANCE PROGRAMME

The Contractor shall establish and implement a QA programme to ensure compliance with requirements. The QA programme shall

a. Provide for an integrated effort between a Contractor's functions necessary to ensure the required quality throughout all phases and areas of contract performance.

b. Ensure that all quality aspects and requirements are identified, properly reflected by the design and implemented into the deliverable items.

c. Ensure that all QA activities are planned and coordinated, supported by procedures and instructions, and objectively documented in quality records and reports.

d. Provide for a comprehensive management approach for the prevention, detection, documentation and disposition of actual and potential nonconformances.

e. Ensure that sub-Contractors' QA programmes are consistent with the overall QA requirements of the contract.

The basic QA programme of the Contractor shall be documented in a QA manual, which shall serve as the basis for the QA assessment of the Contractor by ESA in accordance with PSS-01-12.

2.2 ORGANISATION

The Contractor shall make functional assignments to implement his quality program. Personnel responsible for implementing and performing QA functions shall have well-defined responsibilities, authority, and organisational freedom to develop and implement QA disciplines and controls.

One designated person shall have the responsibility and authority for directing and managing the QA activities for a given project. That person shall be part of the overall PA organisation, as defined in ESA PSS-01-10.

2.3 QUALITY ASSURANCE PROGRAMME PLAN

The Contractor shall prepare, maintain, and implement a QA Programme Plan, which describes how he will ensure compliance with the QA requirements specified in the contract. The plan shall serve as the master planning and control document for the QA programme.

The plan shall be part of the overall Product Assurance Plan, in accordance with ESA PSS-01-10.

The plan shall be approved by the Agency. The submittal, updating and re-submittal of the plan shall be as specified in the contract.

The plan content shall be readily identifiable with the requirements of this specification as made applicable by the contract, and shall include:

a. Description of the Contractor's organisation showing all the organisational elements involved in the performance of QA tasks and their duties, functions and responsibilities related to each QA task. The Plan shall show the lines of communication and interface between the QA Manager and each organisational element performing QA tasks, and indicate his authority to control and monitor their performance.

b. Milestone schedules, which describe the Contractor's plan for the execution and management of each task in the QA programme which can be accomplished on a scheduled basis.

c. Description of how the Contractor will perform all required QA tasks. Reference may be made to the Contractor's basic QA manual, stating the applicability to the specific contract. The QA manual, internal procedures, instructions, directives and methods, when referenced in the Plan, shall be available to the Agency upon request.

d. Subcontractors' QA Programme Plans, and description of how they interface with the prime QA Programme Plan.

2.4 QA MANAGEMENT CONTROL

The Contractor shall periodically prepare and submit to ESA reports on the status of the QA programme.

These reports shall be in accordance with ESA PSS-01-10.

2.5 PERSONNEL TRAINING AND CERTIFICATION

2.5.1 Training programme

The Contractor shall have trained and competent personnel to implement the QA programme. For this purpose, the Contractor shall establish a documented training programme for QA personnel and all other personnel whose performance determine or affect product quality.

The training programme shall provide familiarisation with parts, materials, systems, and production, inspection, test and checkout equipment; and instruction in techniques and methods for processing, fabrication and quality control. Particular emphasis shall be given to the function and mission of the end item, critical items, new parts, fabrication processes or materials, cleanliness and contamination aspects, and safety of operations.

2.5.2 Personnel certification

Operators performing critical processes shall be trained and certified either by internal or external training programmes accepted by ESA.

Inspectors controlling critical processes, or performing nondestructive testing and evaluation, shall be trained and certified according to national or international training programmes and standards accepted by ESA.

It is emphasised that both operators and quality inspectors involved in soldering, crimping and printed-circuit-board repair shall be trained and certified as detailed in the relevant ESA PSS-01-7xx specifications

Evidence of personnel certification and the areas and boundaries of each individual's responsibilities shall be available where duties are being performed.

Personnel shall be recertified periodically according to an established programme. Recertification will also occur as a result of unsatisfactory performance, change in techniques or required skills, and/or extensive interruption of work performance.

2.5.3 Training and certification records

Records of training and certification status of personnel shall be maintained and shall be available upon request.

Data items in the records shall be in accordance with Appendix A.

2.6 QUALITY ASSURANCE PROGRAMME AUDITS

The Contractor shall perform systematic audits on his own performance and on his subcontractors and suppliers, to verify the implementation and effectiveness of the provisions defined in the QA Programme Plan. Audits shall also relate to processes and physical items to assesscompliance with the relevant specifications.

General requirements defined in ESA PSS-01-10 shall apply.

Requirements for external audits in procurement control are defined in Section 5 of this document .

2.7 QUALITY COSTS

The Contractor shall have a system to maintain and use quality costs data as a management element of the quality programme. This system shall identify the quantitative distribution and evolution of both QA costs (prevention plus appraisal) and costs due to failures (internal plus external). The specific implementation shall be determined by the Contractor.

The Contractor shall be able to demonstrate to ESA that he operates a system for the collection, maintenance and use of quality cost data.

SECTION 3: QUALITY ASSURANCE GENERAL REQUIREMENTS

3.1 QUALITY ASSURANCE DOCUMENTATION

3.1.1 Procedures and instructions

All QA activities shall be covered by written procedures. For this purpose the Contractor shall develop and maintain an adequate set of formal procedures to perform his QA tasks.

In addition, detailed instructions, such as inspection and test instructions, shall be available to ensure effective functioning of the QA system and the achievement of the required product quality.

These documents shall be identified, authorised, issued, filed and maintained according to a formally established procedure for their configuration control.

3.1.2 Quality records

The Contractor shall maintain quality records to provide objective evidence of complete and effective performance of QA tasks and to demonstrate achievement of the required quality.

As a minimum, the records required in Appendix A shall be maintained.

Identification and retrieval of records shall be in accordance with Section 3.4. Electronic data storage and retrieval are recommended.

Quality records shall be accessible to ESA upon request.

3.1.2.1 Retention of records

Quality records shall be stored in safe conditions, which prevent alterations, loss or deterioration, and shall be retained for the period specified in the contract, unless release before that time is given by contractual authorisation.

The Contractor shall ensure that quality records are readily accessible and retrievable whenever they are needed.

3.2. DOCUMENTATION CONTROL

The Quality Assurance organisation shall ensure that only the correct issues of documents for the work being performed are available to operating personnel, and that all other issues are promptly removed from the points of issue or use.

3.3 STAMP CONTROL

The Contractor shall establish and maintain a documented stamp control system to ensure correct and legitimate use of all fabrication and inspection stamps.

3.3.1 Use of stamps

Fabrication stamps shall be used to signify performance of operations and processes. Inspection stamps shall be used to indicate inspection performance at source and incoming inspection, in process inspection and tests, final inspection, end point testing, storage and shipment.

Stamps shall be applied to:

- records, to indicate the fabrication or inspection status of associated articles and material;
- tags, cards, or labels attached to individual articles and material or their containers as appropriate;
- directly to articles and materials, when requested by engineering drawings and specifications, and agreed by ESA.

Stamping materials and methods shall be compatible with the articles and their use.

3.3.2 Stamp traceability

Stamps shall be traceable to individuals responsible for their use. Records shall be maintained to identify individuals with specific stamps.

The use of signatures in place of stamps is acceptable provided that similar traceability and responsibility records are maintained and available.

Data items in the records shall be in accordance with Appendix A.

3.3.3 Restrictions in stamp usage

Unissued stamps shall be kept secure to prevent unauthorised use. Stamps issued to personnel being transferred or whose employment has terminated shall be returned and shall not be reissued for a period of at least six months. Worn or damaged stamps shall be destroyed at the time replacements are issued. The identification symbols (e.g. numbers and letters) of lost stamps shall be withdrawn from use.

The use of any stamp by an individual other than the authorised holder shall be prohibited. Stamps on documents shall be confirmed by signature or acronym of the individual responsible for their use.

Periodic checks shall be made to assure that stamps are in possession of the individual to whom they are issued and that they are not worn or damaged.

3.3.4 Stamp design

Inspection stamps shall be designed to identify the Contractor and the authorised individual who affixes the stamp. Fabrication and inspection stamps shall be distinctly different. Contractor stamps shall not exhibit the designation ESA.

3.4 TRACEABILITY

3.4.1 General

The Contractor shall implement a traceability system, which shall be maintained throughout all phases of contract performance, and during the planned operational life of deliverable items, or as otherwise stated in the contract.

The traceability system shall provide for the ability to:

a. Establish bidirectional and unequivocal relationship between parts / materials / products and associated documentation / records.

b. Trace backwards the location of materials, parts, subassemblies.

c. Trace forwards the location of materials from raw stock. Forward traceability may be required also for some critical items, as defined in the contract.

d. Trace data, personnel and equipment related to procurement, fabrication, inspection, test, assembly, integration and operations activities.

The level of traceability to be applied to an item shall be specified on engineering specifications and drawings.

Traceability shall be based on a well-established configuration management system, and implemented by means of an identification, identification marking and data retrieval system.

3.4.2 Identification

3.4.2.1 Identification methods

Each part, material or product shall be identified by a unique and permanent part or type number. These numbers shall be related to the engineering design, and shall be used by all other disciplines.

In addition, parts, materials and products shall be identified as individual entities/groups by means of one or more of the following methods:

a. Date codes indicating date of manufacture, to identify items made by a continuous process or which are subject to degradation with age.

b. Lot or batch numbers, to identify items produced in homogeneous groups and uniform conditions. This identification applies when the items are not required to be individually distinguishable.

c. Serial numbers, to identify individual items for which unique data are to be maintained.

3.4.2.2 Identification controls

Controls shall be established to ensure that:

a. Identification numbers are assigned in a systematic and consecutive manner.

b. Identification numbers of scrapped or destroyed items are not used again.

c. Identification numbers, once allocated, are not changed (except under exceptional circumstances, which shall be approved by ESA).

3.4.3 Identification marking

Identification numbers shall be marked on documentation and, where possible, on respective items.

The method of marking on items shall be defined on engineering drawings and specifications. The method of marking shall be compatible with the nature of the item and its use.

3.4.4 Data retrieval system

Documents and records shall be identified and linked to the respective items by means of their unique identification numbers.

The data retrieval system, either paper based or informatic, shall allow forward and backward traceability starting from any point of the interconnected network existing between records, documents and marking on parts. An informatic system for data retrieval is recommended.

