ECSS–Q–20A

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Space Product Assurance

Quality Assurance

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Foreword

This standard is one of the series of ECSS Standards intended to be applied together for the management, engineering and product assurance in space projects and applications. ECSS is a cooperative effort of the European Space Agency, National Space Agencies and European industry associations for the purpose of developing and maintaining common standards.

Requirements in this standard are defined in terms of what must be accomplished, rather than in terms of how to organise and perform the necessary work. This allows existing organisational structures and methods to be applied where they are effective, and for the structures and methods to evolve as necessary without rewriting the standards.

The formulation of this standard takes into account the existing ISO 9000 family of documents.

This standard has been prepared by the ECSS Product Assurance Working Group, reviewed by the ECSS Technical Panel and approved by the ECSS Steering Board.

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General

1.1 Scope

This Standard defines the Quality Assurance (QA) requirements for the establishment and implementation of QA programmes for projects covering mission definition, design, development, production and operations of space systems, including disposal.

This standard is applicable to the Customer/Supplier relationship of space products to the extent agreed by both parties. The requirements of this standard and its associated level 3 standards should be tailored to the needs and classes of specific projects.

For software quality assurance the software PA standard ECSS–Q–80 is applicable.

1.2 Normative Documents

This ECSS Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and publications are listed hereafter. For dated references, subsequent revisions of any of these apply to this ECSS Standard only when incorporated in it by revision. For undated references the latest edition of the publication referred to applies.

ECSS–P–001	ECSS Glossary of Terms
ECSS–Q–00	Space Product Assurance – Policy and Principles
ECSS–Q–30	Space Product Assurance – Dependability
ECSS–Q–40	Space Product Assurance – Safety
ECSS–Q–60	Space Product Assurance – EEE Components
ECSS–Q–70	Space Product Assurance – Material, Mechanical Parts and Processes
ECSS–Q–80	Space Product Assurance – Software Product Assurance
ECSS–Q–2xx	Mandatory Inspection Points Implementation Procedure
ECSS–Q–2xx	Test Reviews Implementation Procedure
ECSS–Q–2xx	Workmanship standard for space hardware

ECSS–Q–2xx	Critical Items control programme – Definitions and implementation requirements
ECSS–Q–2xx	Preservation, Storage, Handling, Transportation
ECSS–Q–2xx	QA Documentation: Logbook, Acceptance Data Package, Records
ECSS–Q–2xx	Quality Assurance of Test Facilities
ECSS–Q–2xx	Marking and labelling of space hardware
ECSS–Q–2xx	Nonconformance Control System – Implementation procedure
ECSS–Q–2xx	Alert System – Implementation procedure
ECSS–M–20	Project Organisation
ECSS–M–30	Project Phasing and Planning
ECSS–M–40	Configuration Management
ECSS–M–50	Documentation Management
ECSS–E–10	Space Engineering – Systems
ISO 9001	Quality systems: Model for quality assurance in design/development, production, installation and servicing
ISO 9002	Quality systems: Model for quality assurance in production and installation
ISO 9003	Quality systems: Model for quality assurance in final inspection and test

1.3 Definitions and Abbreviations

1.3.1 Definitions

For the purposes of this standard, the definitions given in ECSS–P–001 Issue 1 apply. In particular, it should be noted that the following terms have a specific definition for use in ECSS standards.

Acceptance

Alert

Analysis

Approval

Audit

Business Agreement

Calibration

Configuration Management

Contingency Procedure

Contract

Contractor

Corrective Action

Critical Item

Criticality

Data

Demonstration

Design

Development

Deviation

Document
Documentation
Equipment
Error
Inspection
Maintenance
Material
Mission
Model
Nonconformance
Performance
Procedure
Process
Product
Product Assurance
Project
Reliability
Qualification
Quality
Quality Assurance
Repair
Requirement
Review
Rework
Safety
Service
Specification
Supplier
System
Tailoring
Test
Validation
Verification
Waiver

1.3.2 Abbreviations

The following abbreviations are defined and used within this standard.

Abbreviation	Meaning
AIV	Assembly, Integration, Verification
DRB	Delivery Review Board
EEE	Electrical, Electronic, Electromechanical
EIDP	End Item Data Package
GSE	Ground Support Equipment
MIP	Mandatory Inspection Point

MRB	Material Review Board
QA	Quality Assurance
PA	Product Assurance

2

Quality Assurance Programme Management

2.1 Quality Assurance Programme

2.1.1

The Contractor shall implement a QA programme whereby assurance is given that:

- all requirements are specified through definition and implementation of adequate methods and procedures,
- a set of design rules and methods has been set up and is consistent with the project techniques and technologies,
- methods, procedures and tools have been defined and are implemented in order to prove that each applicable requirement is verified through one or more of the following methods : analysis, inspection, test, review of design, audits;
- for each configuration item there is a defined and implemented qualification approach that makes it possible to demonstrate that the item is so designed that it will perform satisfactorily in the intended environment,
- the approach adopted guarantees that the design is producable and repeatable and that the resulting product can be verified and operated within the required operating limits,
- adequate controls are established for the procurement of components, materials, software and hardware items, services,
- fabrication, integration, test and maintenance are conducted in a controlled manner so that the end item conforms to the applicable baseline,
- a nonconformance control system is established and maintained in order to systematically track and prevent reoccurrence,
- quality records are maintained and analysed so that trends can be detected and reported in time to enable preventive/corrective actions to be taken,
- equipment and tools used for inspecting, measuring and testing project items are regularly calibrated to ensure their accuracy,
- procedures and instructions are established which provide for the identification, segregation, handling, packaging, preservation, storage and transportation of all items,

– assurance is provided that the operations including post-flight and disposal are carried out in a controlled way and in accordance with the relevant requirements.

2.2 Organisation

General requirements for organisation and responsibilities are defined in ECSS–Q–00.

2.2.1

The Supplier shall identify the personnel responsible for implementing and performing QA functions.

2.3 Quality Assurance Programme Plan

2.3.1

The Supplier shall prepare, maintain, and implement a plan of the QA activities, in accordance with the general requirements in ECSS–Q–00.

The plan may be part of the overall project Product Assurance Plan.

2.4 QA Status Reporting

2.4.1

The Supplier shall periodically prepare and submit to the Customer reports on the status and progress of the QA programme, as part of the overall PA reporting.

2.5 Personnel Training and Certification

2.5.1

The Supplier shall establish a documented training programme for QA personnel and all other personnel whose performance determines or affects product quality.

2.5.2

Operators performing critical processes (as defined in ECSS–Q–70) shall be trained and certified by internal or external training programmes accepted by the Customer, or be able to demonstrate a regular and satisfactory use of the related skills.

2.5.3

Those inspecting 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 the Customer, or shall be able to demonstrate a regular and satisfactory use of the related skills.

