SLOVENSKI STANDARD
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Space product assurance - Nonconformance control system

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Raumfahrtproduktsicherung - Nichtkonformitäts-Kontrollsystem

Assurance produit des projets spatiaux - Instruction et traitement des anomalies

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Space product assurance - Nonconformance control system

This European Standard was approved by CEN on 28 September 2001.

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.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This European Standard 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of an identical text or by endorsement, at the latest by April 2002, and conflicting national standards shall be withdrawn at the latest by April 2002.

It is based on a previous version[1] prepared by the ECSS Product Assurance Standards 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.

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.

Annex A is informative. Annex B is normative.

This standard includes a Bibliography.

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, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

As part of the space product assurance standards, this Standard gives specific requirements about the nonconformance control system relating to space projects.

The content of this space standard is coherent with the widely known and used processes for preparing and managing the different structures of projects in many fields of activity throughout the world.

1 Scope

This European Standard defines the control system for nonconformances related to any aspect of a space project, including EEE component nonconformances, software problems, operational nonconformances and anomalies.

This Standard applies to all deliverables, at all levels, which fail to conform to specified requirements and design baselines.

This Standard is applicable throughout

- procurement, production, qualification, integration and test phases,

[1)] ECSS-Q-20-09A.

- acceptance, delivery and transportation phases,
- launch preparation phase and flight/launch readiness,
- operational validation/qualification phase,
- operational phase, and
- refurbishment phase.

This Standard defines also requirements for the interfaces with third party internal nonconformance reporting and processing.

Engineering changes are not a subject of this Standard.

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 13701, *Space systems - Glossary of terms.*

EN 13291-1:1999, *Space product assurance — General requirements — Part 1: Policy and principles.*

ECSS-Q-20A, *Space product assurance — Quality assurance.*

ECSS-Q-80A, *Space product assurance — Software Product Assurance.*

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

For the purposes of this European Standard, the terms and definitions of EN 13701 and the following term and definition apply.

3.1.1
waiver
written authorization to use or release a product which does not conform to the specified requirements

NOTE A waiver is limited to the shipment of a product that has specific nonconforming characteristics within specific deviations, for a limited time or quantity.

[ISO 8402:1994]

3.2 Abbreviated terms

The following abbreviated terms are defined and used within this Standard.

Abbreviation **Meaning**

CIDL	configuration item data list
CIL	critical item list
COTS	commercial off-the-shelf
DJF	design justification file
EEE	electrical, electronic, electromechanical
FMECA	failure mode effect and criticality analysis
NCR	nonconformance report
NRB	nonconformance review board (formerly known as material review board or MRB)
PA	product assurance
QA	quality assurance
RAMS	reliability, availability, maintainability, safety
RFW	request for waiver
SCC	space component coordination
SPR	software problem report

4 Nonconformance control system - Basic requirements

4.1 General principles

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

b) Special attention shall be paid to:

- corrective actions against root causes, to avoid recurrence for other products;
- prompt and effective communication between suppliers and customers;
- the prevention of nonconformance occurrence, from the analysis of nonconformance records and derived lessons learned.

c) The supplier shall document implementation of the nonconformance control system.

4.2 Nonconformance classes

a) Nonconformances shall be classified as major or minor, based on the severity of their consequences, as defined in ECSS-Q-20. Classification of nonconformances is not based on their consequences on cost and schedule.

b) Major nonconformances shall be those which can have an impact on the customer's requirements in the following areas:

1) safety of people or equipment;

2) operational, functional or any technical requirements imposed by the business agreement;

3) reliability, maintainability, availability;

4) lifetime;

5) functional or dimensional interchangeability;

6) interfaces with hardware or software regulated by different business agreements;

7) changes to or deviations from approved qualification or acceptance test procedures;

8) project specific items which are proposed to be scrapped;

9) for EEE components, in case of:

i) lot/batch rejection during manufacturing, screening or testing at the manufacturer's facilities, if the purchaser proposes:

* to use as-is the rejected lot/batch, or

* to continue processing, rework or testing, although the lot/batch does not comply with the specified requirements.

ii) nonconformances detected after delivery from the manufacturer.

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

d) The following EEE discrepancies after delivery from the manufacturer may be classified as minor:

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

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

f) The consequences of several different minor nonconformances on the same item shall be evaluated for proper classification.

4.3 Nonconformance review board (NRB)

4.3.1 General

a) The NRB shall be the sole technical authority for the treatment of nonconformances occurring in the frame of a business agreement.

b) All NRB dispositions and decisions shall be made by consensus by all members.

c) In case of conflict, higher management levels shall be involved.

d) The independence of PA from the project management organization shall be maintained in accordance with EN 13291-1, 4.3.3.

4.3.2 Internal NRB

a) The supplier shall nominate and authorize the internal NRB's core members for the business agreement.

b) The responsibilities and authorities of each member shall be documented.

c) The internal NRB shall include, at least, core members from the following areas:

- Project PA (chairman);
- Engineering.

d) The chairman shall nominate additional members, or experts, depending on the nonconformance report (NCR) subject.

e) The internal NRB shall be responsible for the correct application of this Standard and its proper interfacing with internal nonconformance reporting and processing.