For this purpose, the Contractor shall ensure that identification numbers/methods and retrieval methodology used in different activities, such as design, configuration control, purchase, manufacturing and quality control, are consistent and interrelated.

3.5 METROLOGY AND CALIBRATION

3.5.1 General

The Contractor shall establish and maintain a documented metrology and calibration system for inspection, measuring and test equipment.

Inspection, measuring and test equipment includes all types of instruments, gauges, meters and other devices used to demonstrate the conformance of product to the specified requirements, or used to verify the accuracy of other measurement and test equipment. Test aids, such as test leads, break-out boxes, mains leads and similar items are not subject to the entire set of requirements defined in this section, but shall be validated at least annually.

Equipment shall be used in a manner which ensures that measurement accuracy and precision are known and are consistent with the required measurement capability.

3.5.2 Calibration system

3.5.2.1 General

All inspection, measuring and test equipment shall be calibrated when initially received prior to release for use and at periodic intervals thereafter.

The calibration system shall include calibration facility, calibration procedures, control of calibration standards, calibration labels and records

3.5.2.2 Calibration facility

Inspection, measuring and test equipment shall be calibrated by one of the following:

a. Organisations officially recognised by the national metrological authority.

b. A contractor's own facility, or an external service, provided that all the calibration requirements defined herein are fulfilled.

3.5.2.3 Calibration procedures

Calibration procedures shall include details of equipment type, identification, location, check method, frequency of periodic checks, acceptance criteria and the action to be taken when results are unsatisfactory.

3.5.2.4 Calibration standards

All inspection, measuring and test equipment shall be calibrated against a standard that has greater accuracy (see also Section 3.5.3).

Calibration standards shall have their accuracy verified directly by, or through a precise comparison with, certified standards having a valid and traceable relationship to national standards, or with other basic standards authorised for this purpose by ESA.

3.5.2.5 Calibration intervals

Each piece of inspection, measuring and test equipment shall be calibrated at periodic intervals, established by the Contractor on the basis of the purpose, use and objective evidence of the stability and continued accuracy of the equipment, as derived from historical data. In any case, the maximum period of calibration validity shall be one year.

When equipment is used while out of its calibration interval, any items measured using that equipment since its last acceptable calibration shall be segregated as nonconforming items. The equipment shall be immediately submitted to re-calibration; if it is found within its accuracy requirements without any adjustment, modification or repair, the items can be accepted, otherwise the rules defined in Section 3.5.7 shall apply.

3.5.2.6 Calibration labels

The calibration status shall be clearly identified on each piece of equipment by a calibration label. Such a label shall include, as a minimum:

a. Instrument identifier (e.g., inventory number), which provides for the traceability to the relevant calibration records.

b. Due date of the next calibration.

c. Validation by an authorised control stamp.

Instruments or equipments not suitable for such marking shall at least provide means for traceability to the relevant calibration records.

3.5.2.7 Calibration records

The Contractor shall maintain calibration records for all inspection, measuring and test equipment, to demonstrate the continued capability of each piece of equipment to perform measurements within the designated limits and required accuracy or that appropriate actions have been taken in case of failure.

Data items in the records shall be in accordance with Appendix A.

3.5.3 Measurement accuracy and errors

Unless otherwise specified in the contract or in technical specifications, random and systematic errors of inspection, measuring and test equipment shall not exceed:

a. 10% of the tightest tolerance of any items to be checked by that equipment, when performing measurements on parts, materials and products.

b. 25% of the tolerance of the parameter being measured, when performing calibration.

All measurements shall take into account the total error in the measurement process attributable to the cumulative error from the calibration chain, measuring equipment and, as appropriate, those contributed by personnel, procedures and the environment. The basis for the calculation of the cumulative error shall be recorded.

Corrective action shall be taken when the total error is such as to compromise significantly the ability to make measurements within the required accuracy and precision.

3.5.4. Environmental controls

Inspection, measuring and test equipment shall be calibrated and used in an environment controlled to the extent necessary to ensure valid measurements. Due consideration shall be given to temperature, rate of change of temperature, humidity, lighting, vibration, dust control, cleanliness and other factors affecting the validity of measurement. Compensating corrections shall be applied to measurement data as necessary. When such corrections are made, records shall contain both the original and the corrected data.

3.5.5 Sealing for integrity

Access to adjustable devices on inspection, measuring and test equipment which are fixed at the time of calibration shall be sealed or otherwise safeguarded to prevent tampering by unauthorised personnel.

Seals shall be so designed that tampering will destroy them

3.5.6 Storage and handling

Provisions shall be made for handling, transporting and storing of all inspection, measuring and test equipment which prevent abuse, misuse, damage or change in dimensional or functional characteristics.

3.5.7 Invalidation of calibration

The Contractor shall make provisions for immediate removal or conspicuous identification to prevent use of any inspection, measuring and test equipment which:

a. Has failed in operating.

b Has been found out of its designated limits at periodic checks.

c. Shows evidence of physical damage which might affect equipment accuracy.

d. Is suspected of not performing properly.

The Contractor shall investigate all actual and suspected equipment failures, and the causes of these failures shall be determined before any adjustment or repair is made.

Any items which have been measured by means of equipment found to be out of calibration since the last known calibration shall be segregated as nonconforming items.

The normal recovery action shall be to assess the validity of the results of previous inspections and tests performed with that equipment, by repeating the measurements using calibrated instruments. Where such an action is not possible, or the acceptability of the product is affected or in doubt, the items concerned shall be subject to the nonconformance system (see Section 3.6).

The details of any invalidation of calibration requiring corrective action shall be recorded on the calibration records.

Where limited use of the equipment, or part of it, is acceptable, the equipment shall be clearly identified with its restriction of use.

3.6 NONCONFORMANCE CONTROL SYSTEM

The Contractor shall establish and maintain a documented system for the control of all nonconformances detected at any stage during all project phases, from the time the design is frozen. The system shall provide a disciplined approach to the identification and segregation of nonconforming items, the recording, reporting, review, disposition and analysis of nonconformances, the definition and implementation of corrective actions.

Special attention shall be paid to the prevention of nonconformance recurrence.

The Contractor shall provide a precise definition of the authority and responsibilities assigned to his subcontractors for nonconformance processing.

The nonconformance control system shall be in accordance with Appendix B.

3.7 ALERT SYSTEM

3.7.1 General

An alert is a standardised report used to provide the participants of the system with identification and notification of actual or potential problems on parts, components, materials, manufacturing processes, test equipment or safety conditions.

The Contractor shall establish an alert system for ESA projects, which shall provide for:

a. Issuing of alerts for problems detected by the Contractor or by his Subcontractors.

b. Processing of incoming alerts.

When originating an alert, the Contractor shall ensure the comprehensive description of the problem, rapid flow ofinformation, adequate investigation and item disposition.

For incoming alerts the Contractor shall provide for the assessment of relevance, and the definition, implementation and follow-up of needed actions.

The Contractor shall be responsible for ensuring that the alert system implementation does not infringe any national laws or regulations. In the case conflict exist, the Contractor shall define specific implementation methods to remove these conflicts.

3.7.2 Alert Initiation

An Alert shall be issued according to the following criteria:
- when actual or potential failures or problems may have multiple applications, and not in the case of a random failure of a part, component or material;
- when failures are caused by the application of parts, components or materials inside the known design limitations.

The Contractor shall make every effort to establish the exact circumstances and appropriate data related to the nonconformance or failure generating the alert.

The alert report shall contain only observed facts; opinions and speculations shall be excluded.

The alert report shall contain, as a minimum, the following information:

a. Unique identification number.

b. Item identification, including manufacturer, part number, serial or lot number and any other information permitting the usage of the item in ESA projects to be identified.

c. Description of observed nonconformance or failure, evaluation analysis methods and results.

d. Objective cause, if known.

e. Actions taken.

f. Approval of P.A. representative or alert coordinator.

3.7.3 Alert investigation

Each alert originated by the Contractor shall be formally investigated directly by the Contractor itself. Alerts originated by Subcontractors may be investigated by the Subcontractors themselves, but under Contractor's supervision. In the case of alerts on critical items or having potential impact on safety or system integrity, ESA reserves the right to establish and chair the investigation team.

The Contractor shall issue an investigation report, which shall contain, as a minimum, information on the findings, item isposition and corrective action to prevent recurrence.

3.7.4 Item disposition

After completion of the investigation, the disposition of defective item shall be defined in accordance with the procedure for nonconformances (see Section 3.6).

3.7.5 Alert distribution

The originating Contractor shall transmit alerts to ESA, which reserves the right to inform other Contractors to ensure that immediate attention is focused on all projects that may be affected.

3.7.6 Processing of incoming alerts

The Contractor shall screen incoming alerts by means of the configuration management system and/or the traceability system, as appropriate, to assess the relevance of the problem to any of the ESA contracts he is executing, for which an alert system is required.

If it is found, or cannot be excluded, that an item may be affected, corrective actions shall be taken to prevent or eliminate the problem. This shall take place through the specific procedure for each contract, and be contractually reflected through the relevant contract change procedure.

When a Contractor receives an alert from ESA, he shall respond within 15 working days, stating either its nonapplicability to the contract or the appropriate actions (to be) taken.

3.7.7 Records of alerts

The Contractor shall establish and maintain records of issued and incoming alerts.

Data items in the records shall be in accordance with Appendix A.

3.8 HANDLING, STORAGE, PRESERVATION

3.8.1 Handling

The Contractor shall provide for protection of items during handling, and for handling devices, procedures and instructions to prevent handling damage during all phases of manufacturing, assembly, integration, testing, storage, transportation and operation.

Handling shall be in accordance with ESA PSS-01-202.

3.8.2 Storage

The Contractor shall have secure storage areas available for incoming materials, intermediate items needing temporary storage and end items before shipping.

The items specific to the ESA contract shall have their own assigned, separate areas within the overall storage area.

Limited-life materials, suspended limited-life material, nonconforming items awaiting MRB disposition, and all other items which require to be stored separately for health or safety reasons shall be placed in segregated areas within the storage area. Each segregated area within the stores shall be clearly identified and labelled.

Controls shall be maintained over the acceptance into and withdrawal from the storage area.

The detail requirements in ESA PSS-01-202 shall also apply.

