
**Space systems — Programme
management — Non-conformance control
system**

*Systèmes spatiaux — Management de programme — Système de
maîtrise des non-conformités*



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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.

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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 23461 was prepared by Technical Committee ISO/TC 20, *Aircraft and space vehicles*, Subcommittee SC 14, *Space systems and operations*.

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Introduction

This International Standard applies to non-conformance control in space programmes.

This International Standard applies to all deliverable products and supplies, at all levels, which fail to conform to specification requirements and design baselines.

The objectives of the non-conformance control system are to:

- a) identify and segregate the non-conforming items;
- b) record, report and review effective communication between suppliers and customers;
- c) take corrective action against root causes of failure to ensure conformance of the products.

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Space systems — Programme management — Non-conformance control system

1 Scope

This International Standard specifies a control system for non-conformances related to any product for space systems, such as electrical, electronic, and electromechanical components and software, as well as operational non-conformances and anomalies.

This International Standard applies to all deliverable products and supplies, at all levels, which fail to conform to specification requirements and design baselines.

This International Standard is applicable throughout phases of:

- a) procurement, production, qualification, integration, and test;
- b) acceptance, delivery, and transportation;
- c) launch preparation and flight or launch readiness;
- d) operational validation or qualification;
- e) operation;
- f) refurbishment.

This International Standard also specifies requirements for the interfaces with company internal non-conformance reporting and processing.

Engineering changes lie outside the scope of this International Standard.

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 14300-1, *Space systems — Programme management — Part 1: Structuring of a programme*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14300-1 and ISO 14300-2 apply.

4 Abbreviated terms

CCN	contract change notice
CIL	critical item list
OTS	off-the-shelf
DJF	design justification file
EEE	electrical, electronic, electromechanical
FMECA	failure mode effect and criticality analysis
NCR	non-conformance report
NRB	non-conformance review board (formerly known as material review board or MRB)
QA	quality assurance
PA	product assurance
RFD	request for deviation
RFW	request for waiver

5 Non-conformance control system — basic requirements

5.1 General principles

The following general principles apply.

- a) The system shall provide for a disciplined approach to the identification and segregation of non-conforming items; the recording, reporting, review, disposition and analysis of non-conformances; and the definition and implementation of corrective and preventive actions.
- b) Special attention shall be paid to:
 - 1) corrective actions against root causes, to avoid recurrence for other products;
 - 2) prompt and effective communication between suppliers and customers;
 - 3) the prevention of non-conformance occurrence, from the analysis of non-conformance records and derived lessons learned.
- c) The supplier shall document his implementation of the non-conformance control system.

5.2 Non-conformance classes

5.2.1 General

Non-conformances shall be classified as major or minor, based on the severity of their consequences, as defined in 5.2.2 and 5.2.3. In case of doubt, non-conformances shall be classified as major.

Classification of non-conformances is not based on their consequences on cost and schedule.

5.2.2 Major

Major non-conformances shall be those which can have an impact on the customer's requirements in the following areas:

- a) safety of people or equipment;
- b) operational, functional or any technical requirements imposed by the business agreement;
- c) reliability, maintainability, availability;
- d) lifetime;
- e) functional or dimensional interchangeability;
- f) interfaces with hardware or software regulated by different business agreements, and in the following cases:
 - 1) changes to or deviations from approved qualification or acceptance test procedures,
 - 2) project specific items which are proposed to be scrapped,
 - 3) for EEE components, in case of:
 - i) lot or batch rejection during manufacturing, screening or testing at the manufacturer's facilities, if the purchaser proposes:
 - I) to use as-is the rejected lot or batch,
 - II) to continue processing, rework or testing, although the lot or batch does not conform to the specified requirements;
 - ii) non-conformances detected after delivery from the manufacturer.

5.2.3 Minor

Minor non-conformances are those which by definition cannot be classified as major.

The following discrepancies relating to EEE components after delivery from the manufacturer may be classified as minor:

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

The consequences of several different minor non-conformances on the same item shall be evaluated for proper classification.

5.3 Non-conformance review board

5.3.1 General

The non-conformance review board (NRB) shall:

- a) be the sole technical authority for the treatment of non-conformances occurring in the frame of a business agreement;

- b) have all dispositions and decisions made by consensus by all core members;
- c) involve higher management levels, in case of conflict;
- d) maintain the independence of PA from the project management organization.

