
**Space systems — Programme
management — Quality assurance
requirements**

*Systèmes spatiaux — Management de programme — Exigences pour
assurance qualité*

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 27025 was prepared by Technical Committee ISO/TC 20, *Aircraft and space vehicles*, Subcommittee SC 14, *Space systems and operations*.

Introduction

This International Standard is intended to be applied for the management of quality assurance in space programmes and applications.

The formulation of this International Standard takes into account the existing International Standards prepared by ISO/TC 176 (notably ISO 9000, ISO 9001 and ISO 9004) and the content of ISO 14300-1 and ISO 14300-2.

For programme management, and as required in ISO 14300-2, the following concepts apply.

- The objective of quality assurance is to provide adequate confidence to the customer that the end product or service satisfies the requirements.
- The quality assurance policy is to ensure, in conjunction with other integrated project and product assurance functions, that required quality is specified, designed-in and will be incorporated, verified and maintained in the relevant hardware, software and associated documentation throughout all project phases, by applying a programme where
 - assurance is provided that all requirements are adequately specified,
 - design rules and methods are consistent with the project requirements,
 - each applicable requirement is verified through a verification programme which includes one or more of the following methods: analysis, inspection, test, review of design, audits,
 - design and performance requirements including the specified margin are demonstrated through a qualification process,
 - assurance is provided that the design is producible and repeatable, and that the specification of 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 such that the end item conforms to the applicable baseline,
 - a non-conformance control system is established and maintained in order to track non conformances systematically and to prevent reoccurrence,
 - records are maintained and analysed to report and detect trends in due time for preventive/corrective actions,
 - inspection, measuring and test equipment and tools in use on the contract are controlled to be accurate for their application,
 - procedures and instructions are established which provide for the identification, segregation, handling, packaging, preservation, storage and transportation of all items, and
 - assurance that the operations including post-flight and disposal are carried out in a controlled way and in accordance with the relevant requirements.

Requirements in this International Standard are defined in terms of what shall be accomplished, rather than in terms of how to organize and perform the necessary work. This allows existing organizational structures and methods to be applied, where they are effective, and for the structures and methods to evolve as necessary.

Space systems — Programme management — Quality assurance requirements

1 Scope

This International 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.

It is applicable to the customer-supplier relationship for space products to the extent agreed by both parties. The requirements of this International Standard and its associated referenced standards are tailored to the needs and classes of specific projects.

When viewed from the perspective of a specific project context, the requirements defined in this International Standard are tailored to match the genuine requirements of a particular profile and circumstances of a project.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000, *Quality management systems — Fundamentals and vocabulary*

ISO 14300-2, *Space systems — Programme management — Part 2: Product assurance*

ISO 14620-1, *Space systems — Safety requirements — Part 1: System safety*

ISO 14621-1, *Space systems — Electrical, electronic and electromagnetical (EEE) parts — Part 1: Parts management*

ISO 14621-2:2003, *Space systems — Electrical, electronic and electromagnetical (EEE) parts — Part 2: Control programme requirements*

ISO 23460, *Space projects — Programme management — Dependability assurance requirements*

ISO 23461, *Space systems — Programme management — Non conformance control system*

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000 and the following apply.

3.1.1

business agreement

agreement between two or more parties for the supply of goods or services

3.1.2

ground support equipment

GSE

optical, mechanical, fluidic, electrical and software support equipment or systems used, for example, for calibration, measurements, testing, simulation, transportation and handling of space segments or of space segment elements

3.1.3

tailoring

process by which individual requirements of specifications, standards and related documents are evaluated and made applicable to a specific project by selection, and in some exceptional cases, modification of existing or addition of new requirements

3.2 Abbreviated terms

3.2.1 General

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
NRB	nonconformance review board
QA	quality assurance
PA	product assurance

3.2.2 Abbreviated terms relating to document requirement definition

NOTE For document requirement definition for

- logbook see Annex B,
- EIDP see Annex C, and
- certificate of conformity see Annex D.