3.8.2.1 Storage records

Records shall be maintained to ensure that all stored items are within the useable life limits and adequately controlled and tested, and to provide traceability within the storage area.

Data items in the records shall be in accordance with Appendix A.

3.8.3 Preservation

The Contractor shall ensure that items subject to deterioration, corrosion or contamination through exposure to air, moisture or other environmental elements are preserved by methods which ensure maximum protection consistent with life and usage.

Preservation shall be in accordance with ESA PSS-01-202.

3.9 STATISTICAL QUALITY CONTROL AND ANALYSIS

3.9.1 General

Statistical quality control and analysis methods, such as sample inspection plans, determination of quality levels, statistical process control and process-capability studies, may be used whenever such methods are suitable to maintain or improve the required control of quality.

When the Contractor employs statistical quality control and analysis methods he shall ensure that all the conditions for proper use are enforced (e.g. sample significance, recording and elaboration of data , formulation of clear decision rules).

Statistical quality control applications, when used by the Contractor for acceptance of materials, parts, processes and products, shall be approved by ESA.

3.9.2 Sampling Plans

Sampling plans may be used only when tests are destructive, or when reduction in inspection or testing can be achieved without jeopardising the fulfilment of the contract requirements, because of the inherent characteristics of the product or the noncritical application of the product.

The Contractor shall use existing international sample inspection plans to the maximum degree practicable. Reviews of the sampling procedures by the Contractor's QA organisation shall be focused on such factors as the sample-selection methods, and criteria for inspection severity, acceptance/rejection and screening of rejected lots.

The Contractor shall maintain complete records together with clear identification of the characteristics to which sampling is applied.

SECTION 4: QA REQUIREMENTS FOR DESIGN AND DEVELOPMENT

4.1 DESIGN

4.1.1 QA requirements for engineering drawings and specifications

The Contractor shall establish and maintain design standards and procedures for the preparation and maintenance of engineering drawings and specifications.

These standards and procedures shall include provisions for the following aspects:

a. Engineering requirements shall be expressed in an unambiguous and quantified manner.
b. Identification of critical items on technical documents as required in ESA PSS-01-10.

c. Technical documents shall specify:
- inspections and tests to be performed, including inspection and test procedures, conditions and acceptance/rejection criteria;
- process specifications;
- identification methods;
- marking methods and position;
- required traceability level;
- required cleanliness levels.

d. Physical and functional tolerances shall be always defined, and controlled to avoid the use of irrational limits and to ensure interchangeability.

4.1.2 QA support to design reviews

Quality Assurance personnel shall participate in the internal design reviews, to ensure that:

a. Requirements in Section.4.2.1 above are fulfilled.

b. Design is producible, repeatable, inspectable and testable.

c. Required inspections and tests are appropriate and feasible.

QA participation to design reviews shall be documented.

4.1.3 Change control verification

In conjunction with ESA PSS-01-11 and its requirement implementation, engineering changes shall be reviewed by QA to determine the quality impact.

4.2 DEVELOPMENT

Product development shall proceed according to the Design and Development Plan, and shall include the development of models, as required in the contract, as well the development and validation of processes, inspection and fabrication methods, as appropriate.

QA shall participate in development activities to ensure that quality criteria for product, material and process controls are developed in concert with product requirements. Particular emphasis shall be given to the development of new inspection techniques, such as NDI techniques, and the control of new manufacturing processes.

SECTION 5: QA REQUIREMENTS FOR PROCUREMENT

5.1 GENERAL

The Contractor shall control the procurement activity to ensure that all items and services procured conform to contract requirements.

The control of procurement activity includes selection of procurement sources, control of purchase documents, surveillance of Suppliers and control of incoming items.

5.2 SELECTION OF PROCUREMENT SOURCES

The Contractor Quality Assurance organisation shall participate in and approve the selection of procurement sources

5.2.1 Selection criteria

The Contractor's selection of subcontractors and suppliers shall be based on one of the following criteria:

a. The subcontractor or supplier has been assessed by ESA in accordance with PSS-01-12, and has a current approval to furnish items or services of the type and quality level being procured.

b. The subcontractor or supplier is furnishing, or has furnished within the past two years, items or services of the type and quality level being procured under other ESA contracts.

c. The subcontractor or supplier has demonstrated a continuous capability to furnish items or services of the type and quality evel being procured . This capability shall be supported by objective documentation, such as supplier-performance records in accordance with Section 5.5.4. This criterion shall not apply if the subcontractor or supplier has not furnished items or services of the type being procured for more than two years.

d. Subcontractor's or supplier's capability of satisfying contract requirements is demonstrated by a pre-award audit. The results of pre-award audits shall be documented and maintained on file.

The selection of procurement sources for components shall be in accordance with ESA PSS-01-60.

5.2.2 Record and list of procurement sources

The Contractor shall establish and maintain records of all procurement sources involved in contract performance. Data items in the records shall be in accordance with Appendix A.

The Contractor shall submit to ESA, upon request, the list of procurement sources, including all the information in the records above, for information.

5.3 PROCUREMENT DOCUMENTS

5.3.1 Content

The Contractor shall ensure that supplies are precisely identified and that all applicable requirements, including the end application of the item, are properly defined in the procurement documents.

The procurement documents shall contain, by statement or reference:

a. Comprehensive technical descriptions of the items and services to be procured.

b. Details of the applicable QA requirements, such as requirements for preservation, packaging, marking, shipping, accompanying documentation and provisions for limited life items.

c. Details of QA activities to be performed by the supplier, such as inspection and test characteristics, records and reports.

d. Details of the Contractor's QA activities at source.

e. Special acceptance conditions.

5.3.2 Review

The Contractor's Quality Assurance organisation shall review procurement documents prior to release, to verify that:

- procurement sources have been selected in accordance with Section 5.2;

- content is in accordance with Section 5.3.1.

5.4 SURVEILLANCE OF PROCUREMENT SOURCES

The Contractor shall exercise a surveillance over all the activities carried out by its subcontractors or suppliers during contract performance.

The surveillance programme shall include periodic audits, as well direct supervision by the Contractor's resident personnel at suppliers' facilities and source inspection.

The extent of the surveillance shall be defined according to the degree of responsibility placed on the procurement source.

The Contractor shall ensure that each of his subcontractors implement adequate surveillance on their lower-level subcontractors and suppliers.

5.4.1 Periodic audits of procurement source

Subcontractors and suppliers shall be reassessed periodically. Periodic audit shall be performed at least every two years, unless otherwise stated in the contract.

5.4.1.1 Audit plan

The Contractor shall establish and maintain an audit plan for the procurement sources involved in the ESA project, designating the subcontractors and suppliers to be audited, the current status and the schedule for auditing.

In addition to the planned audits, extra audits shall be performed when necessary to overcome failure, consistent poor quality, or other problems.

ESA reserves the right to be represented in the planned audits. For this purpose, the audit schedule shall be supplied to ESA and updated regularly. No audit shall be performed without giving ESA at least 5 working days' notice, or as otherwise stated in the contract.

ESA reserves also the right to audit any subcontractor or supplier at any time, giving notification to the Contractor and any intervening co-contractor.

5.4.1.2 Audit checklists

Audits shall be performed according to predefined checklists. These checklists shall be subject to ESA acceptance before they are used.

5.4.1.3 Audit reports

The Contractor shall issue a report for each audit performed. The report shall include:

a. Overall conclusions.

b. Identification of areas of non-compliance or weakness.

c. Actions aimed at correcting the points identified above. The actions shall have defined completion dates and shall be clearly accepted by signature by the audited organisation.

d. The completed audit checklist.

Each audit report shall be issued within 5 working days of the audit visit and one copy shall be sent to ESA at that time.

5.4.1.4 Audit follow-up

Corrective actions identified by the audit shall be followed-up to the elimination of all discrepancies found.

The record of procurement sources (see Section 5.2.2) shall be updated in accordance with the audit results.

5.4.2 Quality assurance personnel at source and source inspection

The Contractor shall consider the assignment of resident Quality Assurance personnel at source or source inspection when one or more of the following conditions occur:

a. Testing or critical inspections cannot be accomplished by the Contractor (e. g. environments or test equipment not available at Contractor's facility).

b. Verification tests are destructive in nature and the quality cannot be verified solely by inspection or test at the Contractor's facility.

c. Supplies are designated for direct shipment from source to an ESA site or the using site.

d. Manufacturing and AIT of complex equipment or sub-systems (e.g. payloads).

e. Past performance or quality history of the subcontractor or supplier is marginal

These criteria shall be considered together with the criticality and complexity of the supplies and the Contractor's experience with the subcontractor or supplier.

The trade-off between the assignment of resident personnel or source inspection should be based on cost effectiveness considerations.

ESA shall have the right to assign its own resident QA personnel at the Contractor's, subcontractor's and supplier's facilities, on the basis of the criteria listed above.

Source inspection shall include MIP's/KIP's activities (see Section 6.7.2).

5.5 RECEIVING INSPECTION

5.5.1 General

The Contractor shall inspect all incoming supplies and the associated documentation prior to use or processing, to verify their conformance to the procurement documents.

Inspections shall be performed in accordance with established procedures and instructions, such as inspection cards, to ensure that quality level is properly determined. Sampling plans in receiving inspection shall be in accordance with the requirements defined in Section 3.9.2.

Receiving inspection of components shall be in accordance with ESA PSS-01-60. Lot/batch acceptance of materials shall be in accordance with ESA PSS-01-70.

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

5.5.2 Receiving Inspection Activities

Receiving inspection activities shall include:

a. Verification of correct identification and, where appropriate, configuration identification.

b. Verification of the evidence of inspection and tests performed by the Supplier and associated documentation.

c. Verification of the performance of Contractor's source inspection, when required.

d. Performance of inspection and tests on selected characteristics of incoming supplies and/or test specimens submitted with the supplies.

e. Identification of the shelf life of limited-life items.

f. Identification of the inspection status and physical separation of the supplies in the receiving inspection area according to the following categories:
- Items for which the receiving inspection has not be completed;
- Conforming Items;
- Nonconforming Items.

g. Prevention of unauthorised use of uninspected items.

h. Identification of the items to be released for production with conformance status and traceability data to be recorded in manufacturing documents.

i. Maintenance of receiving inspection records (see Section 5.5.4).