2.6 Quality Assurance Programme Audits

2.6.1

The Supplier shall perform systematic audits on his own performance to verify the implementation and effectiveness of the provisions defined in the QA Programme Plan.

2.6.2

The Supplier shall establish and maintain an audit plan for procurement activities on the project, designating the lower tier Suppliers to be audited, the current status and the schedule for auditing.

2.6.3

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

2.6.4

The Customer shall have the right to be represented in the planned external audits. For this purpose, the external audit schedule shall be supplied to the Customer and updated regularly. No external audit shall be performed without the Customer's being given due notice.

2.6.5

The Customer shall also have the right to audit any lower tier Supplier at any time; such audits shall be arranged by the Supplier and the next/higher level Customers of the audited Supplier as relevant.

2.7 QA Role in Configuration Management

Requirements for configuration and data management are defined in ECSS–M–40 and ECSS–M–50

2.7.1

The Supplier shall ensure that configuration and data management rules are provided for, comply with those specified and are applied both by his own personnel and by his Suppliers' personnel.

2.7.2

A Supplier Product Assurance representative shall attend all Boards established to review the suitability for release of drawings, plans, specifications, procedures and changes thereto.

2.7.3

During the configuration verification process the 'as built' configuration of hardware and software shall be certified on the basis of the latest approved engineering data.

2.7.4

The Supplier's QA function shall ensure that:

a. the as designed status is defined prior to manufacturing

b. the as-built documentation is properly defined, identified and maintained in order to reflect approved modifications;

c. items to be delivered comply with the as-built documentation.

2.8 Critical Items Control

2.8.1

The QA function shall contribute to the overall risk management activities by:

a. Supporting the identification and risk evaluation of critical items for which major difficulties or uncertainties are expected in:

- demonstration of design performances
- development and qualification of new product, processes and technologies
- procurement, manufacturing, assembly, inspection, test, handling, storage and transportation, which may lead to major degradation in the quality of the product
- product utilisation or service implementation

b. Contributing to the risk reduction plan by identifying the QA activities accompanying the individual risk reduction measures.

c. Monitoring and documenting the achievement of the specified risk reduction implementation and the corresponding verification measures throughout all project phases.

3

Quality Assurance General Requirements

3.1 Documentation and Data Control

3.1.1

In support of the implementation of ECSS–M–50 requirements, the QA function shall ensure that:

a. the pertinent issues of appropriate documents and data are available at all locations where operations essential to the effective functioning of the quality system are performed;

b. invalid and/or obsolete documents and data are promptly removed from all points of issue or use, or otherwise assured against unintended use;

c. any obsolete documents and data retained for legal and/or knowledge preservation purposes are suitably identified;

d. proper data and documentation exchange procedures and formats are set up throughout the project organisation;

e. the documents required by the business agreement are verified and signed by the designated people before release;

f. documents are identified and verified for adequacy, currency and incorporation of Product Assurance requirements.

g. the need for document approval by Product Assurance is identified;

h. changes to documents and data are reviewed and approved by the same functions/organisations that performed the original review and approval unless specifically designated otherwise;

i. a master list or equivalent document control procedure identifying the current revision of documents and data support is established and is readily available to preclude the use of invalid and/or obsolete documents and data.

3.1.2

The Supplier shall establish and maintain a current Product Assurance Data file as defined by the business agreement.

3.2 Quality Records

3.2.1

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

3.2.2

Quality records shall be stored in safe conditions, which prevent alterations, loss or deterioration.

3.2.3

Quality records shall be retained for the period specified in the business agreement, unless release before that time is given by contractual authorisation.

3.2.4

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

3.2.5

Quality records shall be accessible to the Customer upon request.

3.3 Stamp Control

3.3.1

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

3.3.2

Stamps shall be used:

a. to signify the completion of operations and processes;

b. to indicate inspection performance at source and incoming inspection, in process inspection and tests, final inspection, end point testing, storage and shipment.

3.3.3

The use of stamps shall be restricted to authorised personnel.

3.3.4

Stamps shall be traceable to individuals responsible for their use.

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

3.3.5

Stamps shall be applied directly to articles and materials, when requested by engineering drawings and specifications, and associated documents, records, labels. Stamping materials and methods shall be compatible with the articles and their use.

3.4 Traceability

3.4.1 General

a. The Supplier shall implement a traceability system, which shall be maintained throughout all phases of business agreement performance, and during the planned operational life of deliverable items.

b. The traceability system shall provide for the ability to:

   1. Establish bidirectional and unequivocal relationship between parts / materials / products and associated documentation / records.
   2. Trace data, personnel and equipment related to procurement, fabrication, inspection, test, assembly, integration and operations activities.
   3. Trace backwards the location of materials, parts, subassemblies.
   4. Trace forwards the location of materials from raw stock. Forward traceability may be required also for some critical items, as defined in the business agreement.

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

3.4.2 Identification

a. Each part, material or product shall be identified by a unique and permanent part or type number.

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

   1. Date codes indicating date of manufacture, to identify items made by a continuous process or subject to degradation with age.
   2. 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.
   3. Serial numbers, to identify individual items for which unique data are to be maintained.

c. Controls shall be established to ensure that:

   1. Identification numbers are assigned in a systematic and consecutive manner.
   2. Identification numbers of scrapped or destroyed items are not used again.
   3. Identification numbers, once allocated, are not changed, unless the change is authorised by the Customer.

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

e. Method of marking on items shall be defined on engineering drawings and specifications.

f. Method of marking shall be compatible with the nature of the item and its use.

3.4.3 Data Retrieval System

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

b. The data retrieval system shall allow traceability starting from any point of the interconnected network existing between records, documents and marking on parts.

c. The Supplier 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

The Supplier shall control, calibrate and maintain inspection, measuring and test equipment, whether owned by the Supplier, on loan, or provided by the Customer to demonstrate the conformance of product to the specified requirements.

3.5.2

Equipment shall be used in a manner which ensures that measurement uncertainty is known and is consistent with the required measurement capability.

3.5.3

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.

3.5.4

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.

3.5.5

The Supplier shall:

a. identify the measurements to be made and the accuracy required and shall select the appropriate inspection, measuring and test equipment;

b. identify, calibrate and adjust all inspection, measuring and test equipment and devices that can affect product quality at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to nationally recognised standards; where no such standards exist, the bases used for calibration shall be documented.

c. establish, document and maintain calibration procedures, including details of equipment type, identification number, location, frequency of checks, check method, acceptance criteria and the action to be taken when results are unsatisfactory;

d. ensure that the inspection, measuring and test equipment is capable of the accuracy and precision necessary;

e. identify inspection, measuring and test equipment with a suitable indicator or approved identification record to show the calibration status.

f. maintain calibration records for inspection, measuring and test equipment (see 3.2);

g. assess and document the validity of previous inspection and test results when inspection, measuring and test equipment is found to be out of calibration.

h. ensure that the environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out;

i. ensure that the handling, preservation and storage of inspection, measuring and test equipment is such that the accuracy and fitness for use is maintained;

j. safeguard inspection, measuring and test facilities, including both test hardware and test software, from adjustments which would invalidate the calibration setting.

