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Space systems — Programme management — Quality assurance requirements

Systèmes spatiaux — Management de programme — Exigences pour assurance qualité

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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:

a) all requirements are specified through definition and implementation of adequate methods and procedures;

b) a set of design rules and methods has been set up and is consistent with the project techniques and technologies;

c) 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;

d) 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;

e) 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;

f) 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;