BB	breadboard
CI	configuration item
DRB	delivery review board
DRD	document requirements definition
DWI	deviation work item
EGSE	electrical ground support equipment
FGSE	fluidic ground support equipment

FM	flight model
KIP	key inspection point
ICD	interface control document
MGSE	mechanical ground support equipment
OGSE	optical ground support equipment
PM	project manager
PTR	post test review
PVS	procedure variation sheet
QM	qualification model
RFD	request for deviation
RFW	request for waiver
SOW	statement of work
TRB	test review board
TRR	test readiness review
WI	work item

4 QA programme management

4.1 QA programme

The supplier 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 performs satisfactorily in the intended environment;
- the approach adopted guarantees that the design is producible 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;

- g) fabrication, integration, test and maintenance are conducted in a controlled manner so that the end item conforms to the applicable baseline;
- h) a nonconformance control system is established and maintained in order to systematically track and prevent recurrence;
- i) records are maintained and analysed so that trends can be detected and reported in time to enable preventive or corrective actions to be taken;
- j) equipment and tools used for inspecting, measuring and testing project items are regularly calibrated to ensure their accuracy;
- k) procedures and instructions are established which provide for the identification, segregation, handling, packaging, preservation, storage and transportation of all items;
- l) 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.

4.2 Organization

General requirements for organization and responsibilities are defined in ISO 14300-2.

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

4.3 QA programme plan

The supplier shall prepare, maintain and implement a plan of the QA activities, in accordance with the general requirements in ISO 14300-2.

The plan may be part of the overall project product assurance plan.

4.4 QA status reporting

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.

4.5 Personnel training and certification

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

4.5.2 Operators performing critical processes shall be trained and certified by internal or external training programmes, or can demonstrate a regular and satisfactory use of the related skills.

4.5.3 Those inspecting or controlling critical processes, or performing non-destructive testing and evaluation, shall be trained and certified according to national or international training programmes and standards, or can demonstrate a regular and satisfactory use of the related skills.

4.6 QA programme audits

4.6.1 The supplier shall perform systematic audits on its own performance to verify the implementation and effectiveness of the provisions defined in the QA programme plan.

4.6.2 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.

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

4.6.4 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.

4.6.5 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 or higher-level customers of the audited supplier as relevant.

4.7 QA role in configuration management

4.7.1 The supplier shall ensure that configuration and data management rules are provided for, conform to those specified and are applied both by its own personnel and by its suppliers' personnel.

4.7.2 A supplier product assurance representative shall attend all boards established to review the suitability for release of drawings, plans, specifications, procedures and changes thereto.

4.7.3 During the configuration verification process the "as-built" configuration of hardware and software shall be certified against the latest approved manufacturing documentation.

4.7.4 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, and
- c) items to be delivered conform to the as-built documentation.

4.8 Critical items control

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 products, processes and technologies,
 - procurement, manufacturing, assembly, inspection, test, handling, storage and transportation, which can lead to major degradation in the quality of the product, and
 - product utilization or service implementation;
- b) contributing to the risk management activity 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.

5 Quality assurance general requirements

5.1 Documentation and data control

5.1.1 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 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 or knowledge preservation purposes are suitably identified and kept separately from the valid documentation;
- d) proper data and documentation exchange procedures and formats are set up throughout the project organization;
- 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 or organizations 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 or obsolete documents and data.

5.1.2 The supplier shall establish and maintain current product assurance data as defined by the business agreement.

5.2 Records

5.2.1 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.

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

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

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

5.2.5 Quality records shall be accessible to the customer upon request.

5.3 Stamp control

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

5.3.2 Stamps shall be used to

- a) signify the completion of operations and processes, and
- b) indicate inspection performance at source and incoming inspection, in process inspection and tests, final inspection, end point testing, storage and shipment.

5.3.3 The use of stamps shall be restricted to authorized personnel.**5.3.4** 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.

5.3.5 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 documentary determined and compatible with the articles and their use.

5.4 Traceability**5.4.1 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 make it possible to:
 - 1) establish bidirectional and unequivocal relationships between parts, materials or products and associated documentation or records;
 - 2) trace data, personnel and equipment related to procurement, fabrication, inspection, test, assembly, integration and operations activities;
 - 3) trace backwards the locations of materials, parts, sub-assemblies;
 - 4) trace forwards the locations of materials from raw stock and also for some critical items, as defined in the business agreement;
 - 5) monitor information such as input data, calculation codes, models and standards used.
- c) The level of traceability to be applied to an item shall be specified in technical specifications and drawings.

5.4.2 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 or 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 under uniform conditions; this identification applies when the items need not be individually distinguishable;
 - 3) serial numbers, to identify individual items for which unique data shall 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 authorized by the customer.
- d) Identification numbers shall be marked on documentation and, where possible, on respective items and parts.
- 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 and to provide safety of marking during the operational life.

5.4.3 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 or methods and retrieval methodology used in different activities, such as design, configuration control, purchase, manufacturing and quality control, are consistent and interrelated.
- d) The supplier shall assure that documents and the registration data are kept during the operational life.

5.5 Metrology and calibration

5.5.1 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.

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

5.5.3 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.

5.5.4 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.

