SLOVENSKI STANDARD
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Space product assurance - General requirements - Part 2: Quality assurance

Space product assurance - General requirements - Part 2: Quality assurance

Raumfahrtproduktsicherung - Allgemeine Anforderungen - Teil 2: Qualitätssicherung

Assurance produits des projets spatiaux - Exigences générales - Partie 2: Assurance qualité

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Space product assurance - General requirements - Part 2: Quality assurance

Assurance produits des projets spatiaux - Exigences générales - Partie 2: Assurance qualité

Luft- und Raumfahrt - Raumfahrtproduktsicherung - Teil 2: Qualitätssicherung

This European Standard was approved by CEN on 22 October 2003.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Foreword

This document (EN 13291-2:2003) has been prepared by CMC.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2004, and conflicting national standards shall be withdrawn at the latest by June 2004.

It is based on a previous version[1)] originally prepared by the ECSS Product Assurance Working Group, reviewed by the ECSS Technical Panel and approved by the ECSS Steering Board. The European Cooperation for Space Standardization (ECSS) is a cooperative effort of the European Space Agency, National Space Agencies and European industry associations for the purpose of developing and maintaining common standards.

EN 13291 Space product assurance is published as four parts:

— Part 1: Policy and principles

— Part 2: Quality assurance

— Part 3: Materials, mechanical parts and processes

— Part 4: Software product assurance

This Standard is one of the series of space standards intended to be applied together for the management, engineering and product assurance in space projects and applications.

Requirements in this 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 without rewriting the standards.

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

Annexes A and C are informative. Annexes B and D are normative.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

1) ECSS-Q-20B.

1 Scope

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

This European Standard is applicable to the customer-supplier relationship for space products to the extent agreed by both parties. The requirements of this standard and its associated level 3 standards should be tailored to the needs and classes of specific projects.

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

NOTE Tailoring is a process by which individual requirements or 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.

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

2 Normative references

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

EN 13291-1, *Space product assurance — General requirements — Part 1: Policy and principles.*

EN 13701:2001, *Space systems — Glossary of terms.*

EN 14097, *Space product assurance — Nonconformance control system.*

EN 14725, *Space engineering — Verification.*

EN ISO 14620-1, *Space systems — Safety requirements — Part 1: System safety (ISO 14620-1:2002).*

ECSS-Q-30, *Space product assurance — Dependability.*

ECSS-Q-60, *Space product assurance — Electrical, electronic and electromechanical (EEE) components.*

EN ISO 9001, *Quality management systems — Requirements (ISO 9001:2000).*

EN 13291-3, *Space product assurance — General requirements — Part 3: Material, mechanical parts and processes.*

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

For the purposes of this European Standard, the terms and definitions given in EN 13701:2001 apply.

3.2 Abbreviated terms

The following abbreviated terms are defined and used within this European Standard:

Abbreviation	Meaning
AIV	assembly, integration, verification
DRB	delivery review board
EEE	electrical, electronic, electromechanical
EIDP	end item data package
GSE	ground support equipment
MIP	mandatory inspection point
NRB	nonconformance review board
QA	quality assurance
PA	product assurance

4 Quality assurance programme management

4.1 Quality assurance programme

The contractor 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) approach adopted guarantees that the design is producable and repeatable and that the resulting product can be verified and operated within the required operating limits;

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) quality 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 EN 13291-1.

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

4.3 Quality assurance programme plan

The supplier shall prepare, maintain, and implement a plan of the QA activities, in accordance with the general requirements in EN 13291-1.

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 (as defined in EN 13291-3) shall be trained and certified by internal or external training programmes accepted by the customer, 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 accepted by the customer, or can demonstrate a regular and satisfactory use of the related skills.

4.6 Quality assurance programme audits

4.6.1

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

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. No external audit shall be performed without the customer being given due notice.

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 his own personnel and by his 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, and

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) 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;

d) proper data and documentation exchange procedures and formats are set up throughout the project organization;

e) 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 Quality 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 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 provide for the ability 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.

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.

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.

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.

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 subclause 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.