3.5.6

Where test hardware (e.g. jigs, fixtures, templates, patterns) or test software is used as suitable forms of inspection, it shall be checked to prove that it is capable of verifying the acceptability of the product prior to release for use during production and installation and re-checked at prescribed intervals. The Supplier shall establish the extent and frequency of such checks and shall maintain records as evidence of control.

3.5.7

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 clause, but shall be validated in a way appropriate to their usage.

3.5.8

Measurement design data shall be made available, when required by the Customer or his representative, for verification that it is functionally adequate.

3.6 Nonconformance Control System

3.6.1

The Supplier shall establish and maintain a nonconformance control system in accordance with the detailed requirements in ECSS–Q–2xx.

3.6.2

The system shall provide for a disciplined approach to the identification and segregation of nonconforming items, the recording, reporting, review, disposition and analysis of nonconformances, and the definition and implementation of corrective actions.

3.6.3

Nonconformances shall be classified as major or minor, on the basis of the severity of their consequences.

3.6.4

Major nonconformances shall be those which may have an impact on the next customer's requirements in the following areas:

a. safety of people or equipment;

b. operational, functional or contractual requirements;

c. reliability, maintainability, availability;

d. lifetime;

e. functional or dimensional interchangeability;

f. interfaces with hardware and/or software of different contractual responsibility.

Additionally, any nonconformances shall be classified as major in the cases of:

g. incorrect qualification or acceptance test procedures or noncompliant test results;

h. for EEE components, the

- lot/batch rejection during manufacturing, screening or testing at the manufacturer's facilities, if:
  * use-as-is of the the rejected lot/batch is proposed, or
  * it is proposed to continue processing, rework or testing, although the lot/batch does not comply with the specification requirements.

- any nonconformances after delivery from the manufacturer. The following discrepancies at incoming inspection 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.

Minor nonconformances are those which by definition cannot be classified as major.

3.6.5

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

3.6.6

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

3.6.7

Major nonconformances shall be formally notified to the next Customer, up to the level of the Customer which specified the affected requirements.

3.6.8

Nonconformances shall be reviewed and dispositioned by a formal Material Review Board (MRB), established at all contractual levels.

3.6.9

The Supplier shall ensure that:

a. responsibilities and authorities for the disposition of nonconformances are properly defined;

b. the MRB includes at least representatives from the PA and Engineering organisations;

c. the Board to review nonconformances is chaired by the Product Assurance Management function;

d. all relevant Product Assurance experts are involved in the review, investigation and disposition of nonconformances;

e. all knowledge acquired from nonconformances results in preventive actions in all relevant engineering, manufacturing and Product Assurance fields.

3.6.10

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

3.6.11

The proposed use or repair of items which do not conform to requirements specified by the Customer or approved baseline shall be handled in accordance with the waiver processing procedure as defined in ECSS–M–40.

3.6.12

Nonconformances shall be reviewed to identify the root causes, and implement corrective actions to prevent recurrence.

3.6.13

The Supplier shall maintain records of all nonconformances.

3.6.14

The Supplier shall review periodically the nonconformance records to evaluate the effectiveness of the system and identify trends.

3.7 Alert System

3.7.1

The Supplier shall participate in the Alert System established by the final Customer, for the prompt interchange of information on failures/problems which may affect more than one user, or may recur in other projects or circumstances, if no preventive actions are taken.

3.7.2

The Supplier shall ensure that all relevant Product Assurance experts are involved in:

– the assessment of any failure to be reported to the customer as a potential for raising an alert by the customer;

– the investigation, until disposition of the items subject of the potential alert;

– the assessment of incoming alerts for the definition, implementation and follow-up of necessary actions.

– The implementation rules of the Alert System are defined in ECSS–Q–2xx.

3.7.3 Generation of Alerts within the Project

a. The system shall provide for:

1. Notification of preliminary information, by the Originator through the contractual chain to the final Customer, on failures/problems that could result in an Alert, detected at any contractual level.
2. Investigation of the failure/problem by the Customer in cooperation with the originator and the Supplier, to define the immediate measures to be taken, to establish the causes, and to recommend corrective actions for similar items.
3. Release of formal Alerts by the Customer, to warn all the participants in the Alert System.

b. An Alert shall be issued only when all the following criteria are met:

1. The item with the observed failure or problem has multiple applications, which may have implications for more than one project, thus requiring prompt action.
2. The failure/problem has occurred in the application of an item within the specified design and usage limitations. However, failures/problems due to usage within reasonably expected limits of performance, but where these limits have not been specified precisely, should also cause the issuing of an Alert.
3. A preliminary investigation has provided sufficient evidence of the root cause of the failure/problem.
4. The failures/problems are confirmed NOT to be of a random nature.

3.7.4 Processing of Alerts from other Sources

a. The Supplier shall process Alerts distributed by the Customer, by:

1. distribution of incoming relevant Alerts to all possible affected users within the project organisation;
2. assessment of incoming Alerts to project work, and definition, implementation and follow-up of necessary corrective actions at any contractual level.

3.8 Handling, Storage, Preservation

3.8.1 Handling

a. The Supplier shall prevent handling damage during all phases of manufacturing, assembly, integration, testing, storage, transportation and operation, by adequate :

   1. protection of items during handling;
   2. handling devices;
   3. procedures and instructions.

Detailed requirements for handling are defined in ECSS–Q–2xx.

3.8.2 Storage

a. The Supplier shall have secure storage areas available for:

   1. incoming materials;
   2. intermediate items needing temporary storage;
   3. end items before shipping.

b. Limited-life materials, suspended limited-life material, nonconforming items awaiting MRB disposition, scrap items 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.

c. Each segregated area within the stores shall be clearly identified and labelled.

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

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

   Detailed requirements for storage are defined in ECSS–Q–2xx.

3.8.3 Preservation

a. The Supplier 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.

   Detailed requirements for preservation are defined in ECSS–Q–2xx.

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 capabilities studies, may be used whenever such methods are suitable to maintain or improve the required control of quality.

a. When employing statistical quality control and analysis methods, the Supplier 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).

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

3.9.2 Sampling Plans

a. Sampling plans shall not be used when tests are nondestructive and the reduction in inspection or testing may jeopardise the fulfilment of the business agreement requirements.

b. The Supplier shall use existing international sample inspection plans to the maximum degree practicable.

c. Sampling procedures shall be validated by the Supplier's QA organisation for the sample selection methods, and criteria for inspection severity, acceptance/rejection and screening of rejected lots.