5.5.5 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 recognized 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 5.2);
- g) assess and document the validity of previous inspection and test results when inspection, measuring or 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 that can invalidate the calibration setting.

5.5.6 Where test hardware (e.g. jigs, fixtures, templates and 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 rechecked at prescribed intervals. The supplier shall establish the extent and frequency of such checks and shall maintain records as evidence of control.

5.5.7 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 5.5, but shall be validated in a way appropriate to their usage.

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

5.6 Nonconformance control system

5.6.1 The supplier shall establish and maintain a non-conformance control system in accordance with the requirements of 5.6.2 to 5.6.13 and the detailed requirements in ISO 23461 specified below.

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

5.6.3 Non-conformances shall be classified as major or minor, on the basis of the severity of their consequences as specified in ISO 23461.

5.6.4 Major non-conformances shall be formally notified to the next customer, up to the level of the customer which specified the affected requirements.

5.6.5 Non-conformances shall be reviewed and dispositioned by a formal non-conformance review board (NRB), established at all contractual levels.

5.6.6 The disposition for a nonconforming item shall be one of the following:

- use as-is;
- return to supplier;

- rework;
- repair;
- scrap;
- as specified in ISO 23461.

5.6.7 The supplier shall ensure that:

- a) responsibilities and authorities for the disposition of nonconformances are properly defined;
- b) the NRB includes at least representatives from the PA and engineering organizations;
- 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 and all preventive actions are realized in full.

5.6.8 The supplier shall provide a precise definition of the authority and responsibilities assigned to its suppliers for non-conformance processing.

5.6.9 The proposed use of items that do not conform to requirements specified by the customer or approved baseline shall be handled in accordance with the waiver processing procedure as specified in ISO 23461.

5.6.10 Non-conformances shall be reviewed to identify the root causes and implement corrective actions to prevent recurrence.

5.6.11 The supplier shall maintain records of all non-conformances.

5.6.12 The supplier shall review periodically the non-conformance records to evaluate the effectiveness of the system and identify trends.

5.6.13 The supplier shall enter to the accompanying documentation the full information on all major nonconformances of products to specifications.

5.7 Alert system

5.7.1 Supplier participation

The supplier shall participate in the alert system established when the final customer has established the system for the prompt interchange of information on failures or problems which can affect more than one user, or can recur in other projects or circumstances, if no preventive actions are taken.

5.7.2 PA experts involvement

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, and
- the development of preventive actions.

5.7.3 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 or problems that can result in an alert, detected at any contractual level with granting concrete actions on prevention of failures;
 - 2) investigation of the failure or 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 participants in the alert system.
- b) An alert shall be issued only when all of the following criteria are met:
 - 1) the item with the observed failure or problem has multiple applications, which can have implications for more than one project, or more than one utilization within the project, thus requiring prompt action;
 - 2) the failure or problem has occurred in the application of an item within the specified design and usage limitations. However, failures or problems due to usage within reasonably expected limits of performance, but where these limits were not 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 or problem;
 - 4) the failures or problems are documentary confirmed not to be of a random nature.

5.7.4 Processing of alerts from other sources

The supplier shall process alerts distributed by the customer through

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

5.8 Handling, storage and preservation

5.8.1 Handling

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

- a) protection of items during handling,
- b) handling devices, and
- c) procedures and instructions.

5.8.2 Storage

- a) The supplier shall have secure storage areas available for
 - 1) incoming materials,
 - 2) intermediate items needing temporary storage, and
 - 3) end items before shipping.
- b) Limited-life materials, suspended limited-life materials, nonconforming items awaiting NRB disposition, scrap items and all other items which are designated 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 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.

5.8.3 Preservation

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 that ensure maximum protection consistent with life and usage.

5.9 Statistical quality control and analysis

5.9.1 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 and 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.

5.9.2 Sampling plans

- a) Sampling plans shall not be used when tests are non-destructive and the reduction in inspection or testing can jeopardize the fulfilment of the business agreement requirements.
- b) The supplier shall use existing international sampling plans to the maximum degree practicable.
- c) Sampling procedures shall be validated by the supplier's QA organization for the sample selection methods and criteria for inspection severity, acceptance or 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.

6 QA requirements for design and verification

6.1 General

The supplier's QA policy is to assure that:

- a) design and operational requirements are specified in terms of quantity or quality, clearly expressed and consistent;
- b) the design definition is expressed for each configuration item and their constituent items, in a way which ensures compatibility of configuration items among themselves and with system requirements;
- c) the customer requirements are understood and taken into account by the functions involved and any deviation properly resolved with the customer;
- d) methods, data and means (including software) required for each activity are developed, available and validated at the right moment;
- e) all technical risks are identified and provisions for their reduction are implemented;
- f) definition qualification criteria shall be established, and the definition is qualified on the basis of these criteria.