5.3.2 Internal NRB

The internal NRB shall:

- a) have core members for the business agreement nominated and authorized by the supplier;
- b) document the responsibilities and authorities of each member;
- c) include core members from at least the following areas:
 - 1) project PA (chair),
 - 2) engineering;
- d) have a chair who nominates additional members, or experts, depending on the subject of the non-conformance report (NCR);
- e) be responsible for the correct application of this International Standard and its proper interfacing with internal non-conformance reporting and processing.

5.3.3 Customer NRB

For major non-conformances (see 5.2.2) the participation of the customer in the NRB is mandatory.

The customer NRB shall include representatives from at least the following areas:

- a) project PA (chair);
- b) engineering;
- c) at least one customer's representative.

The customer's representative shall also nominate additional members or experts, depending on the NCR subject. The customer's representative may, with the supplier's agreement, invite observers or consultants from higher customer level depending on the impacts of the non-conformance.

5.4 Non-conformance dispositions

5.4.1 General

A basic disposition for a non-conforming item can be one of 5.4.2 to 5.4.6.

5.4.2 Return to supplier

This disposition only applies to non-conforming procured items.

5.4.3 Use "as-is"

The item is found to be usable without eliminating the non-conformance.

5.4.4 Rework

The item is recoverable to conform completely to 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 and cleaning). In no case shall the result of earlier applied processes or the precondition for other processes to be applied later on, be affected.

5.4.5 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:

- a) qualified or standard — approved by the customer in advance for defined applications;
- b) specific — drawn up for the specific non-conformance and approved by the NRB.

Any repair procedure shall include the verifications needed to check the repair result.

5.4.6 Scrap

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

5.5 Interfaces with internal non-conformance reporting and processing

The supplier's internal reporting and processing of non-conformances shall:

- a) not conflict with this International Standard;
- b) be open and visible to customer reviews;
- c) not delay the processing of the non-conformance in accordance with this International Standard.

6 Non-conformance processing requirements

6.1 General

A non-conformance processing flow chart appears in Figure A.1.

6.2 Immediate actions

The immediate actions in response to detection of non-conformance shall be:

- a) performance of an immediate preliminary assessment by the project PA member to establish its extent and cause;
- b) follow-up, without delay, of the assessment, consisting of:
 - 1) provision for the safety of personnel and equipment,
 - 2) prevention of unauthorized use of the non-conforming items, by marking and, unless otherwise determined by the PA representative, segregation until their disposition,
 - 3) prevention of the recurrence of the non-conformance on similar or identical items under processing or testing at that time, which can require suspension of manufacturing or testing;

- c) segregation of non-conforming articles, including:
 - 1) establishment by the supplier of a clearly marked holding area for non-conforming items pending NRB disposition,
 - 2) limitation of access to this area to PA members or personnel authorized by the NRB,
 - 3) provisions against unauthorized removal of any item,
 - 4) prominent identification of items whose segregation in the holding area is not practicable.

6.3 Report and recording

Non-conformance shall be reported and recorded by:

- a) submission, after verification that non-conformance exists, of a completed NCR, prepared by any project team member, to the internal NRB;
- b) provision of a clear, unambiguous, and sufficiently detailed description of the non-conformance, so that it can be understood by personnel not involved in its detection;
- c) entry of the NCR reference on to relevant quality and manufacturing records related to the non-conforming item;
- d) entry of the NCR reference, together with key data, on to non-conformance records (see Clause 9).

6.4 Processing by internal NRB

6.4.1 NRB initiation

Immediately after the reporting of non-conformance, its processing by the internal NRB shall be initiated.

Each NRB performed and its participants shall be recorded on the NCR in order to provide traceability of the dispositions and to determine corrective actions derived from it.

Each NRB requires an update of the NCR with higher issue and actual date.

6.4.2 Classification

After verification that the non-conformance has been fully described and that the NCR is correctly completed, the internal NRB shall classify the non-conformance in accordance with the criteria defined in 5.2.