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

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4

QA Requirements for Design and Verification

4.1 General

In support of the requirements in ECSS–M–30 and ECSS–E–10, the Supplier's QA function is intended to assure that:

- Design and operational requirements are specified in terms of quantity and/or quality, clearly expressed and consistent.
- The design definition is expressed for each Configuration Item in a way which ensures compatibility of Configuration Items among themselves and with system requirements.
- The Customer requirements are understood and taken into account by the functions involved and any deviation properly resolved with the customer.
- Methods, data and means (including software) required for each activity are developed, available and validated at the right moment.
- All technical risks are identified and provisions for their reduction are implemented.

4.2 Planning

4.2.1

The Supplier shall implement a QA programme to assure that:

a. Design and verification activities are planned in a consistent and logical way.

b. Critical processes and new technologies are identified in a timely manner and adequate evaluation and/or qualification activities are implemented in line with the overall schedule.

c. Significant deviations from the agreed planning and their consequences are evaluated and accepted by the authorised person responsible and/or the Customer prior to implementation, and the affected documentation is updated.

d. The verification process is adequate (in particular: clear test, test model and verification philosophy).

4.3 Organisational and Technical Interfaces

4.3.1

The Supplier shall implement a QA programme to assure that:

a. Interfaces between different groups which provide input to the design and verification process are defined and supported.

b. Incomplete, ambiguous or conflicting requirements shall be resolved with those responsible for imposing these requirements.

c. Feedback information is maintained from production, test, product assurance, operations, towards design implementation.

d. Methods and procedures are established to ensure that the experience gained in present and past activities is systematically incorporated into design construction.

4.4 Design Rules

4.4.1

The Supplier shall ensure that the design rules and guidelines defined below are properly implemented in the design.

4.4.2 Produceability

a. The product shall be so designed that it can be produced in an efficient manner with the required level of quality, according to capabilities and organisation of the production.

b. Design rules and guidelines shall include provisions for the following aspects:

1. Design simplification and standardization, reduction in part types and part number.
2. Guidelines for selection of preferred parts, materials and processes.
3. All necessary requirements and limits shall be defined, so as to avoid individual interpretation.
4. Tolerance build–up methods shall be defined, in order to simplify manufacturing, assembly, inspection.
5. Standardization of interfaces, wherever possible.
6. Part accessibility for assembly and inspection.
7. Definition of design criteria which are consistent with the capability of manufacturing processes.
8. Definition of proper design methods to ensure the achievement of cleanliness objectives, compatible with the capability of related cleanliness procedures and facilities.

4.4.3 Repeatability

a. The product shall be so designed that its performances and characteristics can be reproduced over different models and serial production.

b. Design rules and guidelines shall include provisions for the following aspects:

1. Definition of standard tolerances generally applicable, unless more stringent values are specifically required.
2. Recommended design concepts and solutions which minimise sensitivity of performances to variation in characteristics of parts, materials and processes.
3. Recommended manufacturing processes having proven repeatability.
4. Design criteria which optimise implementation of automated manufacturing methods, or computer–aided manufacturing.

4.4.4 Inspectability and Testability

a. The product shall be so designed that it can be easily and efficiently inspected and tested under representative conditions, for production, AIV and operational environment.

b. Design rules and guidelines shall include provisions for the following aspects:

   1. Inspection and test requirements, including acceptance/reject criteria, shall be defined, and expressed in an unambiguous and quantified manner.
   2. Part and component accessibility shall be ensured for inspection and test.
   3. Tolerance methods that ease dimensional inspection performance (such as functional tolerances) shall be defined.
   4. Recommended design techniques shall be defined as a means of facilitating fault detection, identification and location (such as: test points, modularity, built-in test software, feedback loops, ...).

4.4.5 Operability

The product shall be so designed that it can be operated safely and easily in accordance with programme constraints and requirements, throughout its whole life cycle including handling, storage, transportation, integration and operations.

4.5 Standards and Procedures

4.5.1

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

4.5.2

Standards and procedures shall include provisions for the following aspects:

a. Requirements shall be clearly expressed and consistent.

b. Critical items shall be identified on technical documents.

c. Technical documents shall specify:

   - functional performances and operational requirements including dependability and safety requirements;
   - applicable design and construction requirements proper to ensure produceability, repeatability, testability and operability of the product;
   - required verifications methods as review of design, analysis, inspection or tests, including acceptance/reject criteria;
   - reference to process and material specifications;
   - identification methods;
   - marking method and position;
   - 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.

4.6 Verification

4.6.1 General

The Supplier shall implement a QA programme to assure that satisfactory provisions are defined and implemented in order to verify that the requirements of ECSS–E–10 are met, and specifically that:

a. Requirement verification is performed progressively, as each stage of the project is completed, and provides the organised base of data upon which qualification and acceptance will be incrementally declared.

b. Top–down requirement allocations and bottom-up requirement verifications are complete and consistent.

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

d. Verification methods are adequate and consistent with the type and criticality of the requirements.

e. Appropriate reference to the verification documentation is recorded and status updated at project reviews up to final acceptance.

4.6.2 Design Verification Analysis

a. The Supplier shall implement a QA programme to assure that the objectives of the analysis are clearly defined in relation with the development logic defined in the verification plan.

b. The following items shall be identified:

- Reference of the Configuration Item definition under analysis.
- Environmental constraints considered in the analysis.
- Basic assumptions, analysis methods, mathematical models.

4.6.3 Design Reviews

a. The Supplier shall implement a QA programme to assure that:

1. Design reviews are conducted in accordance with the requirements of ECSS–M–30, and project requirements and written procedures.
2. Design reviews identify and anticipate problem areas and inadequacies, and initiate corrective actions to ensure that the final design will meet the requirements.

b. The Supplier shall ensure that:

1. Quality requirements and criteria for design, produceability, repeatability and testability are adequately considered in design documentation.
2. Methods and data required for procurement, manufacturing, inspection and test are available and validated.
3. Risks of not achieving requirements are highlighted and adequately controlled.

4.6.4 Qualification Process

4.6.4.1 Qualification

The Supplier shall implement a QA programme to assure that all Configuration Items and their constituent items, either off-the-shelf or specifically designed, are properly qualified with margins commensurate with the application and use environment.

4.6.4.2 Qualification by Similarity

a. Qualification by similarity with an identical or similar product shall be justified by providing evidence that the new application is within the limits of the previously qualified design.

b. Any difference in definition with respect to the reference product and any difference in the required Qualification tests shall be identified. The need for complementary Qualification tests shall be analysed and the decision justified and submitted to the customer for approval.

c. For this purpose, the Supplier shall:

   1. Evaluate the as–designed/as–built configuration and related nonconformances.
   2. Ensure that qualification requirements and qualification ranges are compatible with project requirements.
   3. Ensure that qualification test results meet the requirements and any nonconformances are available for evaluation.
   4. Ensure that a log book of the selected model is available for review.