6.2 Planning

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 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 authorized person responsible or the customer prior to implementation, and the affected documentation is updated;
- d) the verification process is adequate (including, in particular, a clear test, test model and verification philosophy).

6.3 Organizational and technical interfaces

The supplier shall implement a QA programme to assure that:

- a) interfaces between different groups that provide inputs 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.

6.4 Design rules

6.4.1 General

The supplier shall ensure that the design rules and guidelines defined in the following subclauses are properly implemented in the design.

6.4.2 Producibility

- 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 organization 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;
 - 9) ways of manufacturing and the control if they are unique, assuring required quality of a product (for example, it is joint processing, etc.) should be specified.

6.4.3 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 minimize sensitivity of performances to variation in characteristics of parts, materials and processes;
 - 3) recommended manufacturing processes having proven repeatability;
 - 4) design criteria that optimize implementation of automated manufacturing methods, or computer-aided manufacturing;
 - 5) rationally-limited nomenclature of assortments of used account materials (greasing, oils, etc.).

6.4.4 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 or rejection 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 and feedback loops).

6.4.5 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.

6.5 Standards and procedures

6.5.1 General

The supplier shall establish and maintain standards and procedures for the preparation and maintenance of drawings and technical specifications.

6.5.2 Provisions

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
 - 1) functional performances and operational requirements, including dependability and safety requirements,
 - 2) applicable design and construction requirements proper to ensure producibility, repeatability, testability and operability of the product,
 - 3) required verifications methods as review of design, analysis, inspection or tests, including acceptance or rejection criteria,
 - 4) reference to process and material specifications,
 - 5) identification methods,
 - 6) marking method and position,
 - 7) required cleanliness levels, and

- 8) temperature and humidity levels.
- d) Physical and functional tolerances shall always be defined and controlled to avoid the use of irrational limits and to ensure interchangeability.

6.6 Verification

6.6.1 General

The supplier shall implement a QA programme to assure that satisfactory provisions are defined and implemented in order to verify that the project verification requirements are met, by ensuring that:

- a) Requirement verification is performed progressively, as each stage of the project is completed, and provides the organized base of data upon which qualification and acceptance is 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.

6.6.2 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:
 - 1) reference of the configuration item definition under analysis;
 - 2) environmental constraints considered in the analysis;
 - 3) basic assumptions, analysis methods, mathematical models.

6.6.3 Design reviews

- a) The supplier shall implement a QA programme to assure that design reviews
 - 1) are conducted in accordance with project requirements and written procedures, and
 - 2) identify and anticipate problem areas and inadequacies, and initiate corrective actions to ensure that the final design meets the requirements.
- b) The supplier shall ensure that
 - 1) quality requirements and criteria for design, producibility, repeatability and testability are adequately considered in design documentation,
 - 2) methods and data required for procurement, manufacturing, inspection and test are available and validated, and
 - 3) risks of not achieving requirements are highlighted and adequately controlled.

6.6.4 Qualification process

6.6.4.1 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.

6.6.4.2 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 or 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, and
 - 4) ensure that qualification data of the selected model are available for review.

6.6.4.3 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 authorization 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:
 - i) test sequence;
 - ii) test conditions;
 - iii) test standards, if any;
 - iv) applicable test levels, durations and tolerances;
 - v) accuracy in measurement.
 - 3) The qualification test procedures and facilities are defined, available, and conform to the requirements of Clause 9.

6.6.4.4 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.

6.6.4.5 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.

6.7 Design changes

The supplier shall implement a QA programme to assure that all design changes and modifications are identified, documented, reviewed and approved before their implementation.

7 QA requirements for procurement

7.1 General

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.

7.2 Selection of procurement sources

7.2.1 General

The supplier quality assurance organization shall participate in and approve the selection of procurement sources.

7.2.2 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 a period previously defined and approved with the customer.
 - 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 may be given to a third-party certification (e.g. ISO 9001) where 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 ISO 14621.

7.2.3 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.

7.3 Procurement documents

7.3.1 General

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

7.3.1.2 The supplier shall pass on customer PA requirements tailored to reflect the content and complexity of the subject of the procurement activity.

7.3.1.3 The supplier shall ensure that requirements contained in all levels of procurement documents are traceable and can be demonstrated.

7.3.2 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 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, and
- e) special acceptance conditions.

7.3.3 Review of procurement documents

The supplier's quality assurance organization shall review procurement documents prior to release, to verify the correct selection of procurement sources and appropriateness of their content.