6.4.3 Analysis of cause and consequence

Analysis of cause and consequence shall be implemented as follows:

- a) investigation, by the internal NRB or, if necessary, of a separate group of experts engaged for the purpose, of the root cause(s) of the non-conformance;
- b) performance of no irreversible physical operation on the non-conforming item without prior approval by the customer — non-destructive testing may be used, if the techniques involved have previously been approved by the customer;
- c) analysis by the internal NRB of whether human error or poor workmanship are the primary or secondary cause for the non-conformance — in which cases, related documents and the competence level of personnel shall be reviewed in order to prevent recurrence;
- d) support of the investigation of the consequences of the non-conformance, where appropriate, by dependability experts or by documentation such as FMECA, CIL or DJF.

6.4.4 Disposition of minor non-conformances

Minor non-conformances shall be disposed as follows:

- a) by the internal NRB in accordance with 5.4 — unless otherwise stated in the business agreement, minor non-conformances need not be notified to the customer;
- b) inclusion in the summary status report (see 8.3) which is made available to the customer, upon request, for the review of the correct application of classification criteria and appropriate processing.

6.4.5 Processing of major non-conformances

Major non-conformances shall be processed as follows:

- a) submission to customer NRB processing;
- b) submission by the supplier of a report to the customer within 5 working days of detection, e.g. 2 days, unless otherwise specified in the business agreement;
- c) provision of all information defined as mandatory in the recommended NCR format in Annex B, including a proposed disposition.

6.5 Processing by customer NRB

6.5.1 Assessment of higher level impacts

The customer shall assess whether the requirements of the higher level customer are impacted. In case of actual or suspected impacts, the customer shall notify his customer and involve him in the ensuing NRB.

6.5.2 Confirmation of causes and consequences

The causes and consequences shall be determined by:

- a) consideration by the customer NRB of the results of the investigations of the internal NRB (see 6.4.3), and performance of any complementary investigations necessary;
- b) performance of failure and other technical analyses, if requested by the NRB, including support of its disposition;
- c) documentation of failure analysis in reports to be approved by the NRB;
- d) presentation and review, during the NRB meeting, of the non-conformance, including:
 - 1) its detailed circumstances,
 - 2) the causal analyses, tests or simulations performed,
 - 3) its consequences;
- e) adequate summary, before determining a disposition, by the NRB of the causes and consequences of the non-conformance.

6.5.3 Disposition of major non-conformances

Major non-conformances shall be disposed:

- a) in accordance with 5.4;
- b) by the customer NRB undertaking to assess:
 - 1) all pertinent data and information related to the non-conforming item (e.g. alerts from other programmes, FMECA, hazard analysis, supplier records, and qualification test data),
 - 2) records of any previous similar or identical non-conformances,
 - 3) the feasibility of the intended dispositions,
 - 4) the applicability of dispositions and corrective actions to existing and in-process items (including re-inspection and retest),
 - 5) the effect of the non-conformance on the requirements of the business agreement, the intended use of the item, and in particular whether the item is identified as critical,
 - 6) the need to alert other users of similar non-conforming items, and to activate the related procedures established in the business agreement.

6.5.4 Request for waiver

A waiver is a written authorization to use or release a product which does not conform to the specified requirements. Cases of major non-conformance with the “use as-is” disposition are candidates for an RFW.

An RFW disposition shall be treated by identification and recommendation of the need for a waiver by the responsible NRB.

Unless otherwise specified by the business agreement, a separate RFW need not be requested for major non-conformances affecting only a unit with no impact on higher level requirements. In such a case, the departure from the requirements may be processed through the NCR by the customer NRB with the involvement of contracts and programme management, where appropriate.

For follow-on production model of the unit, a request for deviation (RFD) or a contract change notice may be requested by the NRB.

6.6 Corrective and preventive actions

The NRBs shall determine corrective actions to eliminate the cause(s) of the non-conformance and prevent any recurrence. Typical corrective actions consist of changes to tools, equipment, facilities, processes, materials, drawings, specifications, and procedures.

The NRB shall also determine preventive actions to avoid the occurrence of the non-conformance on similar items. The disposition “use as-is” does not require any physical action on the non-conforming item to make it usable, but does require corrective and preventive actions.