5.5.3 Items furnished by ESA

Receiving inspection of items supplied by ESA shall consist, as a minimum, in the verification of identity and integrity after transportation.

Additional inspections and tests shall be as specified in the contract.

5.5.4 Receiving inspection records

Incoming inspection records shall be maintained to ensure traceability and the availability of historical data to monitor supplier performance and quality trends.

Data items in the records shall be in accordance with Appendix A.

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SECTION 6: QA REQUIREMENTS FOR MANUFACTURING

6.1 GENERAL

The Contractor shall ensure that the deliverables are built to the approved design definition and manufacturing baseline, in a planned, controlled and reproducible manner.

6.2 MANUFACTURING DOCUMENTS AND RECORDS

The Contractor, after a complete review of all requirements defined by the design and engineering specifications, shall plan fabrication operations in coordination with inspections and tests.

The Contractor shall describe the manufacturing and inspection sequence and recording of manufacturing and inspection data as defined below.

Fabrication documents shall be issued and maintained in accordance with established and formal procedures.

6.2.1 Manufacturing and Inspection Flow Chart (MIFC)

The planning of manufacturing/assembly operations and inspections shall be reflected in a Manufacturing and Inspection Flow Chart (MIFC) for the product, which shall clearly depict the sequence of manufacturing operations and associated inspections and tests. It shall include the identification of MIP's and KIP's, together with the reference to the procedures to perform the various activities and the required cleanliness levels of facilities.

6.2.2 **Shop Travellers** (Also known as 'Manufacturing Inspection Sheets')

Shop travellers shall direct the actual performance of manufacturing operations and inspections, to ensure that manufacturing proceeds in an orderly manner and according to the planned sequence.

The Quality Assurance function shall review and approve such documents, and any further modifications to them, to ensure that they include or refer to:

a. Identification of the item to be fabricated or equipment to be used.

b. Configuration data, including parts lists, drawings, changes and specifications.

c. Identification of the production and inspection equipment (tools, jigs, fixtures ...) to be used for the fabrication of the item.

d. Detailed definition, by description or reference, of fabrication, inspections and test operations to be performed, and special conditions to be maintained during fabrication.

e. Provisions for KIP's and MIP's (see Section 6.7.2) and inspections and tests to be witnessed by customer representative.

f. Accept/reject criteria (with tolerances) and workmanship standards.

g. Details of sampling inspection procedures to be used, if any.

h. Detailed procedures for the activities to be performed in the operation sequence covered by the traveller.

6.2.3 Support documents

The Contractor shall also provide for detail support documents and instructions, such as operation drawings and operation instruction sheets, to enable correct performance of operations.

These support documents shall be referenced on the shop travellers mentioned above.

6.2.4 Manufacturing records

Manufacturing records shall provide fabrication and inspection data required for traceability.

Data items in the records shall be in accordance with Appendix A.

Provisions for recording of these data may be embedded in the shop travellers.

6.3 MATERIALS AND PARTS CONTROL

The Contractor shall ensure that only conforming materials and parts are released and used, and that those not required for the operation involved are removed from work areas.

Items having limited-life or definite characteristics of quality degradation or drift with age and/or use shall be marked to indicate the dates, test times or cycles at which life was initiated and at which the useful life will expire.

Items to be processed or manufactured in a controlled environment shall be inspected and tested in a similar environment to prevent quality degradation.

6.4 PRODUCTION EQUIPMENT CONTROL

6.4.1 Tooling

The Contractor shall make provisions for accountability, identification and maintenance of manufacturing tooling.

Manufacturing tooling shall be checked for its dimensional accuracy, by reference to the product drawings, and correct function, and approved by Quality Assurance organisation prior to use. The approval shall be stamped on the equipment and recorded.

Tools shall be checked for accuracy during the production life at adequate intervals, and shall be submitted to reapproval following modification. Tools shall be properly stored to prevent misuse, damage and deterioration.

Records shall be kept of all manufacturing equipment. Data items in the records shall be in accordance with Appendix A.

6.4.2 Equipment for computer-aided manufacturing

The Contractor shall ensure that computer-aided techniques and equipment for processing and machining are validated prior to use and controlled during their use in manufacturing.

In particular, provisions shall be made for testing, approval and configuration control of the software involved, and prevention of tampering.

6.5 CLEANLINESS AND CONTAMINATION CONTROL

The Contractor shall establish controls for molecular and particulate cleanliness of spacecraft hardware and facilities, and the limitation of sources of contamination, as defined in ESA PSS-01-201.

6.5.1 Cleanliness levels

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

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

6.5.2 Cleaning materials and methods

The Contractor shall develop detailed methods for attaining the cleanliness levels required for the hardware, as defined in ESA PSS-01-201.

6.5.3 Contamination control

Contamination shall be prevented to the maximum extent 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.

Specific protection measures, such as protective dust covers, shall be implemented to protect contamination-sensitive items when they are integrated in a higher level of assembly.

6.5.4 Cleanliness of facilities

Fabrication and testing of contamination-sensitive items shall be conducted in facilities which provide cleanliness levels compatible with the required product cleanliness.

In cases of contamination-sensitive items where cleaning is not possible (e.g. certain coated optical surfaces), the specification of the cleanliness of facilities and the corresponding measurement shall be done in terms of particle deposition on surfaces in accordance with ESA PSS-01-204. In cases of verification of molecular cleanliness levels, the infrared method according ESA PSS-01-705 is mandatory. In the other cases, cleanliness levels may be determined and classified in accordance with ESA PSS-01-201.

6.6 CONTROL OF MANUFACTURING PROCESSES

The Contractor's QA organisation shall monitor all manufacturing processes and shall enforce all applicable process requirements.

All manufacturing processes shall be covered by documented process specifications/standards according to ESA PSS-01-70. Process specifications shall include QA provisions, methods for inspection and test, number of samples, accept/reject criteria.

6.6.1 Critical processes

The Contractor shall establish and implement special procedures and controls for critical processes. The QA organisation shall ensure that:

a. Critical processes are validated for the intended application in accordance with ESA PSS-01-70.

b. Personnel who perform critical processes or evaluate the process performance are trained and certified in accordance with Section 2.5.2 and proficient.

c. Materials, equipment, computer systems and software and and procedures involved in the performance of the critical process are validated and monitored.

d. Coordination is maintained with the cognizant engineering function to ensure proper selection of the nondestructive and/or destructive methods for the evaluation of process performance.

6.6.2 Statistical process control

When applicable, statistical methods for process control are recommended for early detection of significant variations in manufacturing processes, in order to determine, analyse and eliminate the causes of undesirable variations.

Statistical charts for process control shall be maintained at a location that will provide maximum opportunity for corrective and preventive actions.

6.7 MANUFACTURING QUALITY CONTROL

The Contractor's QA function shall establish and implement a comprehensive programme of surveillance, inspection and test of the manufacturing process, to ensure that technical and quality requirements are met.

The Contractor's Q.A. personnel shall review fabrication documents to ensure that satisfactory inspection and test provisions have been included.

6.7.1 Inspection and test planning

Inspection and tests shall be planned at the points of the manufacturing flow where maximum assurance for correct processing and prevention of unrecoverable or costly nonconformances can be obtained.

As a minimum, inspections and tests shall be performed when one or more of the following conditions exist:

a. When maximum visibility of quality is given.

b. When critical processes are performed.

c. Where the next step of the manufacturing sequence:
   - is irreversible, or
   - makes the item difficult and costly to disassemble for inspection, or
   - renders the location inaccessible for inspection.

d. When the item, once installed in the next higher assembly, could, by its failure, damage the higher assembly.

e. When previous failure history of the item indicates a need for testing.

f. When a potential adverse impact on the properties and integrity of the end product could result, owing to the criticality or complexity of the manufacturing step.

Consideration for inspection and/or test shall also be given when:

g. A significant time has elapsed since the last inspection/test and age/life characteristics of the item indicate the possibility of unacceptable degradation.

h. Implications of received alerts demand an appropriate inspection and or retest.

6.7.2 Key and mandatory inspection points (KIP, MIP)

Among the inspections and tests as part of the production flow, some selected inspections shall be performed with participation of representatives from ESA or relevant contractual customer.

A MIP shall require invitation at least 5 working days, unless otherwise stated in the contract, before the event and participation of ESA or the relevant contractual customer, or their written agreement to proceed without their participation.

A KIP shall require the same invitation, but the notified activity may be performed as scheduled if there is no reaction from ESA or the relevant contractual customer.

6.7.2.1 MIP/KIP selection criteria

The Contractor and his subcontractors shall designate as MIP/KIP the inspections for which one or more of the following apply:

a. The conditions (a) through (f) in Section.6.7.1 above.

b. The conditions (a) through (c) in Section. 5.4.2.

c. Final inspections.

6.7.2.2 MIP/KIP list

The Contractor shall propose a list of MIP's/KIP's to ESA, together with the MIFC. MIP's/KIP's shall be indicated as such on the MIFC.

Following the review of the Contractor's MIFC, ESA will advise the Contractor concerning the selected MIP's/KIP's. The Contractor shall update MIP/KIP list and MIFC accordingly.

The same provisions shall apply to subcontractors with regard to their higher-level Contractor.

6.7.2.3 MIP/KIP records

Records shall be established and maintained for formal IP/KIP tracking and close-out.

Data items in the records shall be in accordance with Appendix A.

6.7.3 Inspection and test equipment

Wherever possible inspections and tests shall be performed using equipment which is employed only for that purpose. Where it is judged necessary to use manufacturing equipment, such as production jigs, fixtures, master tools, templates, patterns and similar devices, it shall be approved by ESA or relevant customer, and subject to the metrology and calibration requirements of Section 3.5.

It shall be possible to verify the correct operation of all items of inspection and test equipment independent of having the test item applied to them.

6.7.4 Inspection and test conditions

During inspection and test operations environment shall be controlled for items which have been manufactured in controlled environments, or when the environmental parameters are specified constraints for the item performance characteristics.

6.7.5 Reinspection and retest

Reinspection and retest shall be conducted when adjustments, modifications, repairs, replacements or reworking are performed after completion of previous inspections and/or tests.

Reinspection and retest may be required at any stage of operations or tests according to a nonconformance or alert disposition.