7.3.4 Product assurance documentation to deliver

A detailed list of the product assurance documentation to be delivered at the different milestones of the project shall be agreed by the customer.

7.4 Surveillance of procurement sources

7.4.1 General

The supplier shall exercise surveillance over all the activities carried out by its suppliers during business agreement performance.

7.4.2 Surveillance programme

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 its suppliers' facilities and source inspection.

7.4.3 Criteria for surveillance

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) Functional criticality and technical complexity of the supplies.
- f) The degree of responsibility placed on the procurement source.
- g) Past performance or quality history of the lower level supplier is marginal.

7.4.4 Surveillance of lower level suppliers

The supplier shall ensure that each of its 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.

7.5 Receiving inspection

7.5.1 General

- a) The supplier shall take appropriate actions to ensure that all incoming supplies, including documentation and packaging, whether delivered on its 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.
 - 1) Sampling plans in receiving inspection are defined in 5.9.2.
 - 2) Receiving, inspection, handling and storage of components shall be as defined in ISO 14621-2:2003, 5.19.
 - 3) Lot or batch acceptance of materials is defined by documented process specifications or standards.
- c) Receiving inspectors shall have available the procurement documents, specifications, drawings and any other document relevant to incoming supplies as required in the procurement documents.

7.5.2 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 inspections and tests on selected characteristics of incoming supplies 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:
 - 1) items for which the receiving inspection has not been completed;
 - 2) conforming items;
 - 3) nonconforming items;
- i) prevention of unauthorized 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 7.5.4).

7.5.3 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.

7.5.4 Receiving inspection records

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

8 QA requirements for manufacturing, assembly and integration

8.1 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.

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

8.2.1 General

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.

8.2.2 Planning content

The planning of manufacturing, assembly and integration operations and inspections shall be reflected in the manufacturing plan or flow chart for the product, which shall clearly depict the sequence of operations and associated inspections and tests. It shall include the identification of KIPs and MIPs (see 8.9), together with the reference to the procedures by which the various activities are performed and the required cleanliness levels and temperature and humidity requirements of the facilities.

8.2.3 Adequate instructions, such as shop travellers which describes and records the flow of an item through the manufacturing process and is associated with the item, 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.

8.2.4 Manufacturing, assembly and integration documents

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

8.2.5 Documents review

8.2.5.1 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 (e.g. tools, jigs and fixtures) to be used for the manufacturing, assembly and integration of the item,
- d) identification of critical characteristics as defined in ISO 23460,
- 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 or reject criteria (with tolerances) and workmanship standards,
- h) details of sampling inspection procedures to be used, if any, and
- i) detailed procedures for the activities to be performed.

8.2.5.2 Only newly-created shop travellers shall be reviewed unless subsequent travellers incorporate a significant change of inspection requirements or order of events.

8.2.6 Support documents and instructions

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

8.3 Manufacturing readiness reviews

8.3.1 General

The supplier shall perform an internal review of the readiness for manufacturing, prior to starting the manufacture of the first flight-standard product.

8.3.2 Objectives

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;
- g) facility temperature and humidity with respect to requirements.

8.4 Control of processes

8.4.1 General

- 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 or standards.
- c) Process specifications shall include QA provisions, methods for inspection and test, number of samples, accept or reject criteria.
- d) Process witness samples shall be stored in proper conditions, as long as necessary.

8.4.2 Critical processes

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

- a) critical processes are validated for the intended application by documented process specifications or standards,
- 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, and
- d) coordination is maintained with the cognizant engineering function to ensure proper selection of the non-destructive or destructive methods for the evaluation of process performance.

8.4.3 Statistical process control

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

8.5 Workmanship standards

8.5.1 General

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

8.5.2 Identification of criteria

Workmanship standards shall identify acceptance or rejection criteria.

8.5.3 Samples

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

8.6 Materials and parts control

8.6.1 General

Requirements for the selection and control of materials and parts are defined by documented process specifications or standards.

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.

8.6.2 Items marks

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

8.6.3 Sensitive items

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

8.7 Equipment control

8.7.1 Tools

- a) The supplier shall make provisions for accountability, identification and maintenance of manufacture, assembly and integration tools.

- b) Manufacture, assembly and integration tools shall be checked for its dimensional accuracy, regarding the product drawings, and correct function.
- c) Tools shall be approved by the quality assurance organization prior to use. The approval shall be stamped on the tools 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 manufacturing tools.

8.7.2 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.

8.8 Cleanliness and contamination control

8.8.1 General

- 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 consistent with requirements as defined in 8.8.2 b).