6.7 Implementation of action and non-conformance close-out

6.7.1 Implementation of actions

The supplier shall ensure:

- a) implementation of a disposition only by performing actions defined by the NRB and approved RFWs, if applicable;

- b) resubmission of reworked and repaired items to all planned inspections and tests — repair can invoke additional inspection and tests, as defined in the applicable repair procedure (see 5.4.5);
- c) prominent identification and segregation from all other material of items with a “scrap” disposition within a bonded area under QA supervision;
- d) maintenance and availability of records at disposal of scrapped items;
- e) traceability to and from the associated NCR of all the performances and results of all actions related to a non-conformance.

6.7.2 Non-conformance close-out

The supplier shall ensure that an NCR is closed out:

- a) only after all related actions have been performed and their results successfully verified — in the case of long-term preventive actions, the NCR may be closed if evidence is provided that their handling, through an agreed management process, has been formally initiated;
- b) only after all necessary inspections and tests have been performed successfully, and their results verified and reported on or traceable from the NCR;
- c) only after related RFWs are approved;
- d) by an authorized PA member of the supplier, by stamping and signing the NCR form.

After close-out, a copy of the NCR disposed by customer NRB shall be sent to the customer(s) involved in its processing, on demand.

7 Special non-conformance control requirements

7.1 Non-conformance of EEE components

7.1.1 Applicability

This subclause applies to all EEE components. Space qualified components under the qualification of one organization shall be processed in accordance with that organization's regulations, prior to delivery to the purchaser.

7.1.2 Basic requirements

The basic requirements specified in Clause 5 shall apply.

7.1.3 Processing requirements

The requirements specified in Clause 6 shall apply, with the following modifications:

- a) the notification of a major non-conformance shall contain, as a minimum:
 - 1) information concerning the history of the component affected (e.g. type, manufacturer, batch number, and selection programme),
 - 2) description of the non-conformance and exact conditions of occurrence,
 - 3) the cause of the non-conformance, whether known or presumed,
 - 4) the possible stress caused to the neighbouring components;

- b) if it is suspected that non-conforming items of the same batch or production have been released to other users, an alert shall be submitted to the final customer, in accordance with the procedures established by the business agreement.

7.2 Software non-conformances

7.2.1 Applicability

This subclause applies to software non-conformances. The supplier shall define and implement procedures for logging, analysis and correction of all software problems encountered during software development. The requirements in this subclause shall be applicable to:

- a) on-board software;
- b) verification software (e.g. simulators, test beds);
- c) mission control software (ground based);
- d) support software for development of types a) to c).

This subclause applies during software development, starting from successful software unit testing.

7.2.2 Basic requirements

The same basic requirements defined in Clause 5 shall apply to software non-conformances, with the following modifications:

- a) the dispositions specified in 5.4 shall be replaced by:
 - 1) use “as-is”, when the software is found to be usable without eliminating the non-conformance,
 - 2) fix, when the software product can be made fully in conformance with all specified requirements, by:
 - i) correction of the software
 - ii) addition of software patches
 - iii) re-design,
 - 3) return to supplier, for procured software products (as OTS);
- b) software fixes shall be validated by appropriate regression testing.

7.3 Operation non-conformances and anomalies

7.3.1 Applicability

This subclause applies to non-conformances to stated requirements, deviations from approved procedures, deviations from expected behaviour and human errors detected during operations, starting from the first acquisition of the spacecraft signal.

The requirements in this subclause apply to the:

- a) flight segment;
- b) ground segment, including hardware, software, documentation, and data;
- c) mission products.

7.3.2 Basic requirements

7.3.2.1 General principles

The general principles specified in 5.1 apply. It shall be considered that operational non-conformances and anomalies can have impacts on several parties: the organization responsible for the operations (called the “operator” in the following text); the owner of the space system; the procurement agency of the space system; the suppliers of its elements; and the customers of the mission products. The same organization may cover more than one of the above roles at the same time.

Taking this into account:

- a) all parties involved shall define clear responsibilities, authorities and procedures for the processing of operational non-conformances and anomalies;
- b) the requirements for the mission products and the associated acceptance criteria shall be documented and agreed among the parties concerned, in order to allow the unambiguous identification of non-conformances;
- c) administrative work shall not hinder the immediate implementation of critical actions, but all activities shall be recorded and controlled in accordance with the established procedures.

7.3.2.2 Classification

Operational non-conformances or anomalies shall be classified in accordance with:

- a) 5.2;
- b) the severity of their consequences on the space system and the mission products, and the importance of the affected function for the global performance of the system;
- c) criteria agreed between the interested parties.