6.7.6 Nondestructive inspection (NDI)

NDI methods such as radiography, ultrasonic testing, dye penetrant inspection, magnetic particles and other applicable methods shall comply with the following requirements:

a. The methods shall be truly nondestructive and nondegrading for the items under inspection.

b. Personnel shall be qualified and certified in accordance with Section 2.5.2.

c. Materials, equipment, computer systems and software, and and procedures involved in the performance of NDI shall be validated and monitored.

d. Quantitative accept/reject criteria shall be established for each NDE application.

e. NDE standards shall be used for calibration of the equipment and establishment of quantitative accept/reject criteria. Existing reference standards may be used when possible, otherwise special standards shall be prepared. NDE standards shall have the maximum representativity of the actual item inspected, and take into account the entire range of potential defects which can be present on that item as a result of the manufacturing sequence.

6.7.7 Inspection and test status

The Contractor shall make provisions for a positive identification of the inspection and test status of any items at any stage of the manufacturing cycle, starting from the incoming inspection up to shipping of the end item.

Identification shall be accomplished by using authorised stamps (see Section 3.3), tags, markings, labels, physical location or other suitable means, which indicate the conformance or nonconformance of the product with regard to inspection and tests performed.

6.7.8 Inspection and test records

The Contractor shall ensure that records of all inspections and tests performed are generated and maintained. Data items in the records shall be in accordance with Appendix A.

6.8 WORKMANSHIP STANDARDS

The Contractor shall employ workmanship standards throughout all phases of hardware manufacture to ensure acceptable and consistent workmanship quality level.

Documentary workmanship specifications shall identify definite acceptance/rejection criteria.

Physical samples or visual aids used to verify the acceptability of workmanship levels shall be reviewed and agreed by ESA. ESA visual aids shall be used when available (e.g. examples of soldered joints in ESA PSS-01-708).

SECTION 7: QA REQUIREMENTS FOR ASSEMBLY, INTEGRATION AND TEST

7.1 GENERAL

The Contractor shall establish and implement a comprehensive programme for QA surveillance throughout all phases of assembly, integration, and functional, physical and environmental testing for formal qualification or flight- acceptance.

The surveillance programme shall define the areas of surveillance, AIT documentation, handling, involvement in test preparation, inspection points, test witnessing, reporting and evaluation of data.

7.2 PLANNING

The Contractor shall establish and maintain an AIT QA plan, which shall provide for:

a. Organisation and responsibilities for the AIT QA programme.

b. Definition of the facilities to be used for the AIT QA programme.

c. Procedures and documentation to be used.

d. Coordination and sequencing of all assembly and integration operations, and tests to be conducted at successive levels of assembly/integration.

e. Coordination of tests to be performed or witnessed by an ESA representative.

7.3 ASSEMBLY AND INTEGRATION

The requirements defined for manufacturing in Section 6 shall apply also to assembly and integration, as appropriate.

In this section, only requirements specific for assembly and integration are defined.

7.3.1 Control of temporary installations and removals

The Contractor shall ensure the management and control of flight items which are temporarily removed or nonflight items which are temporarily installed to facilitate assembly, integration, testing or handling of the end item.

The control shall be initiated upon installation or removal of the first temporarily installed or removed item and shall be maintained through delivery and use of the end item.

Records of temporary installations and removals shall be established and maintained. Data items in the records shall be in accordance with Appendix A.

Temporarily installed items shall be accounted for to prevent them from being incorporated in the final flight configuration. At least during launch campaign, a physical "accountability box" system shall be used to make verification of temporary items obvious. Additionally, duplicate temporary items shall be banned from the launch site. Temporary installed items shall also be brightly coloured and prominently identified so that their presence is also obvious to an observer at ground level.

7.3.2 Logbooks

The Contractor shall prepare and maintain system, subsystem and equipment logbooks for all operations and tests performed on the item during the period to be covered by the logbook. Equipment logbooks shall start with the first qualification or acceptance test after assembly. Subsystem and system logbooks shall follow-on from the individual equipment logbooks to form a full record.

Each logbook shall be kept in close proximity to the relevant system, subsystem or equipment and be readily identifiable with it.

The logbook shall accompany the hardware whenever it is placed under the custody of another organisation and this organisation shall update it. Logbooks shall be ruggedly bound in a manner which permits easy updating.

Entries shall be complete, self explanatory, clearly legible and traceable to the individual and organisation making the entry and include the date on which the entry is made. The logbooks shall contain historical data and information which is significant for operation of the item.

Logbooks shall include:

a. List of contents.

b. Verified configuration, including Waivers summary (see Appendix B- 4.6.4 and ESA PSS-01-11).

c. Acceptance test procedure and data.

d. Chronological history record, in date and time sequence, of all the operations and inspections, including MIP's and KIP's, performed on the item during the period covered by the logbook.

e. Connector mating records, as applicable.

f. List of limited-life items, with the relative serial number and number and record of operating time/cycle.

g. Failure and replacement record, for all failures occurred during testing. Data to be recorded include part and serial numbers, time and cycles to failure, NCR number and disposition of the failed parts.

h. Record of temporary removals and installations.

i. Record of open or deferred work, including unaccomplished tests and inspections.

j. Copy of all NCR's related to the period covered by the logbook.

k. Analogue telemetry calibration curves or tables, to be presented in a clearly identified separate section.

l. Responsible organisation, date, stamp and/or signature for all entries.

The logbook shall be part of the Acceptance Data Package (see Section 8.2).

7.4 TEST

Qualification and acceptance tests shall be performed under full QA surveillance, in controlled facilities, in accordance with formal test procedures and comprehensively documented in test reports. Readiness for testing and testing accomplishment shall be reviewed by formal boards.

7.4.1 Test surveillance

The Contractor's QA personnel shall continuously witness the performance of all test activities where manual intervention is required. They shall witness the setting-up, start and end of continuous fully automated test sequences.

Testing shall be subject to the requirements for the control of hazardous operation, as defined in ESA PSS-01-40. Where safety of personnel or damage to items or associated test equipment is possible, QA personnel shall be given the authority to stop the test.

7.4.2 Test facilities

The Contractor shall assure that test facilities, either internal or external, comply with ESA PSS-01-203.

Contractors performing measurements according to ESA PSS-01-204 and ESA PSS-01-7xx shall be certified by ESA.

7.4.3 Test equipment

It shall be possible to verify the correct operation of all items of test equipment independent of having the test item applied to them.

7.4.4 Test procedures

Test procedures shall be reviewed and approved by PA. Test procedures shall include:

a. General

- list of contents;
- scope of the test, including the identification of the requirement being verified;
- identification of the test object;
- applicable documents, with their revision status;
- test flow.

b. Test organisation

- personnel needed to perform the test and definitions of their responsibilities;
- need of test witnessing by ESA representative, if required;
- requirements for Pre-test and Post-test Review Boards.

c. Test conditions

- General test conditions such as ambient pressure, temperature, humidity and cleanliness;
- general and special precautions for safety and handling be observed during the test.

d. Test equipment and set-up

- Listing of equipment needed to perform the test including definition of sensitivity, accuracy and calibration procedures;
- mechanical and electrical test set-up, including drawings as necessary to show mounting arrangements and connection between test equipment and test specimens.

e. Test performance

- Step-by-step procedure with detailed operating mode, conditions and parameter setting;
- recording of data.

f. Pass/fail criteria and test data evaluation requirements.

7.4.5 Test reports

Test reports shall include:

a. Identification of the test object.

b. Reference to the applicable test procedure and revision status, and description of the deviations from it in actual testing.

c. Records of actual test conditions, test equipment and test set-up.

d. Test data records and evaluation.

e. Conclusions.

Test reports shall be issued or approved by the relevant Test Review Board (see Section 7.4.5.3).

7.4.6 Test reviews

Formal review boards shall perform test reviews before and after major portions (e.g. at the end of vibration test) of qualification or flight-acceptance tests.

Test reviews shall be performed following a formal agenda.

7.4.6.1 Test-readiness review (TRR)

The scope of this review shall be to assess the configuration and readiness of the items to be tested and the readiness of the facilities and documentation. In detail the purposes of this review shall be to:

a. Assess the as-built status of the items to be tested against the required test configuration.

b. Review the status of nonconformances and verify that open nonconformances have no impact whatsoever on the validity of the test.

c. Review the availability and approval status of test procedures.

d Assess the readiness of test facility.

e. Verify calibration status of test equipment.

f. Verify validity of personnel certifications (when required).

g. Review safety readiness in accordance with ESA PSS-01-40 requirements for the control of hazardous operations.

h. Assess the configuration status of any computer software software used with the test equipment or embedded into the test item during or for the test. The software configuration status shall include definition down to the individual module checksum.

i. Verify the availability of the necessary personnel during the test.

7.4.6.2 Post-test review (PTR)

The purposes of this review shall be to:

a. Verify the completeness of all required test data.

b. Verify that all deviations from or modifications, if any, to the initial test procedure were properly authorised.

c. Verify that nonconformances/failures during the test were were recorded and correctly disposed, or at least initial disposition affecting continuation/completion of the test were made appropriately.

d. Review test data for conformance to the relevant requirements.

e. Attest that test results comply with requirements and the item is acceptable for further tests and/or processing.

7.4.6.3 Test review board

The above reviews shall be conducted by a formal Test Review Board (TRB). The TRB shall consist at least of the following members:

a. The Product Assurance representative, as chairman.

b. The Engineering/Design Manager or authorised representative(s).

c. The AIT Manager or authorised representative.

d. Other specialists for the particular test.

e. ESA representative(s), unless specifically waived by ESA.

The board shall report on each test review board activity, showing how the requirements for test reviews are met (see Sections 7.4.5.1 and 7.4.5.2).

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SECTION 8: QA REQUIREMENTS FOR ACCEPTANCE AND DELIVERY

8.1 GENERAL

The Contractor shall establish 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 Contractor shall also ensure that the preparation of the items for delivery and the physical delivery itself are performed in such a way that quality degradation is prevented.

8.2 ACCEPTANCE DATA PACKAGE

The Contractor shall provide an ADP at the delivery of each deliverable item.

The ADP shall constitute the basis for formal acceptance reviews, and shall provide the set of documents and records for further integration, testing and operation in higher-level assemblies.

ADP's shall be maintained and integrated into higher-level ADP's during subsystem/system integration and testing. ADP's shall be ruggedly bound and easy to update.