8.8.2 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.

8.8.3 Cleaning materials and methods

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

8.8.4 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.

8.8.5 Cleanliness of facilities

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

8.9 Inspection

8.9.1 General

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.

8.9.2 Critical characteristics

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

8.9.3 Self-inspection

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

8.9.4 Mandatory inspection points (MIPs)

Among the inspections and tests as part of the manufacturing, assembly and integration flow, some selected inspections among key inspection points (KIPs) performed by the supplier, called mandatory inspection points (MIPs) shall be performed with participation of representatives from the final or next contractual customer.

8.9.5 MIPs agreement

MIPs shall be agreed with the customer.

8.9.6 MIPs selection

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:
 - 1) is irreversible, or
 - 2) makes the item difficult and costly to disassemble for inspection, or
 - 3) renders the location inaccessible for inspection.
- d) When the item, once installed in the next higher assembly damages by its failure the higher assembly.
- e) When previous failure history of the item indicates a need for inspection.

- 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.
- k) When an item is going to final inspection.

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.

8.9.7 MIPs invitation

A 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.

8.9.8 Inspection and tests status identification

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.

8.10 Specific requirements for assembly and integration

8.10.1 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.

8.10.2 Logbooks

- a) The supplier shall prepare and maintain system, subsystem and equipment logbooks in accordance with DRD in Annex B 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 organization and this organization 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.

8.11 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.

9 Testing

9.1 General

The requirements of this chapter shall be applicable, in particular, to development, qualification and acceptance tests, including the maintenance of qualification.

9.2 Test facilities

The supplier shall ensure that test facilities, either internal or external, conform to the business agreement requirements.

9.3 Test equipment

9.3.1 General

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.

9.3.2 Verification of test equipment

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

9.4 Test documentation

9.4.1 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 organization;
 - 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 or fail criteria and test data evaluation requirements;
 - 11) guidelines or criteria for deviation from test procedure and for retest.
- b) Test procedures and reports shall be reviewed and approved by the QA function.

9.4.2 Test reports

The supplier shall ensure that all tests 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.

9.5 Test performance monitoring

9.5.1 General

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.

9.5.2 Test witnessing

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 or results is available.

9.5.3 Test of critical characteristics

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

9.5.4 Self-certification for test activities

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

9.5.5 Testing activities subject to QA certification

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

9.5.6 Testing of hazardous operations

Testing shall be subject to the requirements for the control of hazardous operations defined in ISO 14620-1.

9.5.7 QA authority

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.

9.6 Test reviews

9.6.1 General

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

9.6.2 QA function representation

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

10 QA requirements for acceptance and delivery

10.1 General

10.1.1 Acceptance process

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.

10.1.2 Preparation of items for delivery

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.

10.2 End item data package

10.2.1 General

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

10.2.2 Basis for formal acceptance

The EIDP shall constitute the basis for formal acceptance reviews.

10.2.3 EIDP objectives

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

10.2.4 EIDP content

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

Detailed requirements for the contents of EIDPs are defined in DRD in Annex C.

10.3 Delivery review board (DRB)

10.3.1 General

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

10.3.2 DRB functions

The DRB functions shall be fulfilled by the final acceptance review defined in the business agreement and chaired by the customer.

10.3.3 DRB composition

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

- a) Representatives of the receiving organization:
 - 1) Project manager, or authorized representative, as chairman;
 - 2) PA manager, or authorized representative;
 - 3) Engineering or design manager, or authorized representative.
- b) Submitting supplier's representatives:
 - 1) Project manager, or authorized representative;
 - 2) PA manager, or authorized representative;
 - 3) Engineering or design manager, or authorized representative.
- c) Higher-level customers' representatives, as observers.

10.3.4 Customer participation

If the final customer reserves the right to attend DRBs at any lower level as an observer, they shall be given due notice of such a DRB meeting.

10.3.5 DRB responsibilities

The DRB shall be responsible for authorising the shipment of the items under acceptance, and certifying in 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.

10.3.6 Delivery authorization

Delivery shall only be authorized by the unanimous agreement of the DRB members and the certificate of conformity (see DRD in Annex D) is available and signed by the supplier responsible.

10.4 Preparation for delivery

10.4.1 Packaging

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 their arrival at destination.

10.4.2 Marking and labelling

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

10.5 Delivery

10.5.1 Shipping control

- a) The supplier shall ensure that the items to be shipped from its plant are inspected before release and found to be complete, adequately preserved and packaged, correctly marked and accompanied by all the required documentation.
- b) Accompanying documentation shall include the EIDP and, attached to the outside of the shipping container, the handling and packing or unpacking procedure and any relevant safety procedures.