4.6.4.3 Qualification Testing

a. The product used for Qualification testing shall be produced in accordance with a full and clearly identified manufacturing and inspection file.

b. To obtain authorisation to initiate qualification tests the Supplier shall demonstrate that:

   1. The qualification model is fully representative of the flight model and any differences have been analysed to evaluate their effect on the qualification status.
   2. Inspection and test requirements are expressed in an unambiguous and quantified manner including:
      * test sequence;
      * test conditions;
      * test standards, if any;
      * applicable test levels, duration and tolerances;
      * accuracy in measurement.
   3. The qualification test procedures and facilities are defined, available and conforming to requirements of clause 7.

4.6.4.4 Qualification Status Reporting

a. The Supplier shall track, record and periodically report to the Customer, the qualification status of all deliverable items as well the progress of the qualification programme.

b. Lists showing qualification status of items shall be made available at the various project reviews.

4.6.4.5 Maintenance of Qualification

Once the design has been qualified, all subsequent changes, deviations and anomalies shall be reviewed for their impact on the qualification status and requalified as necessary.

4.7 Design Changes

The Supplier shall implement a QA programme to assure that all design changes and modifications are identified, documented, reviewed and approved in accordance with ECSS–M–40 before their implementation.

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5

QA Requirements for Procurement

5.1 General

a. The Supplier shall control the procurement activity to ensure that all items and services procured conform to business agreement requirements.

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

5.2 Selection of Procurement Sources

5.2.1

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

5.2.2 Selection Criteria

a. The Supplier shall select its Suppliers on the basis of one of the following criteria:

1. The Supplier has been certified by the final Customer, and has a current approval to furnish items or services of the type and quality level being procured.
2. The Supplier is furnishing, or has furnished within the past two years, items or services of the type and quality level being procured under other contracts with the final Customer.
3. The Supplier has demonstrated continuous capability to furnish items or services of the type and quality level being procured. This capability shall be supported by objective documentation.

   This criterion shall not apply if the Supplier has not furnished items or services of the type being procured for more than two years.
4. Supplier's capability of satisfying business agreement requirements is demonstrated by a pre-award audit by the relevant Customer.

   The results of pre-award audits shall be documented and maintained on file.

b. Due consideration shall be given to a third party certification against ISO 9001, ISO 9002 and ISO 90003, as appropriate to the nature of the products or services to be procured.

c. The selection of procurement sources for EEE components shall be in accordance with ECSS–Q–60.

5.2.3 Record and List of Procurement Sources

a. The Supplier shall establish and maintain records of all procurement sources involved in business agreement performance.

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

5.3 Procurement Documents

5.3.1

The Supplier shall ensure that supplies are precisely identified and that all applicable requirements are properly defined in the procurement documents.

5.3.2

The Supplier shall pass on Customer PA requirements tailored to reflect the content and complexity of the subject of the procurement activity.

5.3.3

It shall be possible to demonstrate traceability from Customer requirements to those contained in lower tier procurement documents.

5.3.4

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 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, such as inspection and test characteristics, records and reports.

d. Details of Supplier's QA activities at source.

e. Special acceptance conditions.

5.3.5

The Supplier's Quality Assurance organisation shall review procurement documents prior to release, to verify the correct selection of procurement sources and appropriateness of their content.

5.3.6

A detailed list of the Product Assurance documentation to be supplied at the different stages of the project shall be agreed by the Customer in accordance with ECSS–M–50.

5.4 Surveillance of Procurement Sources

5.4.1

The Supplier shall exercise a surveillance over all the activities carried out by his Suppliers during business agreement performance.

5.4.2

The surveillance programme shall include, to the extent appropriate, audits, reviews (e.g. Manufacturing Readiness Review), Mandatory Inspection Points, as well as direct supervision by Supplier's resident personnel at his Suppliers' facilities and source inspection.

5.4.3

The Supplier shall consider the following criteria to define the most appropriate type and extent of surveillance:

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

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

c. Supplies are designated for direct shipment from source to a Customer site or the using site.

d. Manufacturing and AIV of complex equipment or subsystems (e.g. payloads).

e. Past performance or quality history of the lower level Supplier is marginal.

f. Functional criticality and technical complexity of the supplies.

g. The degree of responsibility placed on the procurement source.

5.4.4

a. The Supplier shall ensure that each of his Suppliers implements adequate surveillance on their lower level Suppliers, in accordance with the same criteria.

Surveillance may be delegated by the Customer to third parties, as defined in ECSS–M–20.

5.5 Receiving Inspection

5.5.1 General

a. The Supplier shall take appropriate actions to ensure that all incoming supplies, including documentation and packaging, whether delivered on his own premises or elsewhere, conform to the requirements of the procurement documents.

b. Inspections shall be performed in accordance with established procedures and instructions, to ensure that quality level is properly determined.

- Sampling plans in receiving inspection are defined in 3.9.2.
- Receiving inspection of components are defined in ECSS–Q–60.
- Lot/batch acceptance of materials are defined in ECSS–Q–70.

c. 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 the packaging conditions and of the status of environmental sensors.

b. Visual inspection of the delivered items.

c. Verification of correct identification and, where appropriate, configuration identification for conformance to the ordering data.

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

e. Verification of the performance of Supplier's source inspection, when required.

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

g. Identification of the shelf life of limited life items.

h. 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.

i. Prevention of unauthorised use of uninspected items.

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

k. Maintenance of Receiving Inspection Records (see 5.5.4).

5.5.3 Customer Furnished Items

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

b. Additional inspections and tests shall be as specified in the business agreement.

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.

6

QA Requirements for Manufacturing, Assembly and Integration

6.1 General

The Supplier shall ensure that the deliverables are built, assembled and integrated to the approved configuration baseline, in a planned, controlled and reproducible manner.

6.2 Planning of Manufacturing, Assembly and Integration Activities and Associated Documents

6.2.1

The Supplier, after a complete review of all requirements defined by the design and engineering documentation, shall plan manufacturing, assembly and integration operations in coordination with inspections and tests.

6.2.2

The planning of manufacturing, assembly and integration operations and inspections shall be reflected in flow charts for the product, which shall clearly depict the sequence of operations and associated inspections and tests. It shall include the identification of MIPs (see 6.9), together with the reference to the procedures by which the various activities are to be performed and the required cleanliness levels of facilities.

6.2.3

Adequate instructions, such as shop travellers, shall direct the actual performance of manufacturing, assembly and integration operations and inspections, to ensure that the activities proceed in an orderly manner and according to the planned sequence.