7.3.2.3 Non-conformance review board

The NRB shall be implemented as follows:

- a) based on the classification of operational non-conformances and anomalies, as defined in 7.3.2.2, the parties concerned shall agree:
 - 1) the classes of operational non-conformances and anomalies that can be decided by the operator's internal NRB,
 - 2) the composition of higher level NRBs, as appropriate;
- b) the operator's internal NRB shall include:
 - 1) at least one PA representative,
 - 2) at least one technical representative responsible for the operations of the space system,
 - 3) additional experts, as necessary.
- c) timely provisions shall be considered to secure the necessary support by relevant parties involved in the development and procurement of the space system for the duration of the space mission.

7.3.3 Processing requirements

The operator shall adapt the processing requirements specified in Clause 6 to the reporting and processing of operational non-conformances and anomalies, by establishing and maintaining documented procedures to be agreed with the relevant parties.

In particular, address the following aspects specific to operational anomalies:

- a) established procedures shall take into account that operational anomalies can call for immediate response, in order to avoid the loss of the spacecraft or major mission degradation;
- b) the operator should be granted the authority to carry out urgent actions for the analysis of the causes and consequences, without systematic prior approval by the other parties concerned (e.g. the spacecraft owner).

8 Documentation requirements

8.1 Non-conformance report

A recommended format for an NCR is given in Annex B.

8.2 Formats for non-conformance reporting

The customer and the supplier shall agree upon an NCR format to process major non-conformances and customer-furnished equipment.

The supplier may use his own NCR formats for internal processing as long as they include all data elements designated as mandatory in Annex B.

NOTE The supplier's working language is acceptable for internal NCRs, unless otherwise required by the business agreement.

8.3 Non-conformance summary status report

The supplier shall maintain an NCR summary list, which provides a complete representation of the status of all non-conformances occurring in the frame of a business agreement, for each product, at any time.

For each NCR, at least the following information shall be included:

- a) NCR unique identification;
- b) non-conforming item identification;
- c) short description of the non-conformance;
- d) date of last NRB meeting;
- e) disposition;
- f) implementation status of the disposition;
- g) reference to RFW, if applicable,
- h) open or closed status.

The non-conformance summary status report shall cover major and minor NCRs.

The non-conformance summary status report shall be part of the periodic PA status report to the customer, unless otherwise required by the business agreement.

The non-conformance summary status report should be generated from the non-conformance database (see 9.2).

9 Record requirements

9.1 Records associated with non-conformances

Each non-conformance shall be fully documented and self-explanatory.

Non-conformance records shall consist of:

- a) the NCRs themselves, as specified in 8.1 and 8.2;
- b) all documents referenced by them, such as minutes of meetings, inspection reports, test reports, and failure analysis reports.

9.2 Non-conformance database

The supplier should maintain a database of non-conformances.

The non-conformance database should be used

- a) for NCR follow-up;
- b) for the generation of an NCR summary status report (see 8.3);
- c) as an electronic tool for complete NCR processing.

The database should contain information related to both minor and major NCRs.

The amount of information stored should be sufficient to allow statistical and trend analysis.

9.3 Analysis of records

The supplier shall periodically review and analyse the non-conformance records to:

- a) evaluate the progress of the actions for the correction and prevention of non-conformances and to ensure their proper and timely close-out;
- b) assess the existence of trends in the occurrence of non-conformances;
- c) detect conditions which can lead to new non-conformances and verify the effectiveness of the implementation of the corrective actions performed for previous non-conformances;
- d) extract lessons learned, useful for preventing the repetition of mistakes or reinforcing successful practices.

The frequency of the reviews shall be appropriate to the volume of non-conformances.

The analysis of the non-conformance records shall provide, as a minimum:

- 1) total number per flight configuration, subsystem and equipment as appropriate;
- 2) trend of open and closed status, both in terms of disposition and corrective action(s) implementation;
- 3) number by cause of the non-conformance, to identify the areas for improvement and verify the effectiveness of corrective actions.

The trends should be shown separately for hardware, EEE parts and software.

For EEE parts, the trend per generic type (e.g. capacitors, power transistors, microprocessors, carbon resistors, and diodes) should also be provided.

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