4.3.3 Customer NRB

For major nonconformances (see 4.2) the participation of the customer in the NRB is mandatory.

a) As a minimum, the internal NRB shall be enlarged by

- Customer's PA representative (chairman),
- Customer's Engineering representative.

b) Also in this case, the chairman shall nominate additional members, or experts, depending on the NCR subject.
The customer's representatives may, with the supplier's agreement, invite observers or consultants from higher customer level, depending on the impacts of the nonconformance.

4.4 Nonconformance dispositions

A basic disposition for a nonconforming item can be one of the following:

a) Return to supplier

This disposition shall only apply to nonconforming procured items.

b) Use "as-is"

The item is found to be usable without eliminating the nonconformance.

c) Rework

The item is recoverable to conform completely with all specified requirements.
By definition, rework is the re-application of the process as originally planned. Additional work shall be performed to prepare the item for the rework (e.g. removal of faulty work, cleaning). But in no case should the result of earlier applied processes or the precondition for other processes to be applied later on, be affected.

d) Repair

The item is recoverable such that it fulfils the intended usage requirements although it does not conform to the originally specified requirements. The repair procedure shall be one of the following.

1) Qualified or standard repair procedure:
Those repair procedures which have been approved by the customer in advance for defined applications.

2) Specific repair procedure:
Those repair procedures which are prepared for the specific nonconformance and are approved by the NRB. Any repair procedure shall include the verifications needed to check the repair result.

e) Scrap

The item is not recoverable by rework or repair, for technical or economic reasons.

4.5 Interfaces with internal nonconformance reporting and processing

The supplier's internal reporting and processing of nonconformances shall:

a) not conflict with this Standard;

b) be open and visible to customer reviews;

c) not delay the processing of the nonconformance in accordance with this Standard.

5 Nonconformance processing requirements

5.1 General

Nonconformance processing is summarized in the flow chart in annex A.

5.2 Immediate actions

a) When a nonconformance is detected, an immediate preliminary assessment shall be performed by the project PA representative to establish its extent and cause.

b) Based on this assessment the following actions shall be taken, as necessary, without delay:

1) Provisions for the safety of the personnel and of the equipment.

2) Prevention of unauthorized use of the nonconforming items, by marking and, unless otherwise determined by the PA representative, segregation until their disposition.

3) Prevention of the recurrence of the nonconformances on similar or identical items under processing or testing at that time. This can require suspension of manufacturing or testing.

c) The following shall apply for the segregation of nonconforming articles:

1) The supplier shall establish a clearly marked holding area for nonconforming items pending NRB disposition.

2) Access to this area shall be limited to NRB members or personnel authorized by the NRB.

3) Provisions shall be made to prevent unauthorized removal of any item.

4) Items whose segregation in the holding area is not practicable shall be prominently identified.

5.3 Reporting and recording

a) After verifying that the nonconformance exists, it shall be reported on an NCR and submitted to the internal NRB.

b) The description of the nonconformance shall be clear, unambiguous and sufficiently detailed that it can be understood by personnel not involved in its detection.

c) The NCR reference shall be entered on relevant quality and manufacturing records related to the nonconforming item.

d) The NCR reference, together with key data, shall be entered on the nonconformance records.

5.4 Processing by internal NRB

5.4.1 General

Immediately after the reporting of a nonconformance, the chairman shall convene the Internal NRB.

5.4.2 Classification

After verification that the nonconformance is fully described and the NCR is filled in correctly, the internal NRB shall classify the nonconformance in accordance with the criteria defined in 4.2.

5.4.3 Analysis of causes and consequences

a) The internal NRB shall investigate the cause(s) of the nonconformance, or if necessary engage a separate group of experts for the investigation.

b) No physical operation of an irreversible nature shall be carried out on the nonconforming item without prior approval by the customer.

c) Non-destructive testing may be used, if the techniques involved have previously been approved by the customer.

d) The internal NRB shall analyse whether human error or poor workmanship are primary or secondary cause for the nonconformance. In these cases, all related documents and the competence level of personnel shall be reviewed in order to prevent recurrence.

e) The investigation of the consequences of the nonconformance shall be supported, where appropriate, by dependability experts or by documentation such as FMECA, CIL, DJF.

5.4.4 Disposition of minor nonconformances

a) The internal NRB shall dispose minor nonconformances in accordance with 4.4.
Unless otherwise stated in the business agreement, minor nonconformances need not to be notified to the customer.

b) Minor nonconformances shall be included in the summary status report (see 7.3) and available to the customer, upon request, for the review of the correct application of classification criteria and appropriate processing.

5.4.5 Processing of major nonconformances

a) Major nonconformances shall be subjected to the customer NRB processing.

b) The supplier shall report major nonconformances to the customer within 5 working days of their detection, unless otherwise specified in the business agreement.

c) All the information defined as mandatory in the generic format in annex B shall be provided, including a proposed disposition.