ADP's shall include the following:

a. Title page identifying the item and the issue status of the ADP. Where the item presents particular hazards or is particularly susceptible to damage by mishandling, this shall be stated prominently on the front page together with references to the relevant procedures.

b. List of ADP contents.

c. Certificate of Conformance (COC), containing a binding statement that the items offered for acceptance have been manufactured, assembled and tested in accordance with the annexed CIDL/CSL (see Paragraph 8.2.d below) and comply in all respects with contract requirements. If there are exceptions, these shall be listed in the Log of Exceptions below. Any limitations on the use of the item which result from nonconformances shall be stated in full on the COC. The COC shall be signed by the QA manager.

c1. Log of Exceptions (LOE), listing all exceptions to the statement of compliance in the COC, with reference to the corresponding NCR's and RFW's and identification of their status. Unequivocal cross reference shall be established between COC and LOE.

d. Copy of the full CIDL/CSL at the issue stated on the COC, and COC, and As-Built Configuration List (ABCL), to document the as-built status.

e. Copies of all NCR's and RFW's listed in the COC, or reference to the relevant section of the logbook if already included therein (see Paragraph 8.2.g below).

f. Full copies of the major drawings including:
- Drawing family tree;
- Interface control drawing;
- Top assembly drawing;
- Functional and electric circuit diagram.

g. Logbook (see Section 7.3.2)

h. Test Plan.

i. Qualification Status List.

j. Packaging, storage, transport, handling and installation procedures.

k. Special safety procedures, if any.

l. Pyrotechnic, radioactive item and laser data sheets, as applicable.

m. Operation and Maintenance Manual.

n. Minutes of the DRB authorising the shipment of the item (see Section 8.3), with evidence of the closure of DRB actions. Evidence of the closure of those DRB actions which were not identified as having to be completed before shipment are to be added as updates to the ADP after delivery.

o. Lower-level ADP's.

8.3 DELIVERY REVIEW BOARD

The Contractor shall ensure that a DRB is convened prior to the delivery of equipment, separately assembled subsystems or test/handling equipment for higher-level activities.

The DRB functions at system level shall be fulfilled by the system reviews defined in the contract and chaired by ESA. ESA reserves the right to attend as an observer DRB's at any lower level. To this end, ESA shall be notified of a DRB's meeting five working days before the event, or as otherwise stated in the contract.

8.3.1 DRB responsibilities

The DRB shall be responsible for authorising the shipment of the items under acceptance and certifying by writing that:

a. The items conform to the contractual requirements and to an approved design configuration.

b. The items are free from material and workmanship deficiences.

c. All nonconformances are closed-out.

d. The relevant ADP is complete and accurate.

8.3.2 DRB membership

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

a. Receiving contractor's representatives:
   - Project Manager, or authorised representative, as chairman.
   - PA Manager, or authorised representative.
   - Engineering/Design Manager,or authorised representative.

b. Submitting contractor's representatives:
   - Project Manager,or authorised representative.
   - PA Manager,or authorised representative.
   - Engineering/Design Manager,or authorised representative.

c. Higher or prime contractor's representative(s), as observers (not required for separate subsystems).

d. ESA representatives, as observers.

Delivery shall only be authorised by the unanimous agreement of the DRB members. The view of observers shall be taken into account, but are not binding on the DRB.

8.4 PREPARATION FOR DELIVERY

8.4.1 Packaging

The Contractor shall ensure that packaging materials, methods, procedures and instructions provide for protection of items while at the Contractor's plant, during transportation and as far as is practicable after arrival at destination.

Packaging shall be in accordance with ESA PSS-01-202.

8.4.2 Marking and labelling

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

Marking and labelling shall be in accordance with ESA PSS-01-202.

8.5 DELIVERY

8.5.1 Shipping control

The Contractor shall ensure that the items to be shipped from his 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/unpacking procedure and any relevant safety procedures.

8.5.2 Transportation

The Contractor shall make provisions for the prevention of damage to items during transportation.

Transportation shall be in accordance with ESA PSS-01-202.

APPENDIX A

QUALITY RECORDS

NOTE : Quality Records in this Appendix are identified by the number of the paragraph where they are cited within the specification.

[2.5.3]	Training and certification records
[3.3.2]	Stamp traceability records
[3.5.2.7]	Calibration records
[3.7.7]	Records of alerts
[3.8.2.1]	Storage records
[5.2.2]	Records of procurement sources
[5.5.4]	Receiving inspection records
[5.5.4.1]	Sequential log
[5.5.4.2]	Supplier performance records
[6.2.4]	Manufacturing records
[6.4.1]	Tooling records
[6.7.2.3]	MIP/KIP records
[6.7.8]	Inspection and test records
[7.3.1]-1	Temporary installation records
[7.3.1]-2	Temporary removal records
[B-5.1]	Nonconformance records
[2.5.3]	Training and certification records

[2.5.3] Training and certification records

These records shall include:

a. Personnel identification.

b. Training received.

c. Type of certification received, including the extent of responsibilities and any limitations.

d. Dates of certification and its expiry .

e. Experience accumulated in the performance of the relevant activities.

[3.3.2] Stamp traceability records

These records shall include:

a. Identification of the individual authorised to use the stamp.

b. Stamp identification.

c. Extent of responsibilities and limitations in stamping operations, inspections and tests.

d. Attribution and expiry dates.

e. Signature of the individual.

[3.5.2.7] Calibration records

These records shall include:

a. Unique identifier of standard or equipment to be calibrated.

b. Manufacturer's name, model number and rated accuracy.

c. Identification of standard equipment and calibration procedure used in the calibration process.

d. Date of receipt and frequency of periodic calibration.

e. Dates and results of each calibration. Calibration results shall be recorded both as measured and corrected, and shall include a statement of the cumulative effects of errors and a description of the environmental conditions during calibration.

f. Due date of next calibration.

g. Calibration facility and individual(s) performing the calibration.

h. Details of any maintenance (servicing, adjustments, repairs) or modification together with an assessment for each of any effects on the calibration status.

i. Any limitations in use.

j. Location where they are used.

[3.7.7] Records of alerts

These records shall include:

a. Alert identification number.

b. Item identification, including manufacturer, part number, serial or lot number.

c. Description of observed nonconformance or failure, evaluation analysis methods and results.

d. Proposed actions.

e. Date of issue.

[3.8.2.1] Storage records

These records shall include:

a. Item identification, including manufacturer, part number serial or lot number.

b. Date of receipt.

c. Location.

d. Storage life and related storage conditions.

e. Details of any maintenance, tests or inspections required during storage.

f. Issuing and stock-control records.

[5.2.2] Records of procurement sources

These records shall include:

a. Subcontractor or supplier denomination and address.

b. Items or services furnished.

c. Location where items are produced or services are executed.

d. Audits performed and their results.

[5.5.4] Receiving inspection records

Receiving records shall consist of a sequential log of receipt and supplier performance records, as described below.

[5.5.4.1] Sequential log

The sequential log of received supplies shall include:

a. Date of receipt.

b. Complete identification of the items.

c. Inspections and tests performed; inspection and test procedure and results.

d. Reference to the sampling plans used, if any.

e. Quantities received, inspected and accepted.

f. Copy of the documentation from the supplier, or reference to their location.

g. Copy of or reference to NCR's, if any.

[5.5.4.2] Supplier-performance records

The supplier-performance records shall consist of the items (a), (b), (e) and (g) above, collected or electronically readable per supplier, to reflect on a continuous basis:

a. The qualitative and quantitative performance of individual suppliers.

b. Quality history of supplies.

[6.2.4] Manufacturing records

Records of manufacturing and inspections operations shall include:

a. Identification of the individuals responsible for the accomplishment of each fabrication operation, inspection and test.

b. Identification of materials, parts and subassemblies used, according to the traceability requirements for the fabricated item.

c. Identification of critical processes performed (e.g. by treatment number).

d. Identification of special tooling or equipment used, when several instances of them are used for manufacturing.

[6.4.1] Tooling records

These records shall include:

a. Reference to relevant drawings.

b. Location.

c. First approval details.

d. Intervals for and results of periodic checks.

[6.7.2.3] MIP/KIP records

MIP/KIP records shall include:

a. Item identification.

b. MIP/KIP description.

c. MIP/KIP procedure.

d. Schedule date and actual performance date.

e. MIP/KIP status.

f. Inspection report reference.

g. MIP/KIP related action items.

h. MIP/KIP close-out references.

[6.7.8] Inspection and test records

Inspection and test records and data shall be appropriate for the type, scope and importance of the inspection or test performed.

The records shall include:

a. Identification of the items concerned.

b. Reference to requirements, drawings and specifications by document number and issue status.

c. Reference to inspection and test procedure.

d. Accept/reject criteria.

e. Inspection and test results. These results shall be in sufficient detail to allow independent verification that the relevant requirements have been met (e.g. actual measured values and the required limits shall be recorded rather than merely an indication of conformance/nonconformance).

f. List of equipment used, giving type, serial/inventory number and calibration due date.

g. Clear statement about the conformance/nonconformance of the items.

[7.3.1]-1 Temporary installation records

These records shall be prepared for each equipment, subsystem or system, and included in the relevant logbook.
The records shall include:

a. Identification of the location where the items are temporary installed, including P/N and S/N.

b. Identification of the temporary installed item, including item number, P/N and S/N.

c. Reason for temporary installation.

d. Authorisation for temporary installation.

e. Statement of satisfactory installation.

f. Verification of final removal.

Items (d) through (f) shall include: date, signatures of the contractor's Engineering and QA, and signature of customer's QA.

[7.3.1]-2 Temporary removal records

These records shall be prepared for each equipment, subsystem or system, and included in the relevant logbook.
The records shall include:

a. Identification of the location from which the items are temporary removed, including P/N and S/N.

b. Identification of the temporary removed item, including item number, P/N and S/N.

c. Reason for temporary removal.

d. Authorisation for temporary removal.

e. Authorisation for re-installation.

f. Verification of final re-installation.

Items (d) through (f) shall include: date, signatures of the Contractor's Engineering and QA, and signature of customer's QA.