6.2.4

Manufacturing, assembly and integration documents shall be issued and maintained in accordance with established and formal procedures.

6.2.5

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

a. Identification of the item to be manufactured 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 manufacturing, assembly and integration of the item.

d. Identification of critical characteristics as defined in ECSS–Q–30, clause 4.3.

e. Detailed definition, by description or reference, of manufacturing, assembly, integration, inspections and test operations to be performed, and special conditions to be maintained.

f. Provisions for inspections and tests to be witnessed by customer representative.

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

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

i. Detailed procedures for the activities to be performed.

6.2.6

The Supplier shall also provide for detail support documents and instructions, such as operation drawings and operation instruction sheets, to enable operations to be correctly performed.

6.3 Manufacturing Readiness Review

6.3.1

The Supplier shall perform an internal review of the readiness for manufacturing, prior to start the manufacturing of the first flight–standard product.

6.3.2

The Manufacturing Readiness Review shall evaluate systematically the following aspects:

a. Status of product definition and requirements, differences with the status of the qualification model, and impacts of these differences.

b. Status of manufacturing, assembly, inspection and test documentation, differences with the status of the qualification model, and impacts of these differences.

c. Validation status of manufacturing processes, with particular emphasis on critical processes.

d. Implementation of adequate dispositions for risk reduction, as defined by risk assessment, into the manufacturing, assembly, integration, inspection and test procedures.

e. Availability of required production, measuring and inspection equipment, and calibration status, when relevant.

f. Cleanliness of facilities, with respect to the required cleanliness levels.

6.4 Control of Processes

6.4.1

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

b. All manufacturing processes shall be covered by documented process specifications / standards according to ECSS–Q–70.

c. Process specifications shall include QA provisions, methods for inspection and test, number of samples, accept/reject criteria.

d. Process witness samples shall be stored in proper conditions, as long as necessary.

6.4.2 Critical processes

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

a. Critical processes are validated for the intended application in accordance with ECSS–Q–70.

b. Personnel who perform critical processes or evaluate the process performance are trained and certified or can demonstrate their proficiency through their regular activity.

c. Materials, equipment, computer systems and software, 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.

6.4.3 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.

6.5 Workmanship Standards

6.5.1

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

6.5.2

Documentary workmanship specifications shall identify definite acceptance/rejection criteria.

6.5.3

a. Physical samples or visual aids shall be reviewed and agreed by the Customer when they are used for the purpose of acceptance/rejection of items.

b. Visual aids provided in ECSS–Q–xxx shall be used.

6.6 Materials and Parts Control

Requirements for the selection and control of materials and parts are defined in ECSS–Q–70.

6.6.1

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

6.6.2

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.

6.6.3

Sensitive items shall be processed or manufactured, inspected and tested in a controlled environment to prevent any degradation.

6.7 Equipment Control

6.7.1 Tooling

a. The Supplier shall make provisions for accountability, identification and maintenance of manufacture, assembly and integration tooling.

b. Manufacture, assembly and integration tooling shall be checked for its dimensional accuracy, regarding the product drawings, and correct function.

c. Tooling shall be approved by the Quality Assurance organisation prior to use. The approval shall be stamped on the equipment and recorded.

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

e. Tools shall be submitted to re-approval following modification.

f. Tools shall be properly stored to prevent misuse, damage and deterioration.

g. Unnecessary tools shall be removed from working areas.

h. Records shall be kept of all manufacture equipment.

6.7.2 Equipment for Computer–Aided Manufacturing

a. The Supplier shall ensure that computer–aided techniques and data for processing and machining are validated prior to use and controlled during their use in manufacturing.

b. In particular, provisions shall be made for the testing, approval and configuration control of the software involved and prevention of its being tampered with.

6.8 Cleanliness and Contamination Control

6.8.1

a. The Supplier shall establish controls for molecular and particulate cleanliness of spacecraft hardware and facilities, and the limitation of sources of contamination.

b. The controls to be applied shall be defined in a Cleanliness and Contamination Control Plan.

6.8.2 Cleanliness Levels

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

b. 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.

6.8.3 Cleaning Materials and Methods

The Supplier shall develop detailed methods for attaining the cleanliness levels required for the hardware.

6.8.4 Contamination Control

a. Contamination shall be prevented to the maximum extent possible by operating in clean working areas and by proper handling, preservation, packaging and storage.

b. 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.

c. 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.

6.8.5 Cleanliness of Facilities

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

6.9 Inspection

6.9.1

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

6.9.2

All critical characteristics identified in the critical item control programme shall be inspected, where feasible.

6.9.3

Self-inspection by the operators performing the associated manufacturing, assembly and integration activities shall not be considered sufficient for critical characteristics.

6.9.4

Among the inspections and tests as part of the manufacturing, assembly and integration flow, some selected inspections, called MIPs (Mandatory Inspection Points) shall be performed with participation of representatives from the final or next contractual Customer.

6.9.5

MIPs shall be agreed with the Customer.

6.9.6

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

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.

g. When testing or critical inspections cannot be accomplished by the Supplier (e.g. environments or test equipment not available at Supplier's facility).

h. When verification tests are destructive in nature and the quality cannot be verified solely by inspection or test at the Supplier's facility.

i. When manufacturing and AIV of complex equipment or subsystems (e.g. payloads) is planned

j. When past performance or quality history of the lower level Supplier is marginal

Criteria g. to j. shall be considered together with the criticality and complexity of the supplies and the Supplier's experience with the lower level Supplier.

k. When an item is going to final inspection

6.9.7

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

6.9.8

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

6.10 Specific Requirements for Assembly and Integration

6.10.1 Control of Temporary Installations and Removals

a. The Supplier shall ensure the management and control of flight items which are temporarily removed or non-flight items which are temporarily installed to facilitate assembly, integration, testing, handling or preservation of the end item.

b. 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.

c. Records of temporary installations and removals shall be established and maintained.

d. Temporarily installed items shall be accounted for to prevent their being incorporated in the final flight configuration.

6.10.2 Logbooks

a. The Supplier shall prepare and maintain system, subsystem and equipment logbooks in accordance with ECSS–Q–xxx, for all operations and tests performed on the item during the period to be covered by the logbook.

b. Equipment logbooks shall start with the first qualification or acceptance test after assembly.

c. Subsystem and system logbooks shall follow-on from the individual equipment logbooks to form a full record.

d. The logbook shall accompany the hardware whenever it is placed in the custody of another organisation and this organisation shall update it.

e. The logbooks shall contain historical and quality data and information which is significant for operation of the item, including nonconformances, deviations and open tasks.

6.11 Manufacturing, Assembly and Integration Records

Manufacturing, assembly and integration records shall be established and maintained, to provide all manufacturing, assembly, integration and inspection data required for traceability.