10.5.2 Transportation

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

11 Operations

11.1 General

The QA requirements for operations affect

- the space segment,
- the space transportation system,
- the mission products and services,
- the ground segment, and
- the operators.

The operation of a system starts after final acceptance.

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

11.2 Basic quality concepts for operations

11.2.1 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, and
- service life.

11.2.2 Quality of mission products and services

- a) As part of the ground mission support, the QA function shall assure that
 - 1) the products, results, or services obtained from operating the system meet customer requirements and needs, and
 - 2) the quality level of mission products is maintained throughout the specified mission lifetime.
- b) Quality of mission products, or services shall be agreed with their customers or users. Definition of quality includes such parameters as
 - 1) timely availability of products and services,
 - 2) correctness of data,
 - 3) availability of data,
 - 4) permissible information degradation,
 - 5) maximum tolerable outages, and
 - 6) user friendliness.

11.3 Validation of the system

Both the ground and space segment shall be validated before the system is declared operational.

11.4 QA requirements

11.4.1 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 are 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 conform to mission requirements and minimize associated risks.

11.4.2 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 (e.g. time critical, and safety critical) are covered by written procedures.

11.4.3 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, such as vacuum, microgravity and temperature,
 - 2) configuration of flight and ground segments, including hardware, software, databases, and simulators,
 - 3) sequence of operations,
 - 4) operational procedures and associated tools, and
 - 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 or availability,
 - 2) safety or human interface,
 - 3) environment,
 - 4) cleanliness, and
 - 5) ability to supply products or services meeting quality requirements as expressed in 11.2.
- d) Where an operational phase or subphase includes critical operations (e.g. safety, and 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.

11.4.4 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 recognized as sufficiently representative of the real operational configuration, in particular for critical operations (e.g. emergency, and time critical situations).
- c) When the operational environment changes, the need for additional training shall be assessed.

11.4.5 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, with regard to
 - 1) the spacecraft,
 - 2) operational documents and data,

- 3) facilities, hardware and software related to operations,
 - 4) human errors,
 - 5) end product and services, and
 - 6) complaints from 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 conform to the requirements of 5.6.
 - c) Competent and authorized personnel from quality assurance, engineering and operations shall be available and support the NRB functions in close cooperation with the flight control, training, and mission centres as appropriate.

11.4.6 Alerts

Identified anomalies likely to recur during similar missions shall be reported in conformance to the provisions defined in 5.7.

11.4.7 Procedural deviations

- a) The QA function shall verify that deviations from procedures defined in relevant documents such as user manuals, operations procedures and other operations-supporting documents are justified, documented and validated before application.
- b) When changes to procedures are implemented without validation, the QA function shall ensure that these changes have no impacts on the space segments safety or reliability or on the mission product quality.
- c) Implementation of contingency procedures to meet an urgent safety demand, not identified by the initial operational procedures, shall be documented and traceable.

11.4.8 General requirements

The following requirements shall be applied:

- a) cleanliness and contamination control (see 8.8);
- b) testing (see Clause 9);
- c) acceptance and delivery (see Clause 10);
- d) traceability (see 5.4).

Annex A (informative)

Ground support equipment (GSE)

A.1 General

For the definition of GSE, see 3.1.2.

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 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 anticipated;
 - 3) the verification method and process are tailored to the
 - complexity of the item to be verified,
 - criticality of the function to be implemented by the GSE item, and
 - inherent criticality of the item itself.
- b) As a minimum, all GSE requirements that 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, as a minimum, allows to:

- a) identify the baseline documentation and product definition associated with formal contractual milestones, and
- b) 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,
 - 2) certification covering similar design, development and production as applicable for similar items (see 7.2.2), 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 conform to the requirements in 7.3.

A.4.2 Manufacturing, assembly, integration and test

Unless proven necessary, the supplier and its lower-tier suppliers should not deviate from their usual practices when these are already documented and recognized for similar items.

A.5 Delivery

A.5.1 End item data package

The acceptance data package shall contain as a minimum:

- a) 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, and
- e) safety data 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.

NOTE Acceptance can 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 listed subclauses are applicable to the delivery of ground items and handling, storage, packing and shipping activities:

- a) preparation for delivery (see 10.4);
- b) delivery (see 10.5);
- c) handling, storage and preservation (see 5.8).

A.6 General requirements

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

- a) documentation and data control (see 5.1);
- b) traceability (see 5.4);
- c) metrology and calibration (see 5.5);
- d) nonconformance control system (see 5.6).

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.