[B-5.1] Nonconformance records

The records shall include:

a. NCR number.

b. Project name and spacecraft model, if known.

c. Identification of the nonconforming item.
In the case of incoming nonconforming items:
Manufacturer, supplier, date received, purchase order and batch/lot number, as applicable.

d. Date, location and facility of occurrence or observation.

e. Operation, inspection or test, and step at which the nonconformance was observed.

f. Description of the nonconformance.

g. Nonconformance classification.

h. MRB Disposition.

i. Causes of nonconformance.

j. Associated documents and references.

k. Corrective actions performed.

l. Close-out date and references.

APPENDIX B

NONCONFORMANCE CONTROL SYSTEM

Table of Contents

B-1 APPLICABILITY

The nonconformance control system shall apply to:

a. Flight standard hardware and spares.

b. Flight software and all related interfaces.

c. Any hardware and software involved in design qualification.

d. Ground equipment and software involved in mission operations.

e. Equipment and software involved in spacecraft and subsystem ground operations, starting with their acceptance testing.

f. Check out equipment and software, starting with their acceptance testing.

g. Components and materials.

B-2 NONCONFORMANCE CLASSIFICATION

Nonconformances shall be classified as major or minor.

Unless specified otherwise in the contract, nonconformances shall be classified according to the following criteria:

Major nonconformance: a nonconformance is classified as major when it may adversely affect:

a. Functional and/or operational performances.

b. Functional and/or dimensional interfaces and/or interchangeability.

c. Form, materials, weight, centre of gravity.

d. Safety.
Nonconformances affecting safety shall be identified in accordance with ESA PSS-01-40.

e. Reliability, maintainability, availability.

f. Specified operational life, maintenance and durability.

g. Acceptance or qualification test procedures and results.

h. Personnel health and safety.

i. Programme schedule and cost.

Minor nonconformance: any nonconformance which by definition cannot be classified as major shall be classified as minor. A minor nonconformance is of inconsequential nature as regards the above features, or is trivial with regard to workmanship criteria.

In case of doubt, nonconformances shall be classified as major.

The consequences of several different nonconformances on the same item shall be evaluated.

B-2.1 Component nonconformances

If a lot/batch of components is rejected during manufacturing, screening or testing at the manufacturer's facilities, the nonconformance shall be classified as major if:

- it is proposed to use the rejected lot/batch as is, or
- it is proposed to continue processing, rework or testing, although the lot/batch does not comply with the specification requirements.

All component nonconformances after delivery from the manufacturer shall be classified as major, except the following nonconformances at incoming inspection, which may be classified as minor:

- random failures, where no risk for a lot -related reliability or quality problem exists;
- the form, fit or function are not affected;
- minor inconsistencies in the accompanying documentation.

B-3 NONCONFORMANCE DISPOSITION CRITERIA

The Contractor shall dispose nonconforming items in accordance with the following criteria.

B-3.1 Use-as-is

This disposition shall apply when the item is found to be completely useable without eliminating the nonconformance. When this disposition is applied to major nonconformances, a Request for Waiver (RFW) shall be issued (see Section B-4.6.4).

B-3.2 Rework

This disposition shall apply when the item is recoverable to complete conformance to the drawings, specifications or contract requirements, by the re-application of the process as originally performed according to the manufacturing operations schedule.

By definition, rework completely eliminates the nonconformance, and does not imply the use of any additional materials or processes. There may however be additional operations to be performed to prepare the work item for process re-application (e.g. removal of faulty work, cleaning, surface preparation ...).

After such rework, items shall be resubmitted for normal inspection and test operations.

B-3.3 Repair

This disposition shall apply when the item is recoverable to useable and acceptable conditions by the application of additional materials and processes above that which was performed according to the manufacturing operations schedule.

Repair reduces but does not completely eliminates a nonconformance, and it will always result in a change in the geometric form and most probably also in the mass of the item.

The repair operations shall be covered by:

a. Standard repair procedures (SRP), which are documented techniques for repair of a specific type of nonconformance, are developed by the Contractor, reviewed and concurred to by the MRB (see App. A, Section 4.5) and approved by ESA.
SRP's shall be approved for recurrent use under defined conditions, such as an expiration date and/or a limited number of applications.

The ESA approval of SRP's shall not relieve the Contractor of the responsibility for initiating corrective actions to prevent nonconformance recurrence.
SRP's shall be based on ESA specifications of the PSS-01-7xx series, when existing.

b. A repair procedure approved by the MRB for the specific nonconformance on a one-time basis only.

When a major nonconformance is repaired according to a procedure other than a SRP, a Request for Waiver (RFW) shall be issued to document the impact on the configuration of the item (see Section B-4.6.4).
After repair, items shall be re-submitted for normal inspection and test operations.

B-3.4 Scrap

This disposition applies to nonconforming items which are unfit for use and are not recoverable by rework or repair.

Scrapped items shall be identified, controlled and disposed of according to established procedures.

B-3.5 Return to supplier

This disposition applies to nonconforming procured items.

In this case the Contractor shall rapidly feedback information to the supplier and ensure that the supplier takes prompt corrective actions to prevent recurrence of nonconformances.

B-4 NONCONFORMANCE PROCESSING

B-4.1 General requirements

The Contractor shall establish detailed written procedures to accomplish the tasks for nonconformance processing defined herein. These procedures shall include the identification of the personnel appointed by the Contractor for nonconformance disposition (see Paragraph B-4.5.1), the definition of the extent of their authority and responsibilities and their signatures.

The Contractor shall establish a holding area for nonconforming items pending MRB disposition. Access to such area shall be limited to MRB members or personnel authorised by the MRB. Provisions shall be made to prevent unauthorised removal of nonconforming items. Items whose segregation in the holding area is not practical, either because of their size or having been already installed, shall be prominently identified.

In the event of a nonconformance the following sequence of actions shall be taken:

a. Nonconformance reporting and immediate actions.
b. Nonconformance review and classification by the local material review board.
c. Disposition of minor nonconformances by the local material review board.
d. Notification to ESA of major nonconformances.
e. Review and disposition of major nonconformances by the material review board.
f. Request for waiver, when applicable.
g Disposition implementation and recurrence control.
h. Close out and archiving.

This procedure is outlined in the flow chart in Figure 1.

B-4.2 Nonconformance reporting and immediate actions

B-4.2.1 General requirements

The Contractor shall ensure that all nonconformances are fully documented. Provision shall be made for the timely dissemination of nonconformance reports to appropriate elements of his organisation and his subcontractors' organisations.

The reporting shall be integrated into the flow of actions performed and sufficient data shall be included to provide a basis for decisions.

B-4.2.2 First actions after nonconformance detection

When a nonconformance is detected, a preliminary assessment shall be performed by the QA organisation to establish its extent and cause. Immediately after the following actions shall be taken:

a. Issue of a nonconformance report (NCR) (see Section B-4.2.3.below).

b. Provisions for the safety of the personnel and of the equipment.

c. Marking and segregation of the nonconforming item in the designated area, to prevent unauthorised use and mixing with conforming items.

d. Prevention of the repetition of the nonconformances on similar or identical items under processing or testing at that time. This may require suspension of manufacture or testing, if necessary.

e. Recording of the NCR on all quality and manufacturing records belonging to the nonconforming item.

f. Recording of the NCR on the nonconformance records (see Section B- 5).

B-4.2.3 Nonconformance report (NCR)

Nonconformances shall be reported on a NCR form to be agreed with ESA.

The minimum information to be included in NCR's for the notification to ESA shall be in accordance with Paragraph B-4.4.1; the additional content of full NCR's after MRB disposition shall be in accordance with the Par. B-4.6.

B-4.3 Local Material Review Board (Local MRB): nonconformance review and classification; disposition of minor nonconformances

B-4.3.1 Local MRB

The NCR shall be submitted to the local or internal MRB for the review, classification and investigation of nonconformances, the disposition of minor nonconformances, and the proposal of an initial disposition for major nonconformances.

The membership of the local MRB shall include at least a QA representative, as chairman, and a design engineering representative.

B-4.3.2 Nonconformance review and classification

In determining the dispositions for nonconforming items, the local MRB shall review the impact of nonconformances in accordance with Paragraph B-4.6.1.

Nonconformances shall be classified according to the criteria defined in Section B-3, within 1 working day after they are detected.

B-4.3.3 Disposition of minor nonconformances

The local MRB shall dispose minor nonconformances in accordance with the Section B-3, with the following exceptions:

a. The "repair" disposition shall apply only when a SRP exists.

b. The RFW is not applicable.

The local MRB disposition shall be made within 5 working days of the detection of the nonconformance, unless otherwise stated by the contract. If the decision is not unanimous for all local MRB members, the nonconformance shall be processed by the higher MRB.

Unless otherwise stated in the contract, minor nonconformances are not to be notified to ESA. Minor nonconformances shall be included in the summary status report (see Section B-5.3) and available to ESA upon request for the review of the correct application of classification criteria and appropriate processing.

B-4.4 Notification of major nonconformances

B-4.4.1 Notification

Major nonconformances shall be notified to ESA by telex, telefax or note to an on-site ESA resident within 1 working day after the review by the local MRB, unless otherwise stated by the contract. Subcontractors shall notify in a similar way to the Contractor, with copy to ESA, the nonconformances occurred at their facilities.

At least the following information shall be included in the NCR sent to ESA:

a. Unique NCR number.
NCR's shall be identified by numbers from a single uninterrupted sequence specially allocated for the project. Within this sequence, a single uninterrupted subsequence shall be reserved to AIT nonconformances.

b. Project name and spacecraft model, if known.

c. Identification of the nonconforming item.

d. Identification of the next higher assembly.

e. Date, location and facility of occurrence or observation.

f. Operation, inspection or test, and step at which the nonconformance was observed, including the relevant detailed environmental and operational conditions.

g. In the case of incoming nonconforming items:
manufacturer, supplier, date received, purchase order and batch/lot number or date code, as applicable.

h. Description of the nonconformance.

i. Nonconformance classification.

j. Initial/proposed disposition.

k. Causes of nonconformance as far as already known.

l. Remarks, such as suspected failure effects, schedule impact.

m. Preliminary taken or proposed actions to prevent recurrence of the nonconformance.

n. Associated documents and references.

B-4.4.2 Reaction from ESA

Within three working days after receipt of the notification of a major nonconformance, ESA will respond to the Contractor:

a. If further information, evaluation or analysis is required.

b. If ESA disagrees with the proposed disposition.

c. If ESA wishes to participate in the follow-on Material Review Board.