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7

Testing

7.1 Test Facilities

The Supplier shall ensure that test facilities, either internal or external, comply with ECSS–Q–2xx.

7.2 Test Equipment

7.2.1

The Supplier shall ensure that computer–aided testing techniques and data are validated prior to use and controlled during their use in testing. In particular, provisions shall be made for testing, approval and configuration control of the software involved and prevention of its being tampered with.

7.2.2

It shall be possible to verify the correct operation of all items of test equipment without having to apply them to the test item.

7.3 Test Documentation

7.3.1 Test Procedures

a. The Supplier shall implement a QA programme to assure that tests are performed in accordance with documented procedures, which shall include, as a minimum:

1. scope of the test, including the identification of the requirement being verified;
2. identification of the test object;
3. applicable documents, with their revision status;
4. test flow;
5. test organisation;
6. test conditions;
7. test equipment and set-up;
8. step-by-step procedure, including definition of specific steps to be witnessed by QA personnel;

9. recording of data;
10. pass/fail criteria and test data evaluation requirements;
11. guidelines / criteria for deviation from test procedure and for retest.

b. Test procedures and reports shall be reviewed and approved by the QA function.

7.3.2 Test Reports

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

a. reference to the applicable test procedure, and description of the deviations from it during the actual testing.

b. test data records and evaluation.

c. summary of test results.

7.4 Test Performance Monitoring

7.4.1

On the basis of an analysis of the Test Plan, the Supplier's QA function shall define within the Test Plan the most appropriate way to monitor the performance of test activities, to ensure the adherence to the test procedures, and that any deviations are properly documented and treated.

7.4.2

Test witnessing by Supplier's QA personnel shall be considered when manual intervention is performed, at the setting-up, start and end of continuous fully automated test sequences, or when no automatic recording of test parameters/results is available.

7.4.3

All testing activities related to critical characteristics as identified in the critical items control programme shall be certified.

7.4.4

Self-certification by the operators performing the test activities shall not be considered sufficient for critical characteristics.

7.4.5

Testing activities or results to be subject to formal QA certification shall be identified as such in the relevant test procedure.

7.4.6

Testing shall be subject to the requirements for the control of hazardous operations defined in ECSS–Q–40.

7.4.7

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

7.5 Test Reviews

7.5.1

The Supplier shall implement a QA programme to assure that formal reviews are performed before and after major portions of qualification or acceptance tests.

7.5.2

The QA function shall be represented in the formal boards established for the review of readiness for testing and testing accomplishment.

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8

QA Requirements for Acceptance and Delivery

8.1 General

8.1.1

The Supplier 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.

8.1.2

The Supplier 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

8.2.1

The Supplier shall provide an EIDP for each deliverable end item.

8.2.2

The EIDP shall constitute the basis for formal acceptance reviews.

8.2.3

The EIDP shall include the set of documents and records for further integration, testing and operation in higher level assemblies.

8.2.4

EIDPs shall be maintained and integrated into higher level EIDPs during subsystem/system integration and testing.

Detailed requirements for the contents of EIDPs are defined in ECSS–Q–2xx.

8.3 Delivery Review Board

8.3.1

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

8.3.2

The DRB functions at system level shall be fulfilled by the final acceptance review defined in the business agreement and chaired by the Customer.

8.3.3

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

a. Representatives of the receiving organisation :
   - Project Manager, or authorised representative, as chairman.
   - PA Manager, or authorised representative.
   - Engineering/Design Manager, or authorised representative.

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

c. Higher level Customers' representative(s), as observers (not required for separate sub-systems).

8.3.4

If the final Customer reserves the right to attend DRB's at any lower level as an observer, he shall be given due notice of such a DRB meeting.

8.3.5

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 deficiencies.

c. All nonconformances are closed-out, or corresponding plans, compatible with the delivery, are accepted.

d. The relevant EIDP is complete and accurate.

8.3.6

Delivery shall only be authorised by the unanimous agreement of the DRB members.

8.4 Preparation for Delivery

8.4.1 Packaging

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

Detailed requirements for packaging are defined in ECSS–Q–2xx.

8.4.2 Marking and Labelling

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

Detailed requirements for marking and labelling are defined in ECSS–Q–2xx.

8.5 Delivery

8.5.1 Shipping Control

a. The Supplier 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.

b. Accompanying documentation shall include the EIDP and, attached to the outside of the shipping container, the handling and packing/unpacking procedure and any relevant safety procedures.

8.5.2 Transportation

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

Detailed requirements for transportation are defined in ECSS–Q–2xx.

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9

Operations

9.1 General

The QA requirements for operations affect:

- the Space Segment
- space transportation system
- the mission products and services
- the Ground Segment
- the operators.

The operation of a system starts after final acceptance. Typically, it includes the subphases and activities defined in ECSS–E–70.

9.1.1

Reusable flight equipment shall be controlled at each reflight in the same manner as other equipment.

9.2 Basic Quality Concepts for Operations

9.2.1 Mission Quality

Mission quality is the totality of features and characteristics of a mission that bear on its ability to satisfy the customer requirements.

Mission quality includes:

- degree of achievement of the required performance levels;
- successful prediction of real-life environment;
- securing of adequate margins;
- validation of in-orbit test and calibration methods (including Ground Segment) ;
- availability of the delivered services (e.g. outages);
- performance of the logistic support;
- quality of mission products;
- service life.

9.2.2 Quality of Mission Products and Services

a. As part of the ground mission support, the QA function shall assure that:
   1. the products/results/services obtained from operating the system meet customer requirements and needs;
   2. the quality level of mission products is maintained throughout the specified mission lifetime.

b. Quality of mission products and services shall be agreed with their customers/users. Definition of quality includes parameters such as:
   1. timely availability of products and services;
   2. correctness of data;
   3. availability of data;
   4. permissible information degradation;
   5. maximum tolerable outages;
   6. user friendliness.

9.3 Validation and Qualification of Ground Support Segments

The Supplier shall ensure that operations validation and/or qualification of ground and space segments have been satisfactorily accomplished prior to the operational phase.

9.4 QA Requirements

9.4.1 QA Plan for Operations

a. The Supplier shall prepare, maintain and implement a QA Plan for operations or for major phases of the operations to describe how all QA applicable requirements will be implemented.

b. For all operational phases or subphases having different features, different hazards and different critical operational requirements, the QA Plan shall highlight those specific features and identify which corresponding QA provisions are made in order to satisfy mission requirements and minimise associated risks.

9.4.2 Operations Planning

The Supplier shall implement a QA programme to assure that operations are carried out in accordance with a planned and demonstrated process, and that all elementary operations including back–up operations, especially the critical ones (time critical, safety critical...), are covered by written procedures.

