

Space product assurance — Nonconformance control system

The European Standard EN 14097:2001 has the status of a
British Standard

ICS 49.140

National foreword

This British Standard is the official English language version of EN 14097:2001.

The UK participation in its preparation was entrusted to Technical Committee ACE/68, Space systems and operations, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

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This British Standard, having been prepared under the direction of the Engineering Sector Policy and Strategy Committee, was published under the authority of the Standards Policy and Strategy Committee on 19 March 2002

Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 23 and a back cover.

The BSI copyright date displayed in this document indicates when the document was last issued.

Amendments issued since publication

Amd. No.	Date	Comments

© BSI 19 March 2002

ISBN 0 580 39290 2

English version

Space product assurance - Nonconformance control system

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

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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

Management Centre: rue de Stassart, 36 B-1050 Brussels

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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 version¹ 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
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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.