Annex B (informative)

Logbook — Document requirements definition

B.1 Scope and applicability

B.1.1 Scope

This document requirements definition (DRD) establishes the data content requirements for the logbooks.

This DRD does not define format, presentation or delivery requirements for the logbooks, which can vary depending on product level (i.e. equipment, subsystem, and system) and specific contractual requirements.

B.1.2 Applicability

This DRD is applicable to all projects using International Standards.

B.2 References

B.2.1 Glossary and dictionary

This DRD uses terminology and definitions controlled by ISO 9000.

B.2.2 Source document

This DRD defines the data requirements of the logbooks required by 8.10.2.

B.3 Definitions, abbreviated terms and symbols

B.3.1 Definitions

For the purposes of this DRD the terms and definitions given in ISO 14300-2 apply.

B.3.2 Abbreviated terms

For abbreviated terms, see 3.2.

B.4 Description and purpose

The logbook is the document in which the data related to the integration and testing of a configuration item are recorded in chronological order to provide the necessary events traceability at any time during the programme life cycle, beginning with the first qualification or acceptance test.

This document shall be included in the EIDP to allow a full visibility of the product history during the acceptance of the deliverable hardware by the customer.

B.5 Application and interrelationship

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

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

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

The logbooks shall contain historical and quality data and information that is significant for the operation of the item.

The logbooks shall be used to perform the intermediate TRRs or PTRs, KIPs, MIPs, and included in the EIDP for the formal product acceptance review.

B.6 Logbook general information

B.6.1 Title

This document shall be titled "Logbook"

Proper references shall be selected to clearly identify the product and the relevant applicable documents, for example:

- configuration item description;
- programme;
- serial number;
- part number;
- model;
- contract number.

B.6.2 Cover page

The cover page for this document (see Figure B.1 for an example) shall carry the project document identification number, title of the document (including project identification), date of release and release authority.

The "contents" section shall identify the title and location of every section, figure, table and annex contained in the document.

B.7 Content

B.7.1 Cover page

The logbook cover page shall contain the following:

- general information,
- contents,

- approvals of the relevant authorities (QA, PA, PM), and
- customer acceptance (if required by the contract).

B.7.2 Section 1

This section shall contain the “hardware configuration and traceability” table, which reports all the identification references of single elements composing the CI.

B.7.3 Section 2

This section shall contain the “hardware configuration change and status” table, which reports for each single element of the CI all the events relevant to integration, removal and replacement on the higher-level.

B.7.4 Section 3

This section shall contain the summary list of the integration and test instructions, such as shop traveller.

For each entry, the action start date, action performed date and action close-out date shall also be reported.

B.7.5 Section 4

This section shall contain the summary list of non conformances with relevant identification references, issue date, closure dates and status, plus copy of major NCR.

B.7.6 Section 5

This section shall contain, where applicable, the electrical connector (or other limited cycles items) mate and demate cycles in order to ensure the conformance with the project requirements.

B.7.7 Section 6

This section shall contain the records of total operating hours for each limited-life element identified in the test procedures.

B.7.8 Section 7

This section shall contain, in chronological order, the events related to the integration and test activities performed on the relevant item (i.e. system, subsystem, and equipment).

On a case-by-case basis, the following subsections shall be included.

- Action requested form: reporting all the operations performed with the references to the applicable documents or procedures, start date, completion date and quality inspection stamps.
- Step by step procedures and results: in which copies of the as-run procedures are included in a suitable format.
- Procedures variation form: in which copies of modified procedures (red marked) identified with a procedure variation number and duly approved by responsible authorities, are included.

B.7.9 Section 8

This section shall contain the list of open action or open test at the time of the product shipment to the customer, test facility or launch pad.

Logbook General information			Log No.	
			Model	
			Sheet 1 of 1	
Program	Item name	Item part no.	Item serial no.	
Customer	Contract no.	Log start date	Log finish date	
Contents:				
Section 1	Hardware configuration and traceability	Total Sheets		
Section 2	Hardware configuration change and status	" "		
Section 3	Shop traveller list (or similar documents)	" "		
Section 4	Non conformances summary list	" "		
Section 5	Connectors mate and demate	" "		
Section 6	Operating hours log	" "		
Section 7	Log of actions	" "		
Section 7.1	Action requested	" "		
Section 7.2	Additional actions undertaken	" "		
Section 7.3	Step by step procedure and results	" "		
Section 8	Open works	" "		
Date programme manager acceptance:		Date PA manager acceptance:		
Customer acceptance: 				
Date: _____		Customer signature: _____		

Figure B.1 — Example of logbook cover page