B-4.5 Material Review Board (MRB)

The Material Review Board is a formal board to be established by the Contractor for the review and disposition of all major nonconformances, and the definitions of related corrective actions for recurrence prevention.

B-4.5.1 MRB membership

MRB membership shall include:

a. Chairman, assigned from the Contractor's PA organisation for direction of the meeting and assignment of action items.

b. Engineering representative, assigned from the Contractor's and/or Subcontractor's (if applicable) design engineering function.

c. ESA representative, when assigned by ESA project manager.

d. Safety or reliability representative, in accordance with with ESA PSS-01-40 or ESA PSS-01-30, when the nonconformance affects safety or reliability.

e. Specialists, assigned by the Contractor and/or Subcontractor (if applicable) or ESA on an "as required" basis, to provide specialised technical knowledge relevant to the nonconformance being considered. The "specialists" shall have no vote in board proceedings.

B-4.5.2 MRB convening

The Contractor shall give five working days' notice of the convening of an MRB to ESA. This notice shall be given in writing via telex, telefax, or note to an on-site ESA resident.

B-4.5.3 Subcontractors' MRB

The Contractor may, upon determining that a subcontractor has the capability to meet the requirements for nonconformances processing as described herein, delegate MRB responsibility to that subcontractor.

It will be responsibility of the Contractor to make adequate provisions to ensure that nonconformances are properly classified and disposed by the subcontractor's MRB.

The Contractor shall reserve the right to attend subcontractor's MRB meetings and shall reserve similar rights for, and on behalf of ESA.

B-4.6 Review and disposition of major nonconformances

B-4.6.1 Nonconformance review

In determining dispositions for nonconforming items, the MRB shall:

a. Assess the causes of nonconformances.

b. Consider the available data and information related to the nonconforming item (e.g. alerts from other programmes, FMECA, hazard analysis, supplier records, qualification test data).

c. Review records of previous similar or identical nonconformances, if applicable .

d. Assess the applicability of the intended dispositions.

e. Assess the effect of the nonconformance on contractual requirements and the intended use of the item.

f. Determine and implement the corrective actions to eliminate the cause(s) of nonconformances and prevent the recurrence of similar nonconformances.

g. Assess the applicability of dispositions and corrective actions to existing and in process items (including reinspection and retest).

B-4.6.2 Failure analysis and other technical support

In reviewing nonconformances, failure analysis and any technical analysis deemed necessary by the MRB to assess the cause of nonconformances and the possible disposition shall be performed.

Failure analysis and other investigations shall not be performed on the nonconforming items unless required by the MRB.

The Contractor shall maintain an appropriate failure analysis laboratory for electrical and mechanical measurements, microscopic inspection, X-ray, leak detection, metallographic examination, etc. or have access to such a laboratory. Failure analyses shall be documented in reports and submitted to the MRB.

B-4.6.3 MRB dispositions

Major nonconformances shall be subject to the dispositions defined in Section B-3.

Nonconformance disposition requires unanimous agreement of all MRB members. If the decision is not unanimous, the board shall call for the next higher level in management or assembly for a unanimous decision, when it exists, or otherwise dispose the nonconformance as "scrap".

Any item which has been disposed as "use-as-is", "rework" or "repair" shall, after successful completion of corrective actions, be processed in the same manner as conforming items.

B-4.6.4 Request for waiver

When dispositions of nonconformances by the MRB result in "use-as-is" or "repair", the differences from the required baseline shall be formalised by a Request for Waiver (RFW), through the Contractors' Configuration Control Board (CCB).

The Contractors' CCB shall submit the RFW to ESA for approval , according to the requirements established in ESA PSS-01-11.

A nonconformance may be disposed and closed-out by raising and submitting the related RFW to ESA. Agreement by the MRB ESA representative on the MRB dispositions does not imply approval on any RFW submitted.

B-4.6.5 Full nonconformance report

In addition to the information defined in Paragraph B-4.4.1, at the end of the nonconformance processing by the MRB the full nonconformance record shall include:

a. Established identification of the cause of the nonconformance.

b. MRB disposition.

c. Final failure analysis and any other supplementary test and/or analysis performed.

d. All corrective actions to avoid the recurrence of the nonconformance, including necessary document changes or recommendation to CCB for RFW.

e. All reinspection and retesting to be performed.

A copy of the full nonconformance record shall be submitted to ESA within two days after the MRB session, unless otherwise stated by the contract.

B-4.7 Disposition implementation and recurrence control

The dispositions shall be implemented by performing the actions necessary to transform the unacceptable state of the nonconforming item into an acceptable state (e.g. rework, repair), including all necessary reinspection and retesting. Corrective actions, such as changes to tools, equipment, facilities, processes, materials, drawings, specifications, procedures etc. shall be performed to remove the established causes of nonconformances and prevent recurrence. The disposition "use-as-is" does not require any physical action on the item to make it useable, but does require corrective action to prevent recurrence.

B-4.8 Nonconformance close-out

The Contractor's QA organisation shall ensure that all actions on nonconformances are closed-out for all items affected.

Close-out shall require at least that

a. The disposition has been fully accomplished and verified.

b. Corrective actions have been implemented and their effectiveness has been proved.

c. The necessary design and/or software changes have been accomplished and verified by test.

d. All inspection and test reports to certify completion of all close out actions are referenced/attached on/to the NCR.

An update of the NCR's of major nonconformances shall be sent to ESA after they are closed-out.

B-5 NONCONFORMANCE RECORDS AND SUMMARY

B-5.1 Nonconformance records

The Contractor shall maintain records of all nonconformances.

These records shall contain sufficient data for the complete identification of nonconforming items, the description of nonconformances and the status of the related actions, to allow a tight control, follow-up and analysis of nonconformances.

Data items in the records shall be in accordance with Appendix A.

B-5.2 Records review and nonconformance trend analysis

The Contractor shall review periodically the nonconformance records to evaluate the progress of the actions for the correction and prevention of nonconformances and to ensure their proper and timely close-out.

The nonconformance records shall also be analysed to assess the existence of trends in the occurrence and the extent of nonconformances. This analysis shall be aimed to detect the rise of conditions leading to new nonconformances and verify the effectiveness of the implementation of the preventive actions performed for previous nonconformances.

The frequency of the reviews shall be appropriate to the volume of nonconformances, but shall not be less than every 3 months.

B-5.3 Summary of nonconformances

The Contractor shall maintain current status lists of:

- all nonconformances and their respective status, sorted by spacecraft model;
- RFW, their approval status and link to the originating NCR.

These lists shall be submitted to ESA together with the regular project progress reports, as defined in the contract.

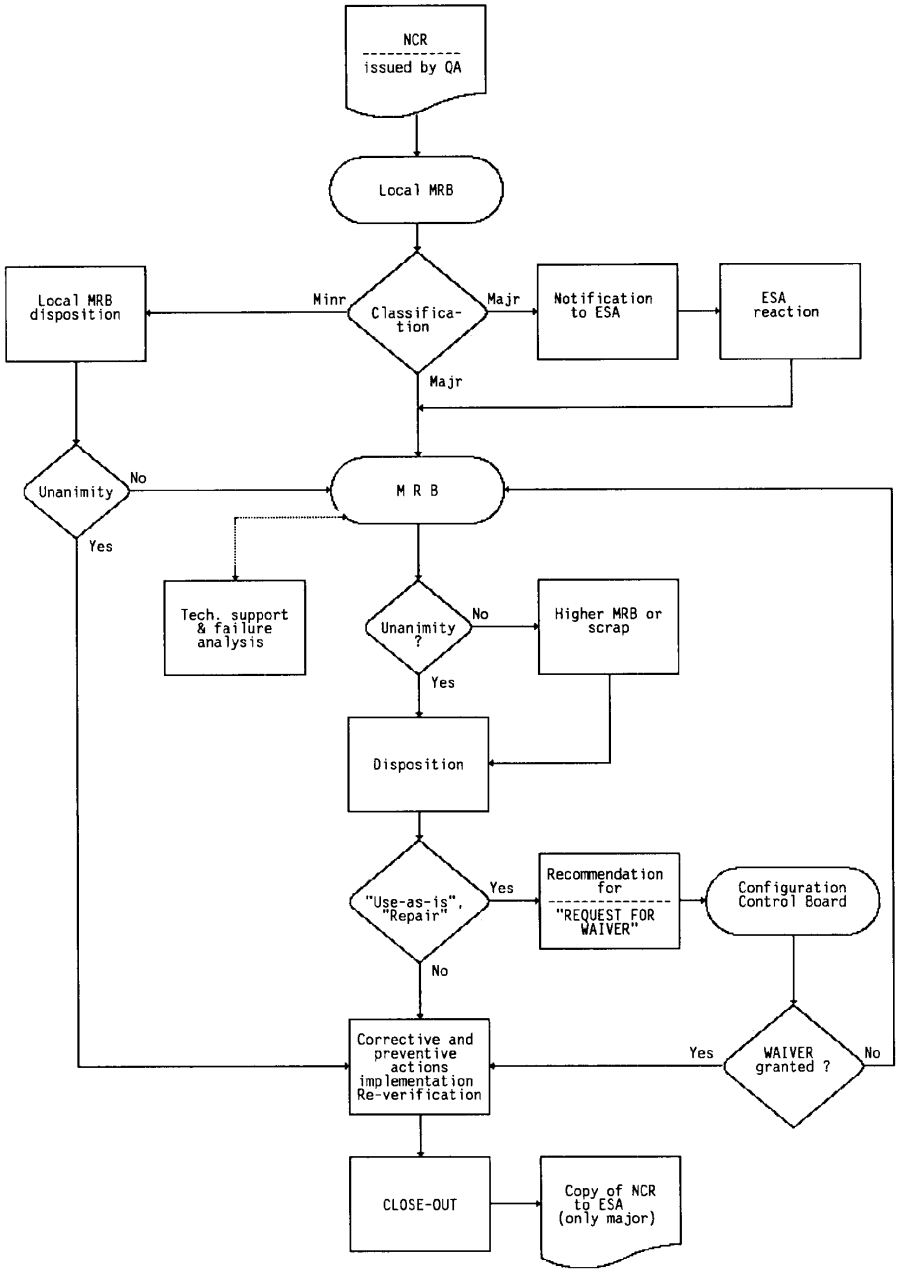

Figure 1: Nonconformance disposition

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