9.4.3 Operational Demonstration

a. The Supplier shall assure that a demonstration of the operational ability has been achieved prior to the start of an operational phase, through simulations of operations in a sufficiently representative environment, with regard to:
   1. physical environment: vacuum, microgravity, temperature ...;
   2. configuration of flight and ground segments, including hardware, software, databases, simulators;
   3. sequence of operations;
   4. operational procedures and associated tools;
   5. operators.

b. Major deviations from the operational environment shall be assessed for the impacts on the validity of the conclusions of the demonstration.

c. Demonstration of the operational ability shall specifically include:
   1. maintainability / availability;
   2. safety/human interface;
   3. environment;
   4. cleanliness;
   5. ability to supply products or services meeting quality requirements as expressed in 9.2.

d. Where an operational phase or subphase includes critical operations (safety, mission...), the related critical operations or all the operational phase or subphase demonstrations shall be approved by a Board independent of the Project.

e. The Board shall include space– and ground–segment representatives, Customer representatives and QA personnel of represented entities.

f. When the operational environment changes, the need to reperform the demonstration of operational ability shall be assessed.

9.4.4 Training and Operator Certification

a. The Supplier shall identify areas requiring training and operator certification for the operational phase.

b. Training shall be performed in an environment recognised as sufficiently representative of the real operational configuration, in particular for critical operations (emergency, time critical situations...).

c. When the operational environment changes, the need for additional training shall be assessed.

9.4.5 Operations Anomalies and Feedback Corrective Loop

a. The Supplier shall establish and maintain a documented system for the control of all nonconformances and anomalies detected at any stage during operations, and regarding:
   1. the spacecraft;
   2. operational documents and data;
   3. facilities, hardware and software related to operations;
   4. human errors;
   5. end product and services;
   6. complaints of final customer and users.

b. The system shall provide for an effective feedback loop to prevent recurrence. In general, the established system for the handling of any anomaly shall comply with the requirements of clause 3.6.

c. Competent and authorised personnel from quality assurance, engineering and operations shall be available and support the MRB functions in close cooperation with the flight control, training, mission centres as appropriate.

9.4.6 Alerts

Identified anomalies likely to recur during similar missions shall be reported in compliance with the provisions defined in 3.7.

9.4.7 Procedural Deviations

a. The QA function shall verify that deviations from nominal procedures defined in relevant documents such as user manuals, operations procedures and other operations-supporting documents are duly justified, documented and validated before application.

b. Deviations from the nominal procedures shall be validated prior to application.

c. When changes to procedures are implemented without validation, the QA function shall ensure that these changes have no impacts on the space segments safety and/or reliability or on the mission product quality.

d. Implementation of contingency procedures to meet an urgent safety demand, not identified by the initial operational procedures, shall be documented and traceable.

9.4.8 General Requirements

The following requirements shall be applied:

a. Cleanliness and Contamination Control (see 6.8)

b. Testing (see 7)

c. Acceptance and delivery (see 8)

d. Traceability (see 3.4)

Annex A (informative)

Ground Support Equipment

This annex is temporally introduced in ECSS–Q–20. It will be later transferred into one specific PA document (level 3).

A.1 General

Ground Support Equipment (GSE) is clarified as:

“Optical, mechanical, fluidic, electrical and software support equipment or systems used for calibration, measurements, testing, simulation, transportation, handling... of space segment or of space segment elements.”

A.2 Development

A.2.1 Design Quality Requirements for GSE

Design Quality requirements are strongly linked to the function to be implemented by the GSE item. Nevertheless, the following requirements will generally apply:

- Testability
- Availability (Reliability plus Maintainability)
- Safety
- Life duration
- Operability (Man/Machine Interface, completeness and clarity of operational procedures and manuals
- Ability to interface as necessary with space segment in a safe way.

A.2.2 Design and Verification

a. The Supplier shall implement a QA programme to assure that:

1. Internal design and verification standards are used or developed corresponding with the techniques to be used and fitting with the level of complexity of the items to be developed.
2. Major development risks are identified and appropriate back–up solutions are foreseen.
3. the verification method and process are tailored to:
   * the complexity of the item to be verified;
   * the criticality of the function to be implemented by the GSE item;

* the inherent criticality of the item itself.

b. As a minimum, all GSE requirements which affect the interface to flight hardware or affect safety shall be verified.

A.3 Configuration Control

The Supplier shall implement a QA programme to assure that a Configuration Control function is implemented covering all elements of the GSE, and allows, as a minimum:

a. to identify the baseline documentation and product definition associated with formal contractual milestones;

b. to trace subsequent modifications when affecting contractual requirements.

A.4 Production

A.4.1 Procurement

a. The Supplier shall ensure that selected Suppliers have a demonstrated ability to perform satisfactorily, through:

1. previous supply of items similar or more complex in the same field of techniques and technologies; and/or
2. certification covering similar design, development and production as applicable for similar items (see 5.2.2); and/or
3. evidence, documented by existing design, development, production and quality standards, of having similar experience associated with known success.

b. Procurement documents shall clearly identify qualification and receiving inspection requirements as appropriate, and comply with the requirements in 5.3.

A.4.2 Manufacturing, Assembly, Integration and Test

As a minimum, ISO 9002 requirements should be satisfied.

Unless proven necessary, the Supplier and his lower tier Suppliers should not deviate from their standard practices when these are already documented and recognised for similar items.

A.5 Delivery Phase

A.5.1 Acceptance Data Package

The Acceptance Data Package shall contain as a minimum:

a. the information regarding interfaces;

b. deviations from contractual requirements;

c. certification of conformance to an identified baseline;

d. data necessary to understand the functioning of the item, and to operate and maintain it in a safe and easy way;

e. safety data and/or certification(s).

A.5.2 Acceptance

a. Acceptance shall be achieved through a formal review process.

b. The acceptance process shall include:

1. acceptance plan;
2. necessary inspection and test procedures;
3. comprehensive inspection and test reports.

4. Acceptance may be through a simple inspection process for simple items.

A.5.3 Delivery Board

a. Acceptance of major elements of the GSE shall be granted by a Delivery Board.

b. The Delivery Board shall include QA representatives from the Supplier and the Customer.

A.5.4 Delivery

The requirements of the following sub–clauses are applicable to the delivery of ground items and handling, storage, packing and shipping activities:

a. Preparation for delivery (see 8.4)

b. Delivery (see 8.5)

c. Handling, storage, presentation (see 3.8)

A.6 General Requirements

The following requirements shall be tailored in accordance with the complexity and criticality of the GSE item:

a. Documentation and data control (see 3.1)

b. Traceability (see 3.4)

c. Metrology and calibration (see 3.5)

d. Nonconformance control system (see 3.6)

A.7 Maintenance

a. Maintenance activities shall be planned.

b. Maintenance demonstration shall be performed in order to prove that maintainability requirements are satisfied in the real operational environment.