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Space systems — Programme management —

Part 2: Product assurance

Systèmes spatiaux — Management de programmes —

Partie 2: Assurance produit

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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 14300-2 was prepared by Technical Committee ISO/TC 20, *Aircraft and space vehicles*, Subcommittee SC 14, *Space systems and operations*.

This second edition cancels and replaces the first edition (ISO 14300-2:2002), which has been technically revised.

ISO 14300 consists of the following parts, under the general title *Space systems — Programme management*:

— *Part 1: Structuring of a project*

— *Part 2: Product assurance*

Introduction

This part of ISO 14300 is intended to be applied for the product assurance in space programmes/projects and applications.

Requirements in this part of ISO 14300 are defined in terms of what is intended to 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 part of ISO 14300 takes into account the existing “ISO 9000 family of standards” and the content of ISO 14300-1.

Space systems — Programme management —

Part 2: Product assurance

1 Scope

This part of ISO 14300 defines the product assurance (PA) policy, objectives, principles, and requirements for the establishment and implementation of PA programmes for space programmes covering mission definition, design, development, production and operations of space products, including disposal.

The PA discipline covers: PA management, quality assurance, safety assurance, dependability (reliability, availability and maintainability) assurance of software and hardware products, as well as parts (including electrical, electromechanical and electronic components, and mechanical parts), materials and processes assurance.

This part of ISO 14300 defines their respective objectives, policies, and principles to achieve the stated overall PA objectives throughout the complete life cycle of the products.

The provisions of this part of ISO 14300 apply to space products.

The term “programme” is understood as a group of several projects. Both “programme” and “project” can be used in the same context throughout this part of ISO 14300.

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 9000:2005, *Quality management systems — Fundamentals and vocabulary*

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

ISO 14620-1, *Space systems — Safety requirements — Part 1: System safety*

ISO 14621-1, *Space systems — Electrical, electronic and electromechanical (EEE) parts — Part 1: Parts management*

ISO 14621-2, *Space systems — Electrical, electronic and electromechanical (EEE) parts — Part 2: Control programme requirements*

ISO 17666, *Space systems — Risk management*

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2005 and the following apply.

3.1.1
product assurance
discipline devoted to the study, planning and implementation of activities intended to ensure that the design, controls, methods and techniques in a programme result in a satisfactory level of quality in a product

3.2 Abbreviated terms

For the purposes of this document, the following abbreviated terms apply.

EEE Electrical, electronic, electromechanical

PA Product assurance

4 Objectives, policy and principles — General

4.1 Objectives

The prime objective of PA is to ensure that the space products accomplish their defined mission objectives and, more specifically, that they are safe, available and reliable.

An additional objective is to achieve more cost effective space programmes by coordinating the development and implementation of appropriate PA methods and standards.

In support of programme risk management, PA will ensure an adequate identification, appraisal, prevention and control of technical and programmatic risks within programme constraints.

4.2 Policy and principles

In order to meet these objectives, a PA policy is defined in this part of ISO 14300, which requires a PA programme derived from a system based on preventive approach and includes:

a) protection of human life, space products, investment and environment;

b) definition and maintenance of a programme PA function, with appropriate autonomy with respect to other lines and programme level organizations;

c) integrated application of the PA disciplines and coordination with the associated functions of programme management and programme engineering;

d) tailoring of the PA requirements to the specific programme needs;

e) assignment of PA requirements and their control commensurate with the function criticality within the system;

f) integrated PA participation to the overall risk management process;

g) PA contribution to proper control of the technical risks and ensuring awareness by the appropriate levels of management until the end of the disposal phase;

h) implementation of a preventive approach, i.e. early identification of potential problems and continuous influence on the development process;

i) verification activities consistent with programme objectives;

j) certification activities by the supplier on the end product for the customer’s final acceptance.

5 Product assurance management

5.1 Objective

The objective of product assurance management is to ensure and achieve an adequate, effective and efficient coordination and implementation of the PA activities through a proper integration of the PA disciplines, as well as the integration of PA with all programme management and engineering activities.

5.2 Policy and principles

5.2.1 The PA management policy is that a PA programme is implemented throughout all programme phases and coordinated with all the actors, and is managed in such a way as to ensure that:

a) the PA programme and organization, requirements, methods, tools and resources are well defined and implemented at each level from system down to piece part;

b) the applicable standards are tailored appropriately;

c) aspects are identified, which can affect programme requirements having major impacts on safety, mission success and the related cost and schedule consequences;

d) adverse consequences of these aspects are prevented by the early detection, characterization, elimination, minimization and containment of problem contributors and initiators;

e) risks are assessed and controlled, and acceptability of the residual risks is evaluated;

f) the end product conforms to its specifications and observed non-conformances are properly disposed of.

Such a programme provides, at any time, the necessary visibility of the quality status of the product.

5.2.2 The basic implementation principles are to:

a) define all PA activities consistent with the programme objectives, requirements, criticality and constraints;

b) ensure the allocation and availability of adequate resources, personnel and facilities to carry out the required PA tasks;

c) ensure that lower level contractors/suppliers perform proper PA implementation, monitoring and control;

d) ensure proper progress monitoring, reporting and visibility of all PA matters, in particular those related to risk dispositions, alerts, critical items, non-conformances, changes, deviations, waivers, actions and/or recommendations resulting from reviews, inspection and audits, qualification, verification and acceptance.

5.3 Requirements

5.3.1 Responsibility and authority

The following are the responsibility and authority requirements.

a) The responsibility, the authority and the interrelation of PA shall be defined.

b) The PA responsibilities and the interfaces of each organization, either external or internal, involved in a programme shall be defined and documented.

c) The delegation of PA tasks by a supplier to another lower tier supplier shall be carried out in a documented and controlled way. The supplier retains the responsibility towards the customer.

d) The parties involved shall perform risk management in accordance with ISO 17666.

5.3.2 Resources

The following are the resource requirements.

a) The supplier shall provide adequate resources to perform the required PA tasks.

b) Trained personnel shall be assigned to the various PA activities.

c) The supplier shall assign a programme PA manager reporting to the programme manager and having unimpeded access to higher management through the company PA (or equivalent) executive as necessary to fulfil his/her duties.

d) The supplier shall establish a documented training programme for all personnel whose performance determines or affects product quality.

e) Reviews and audits of the PA programme, of processes and/or of product shall be carried out by personnel not directly involved in the work being performed.

5.3.3 Product assurance programme management

The following are the product asurance prgramme management requirements.

a) The appointed programme PA manager, irrespective of other responsibilities, shall have sufficient organizational authority and independence to propose and maintain a PA programme in accordance with the programme PA requirements.

b) The supplier shall prepare and implement a programme PA plan.

c) The supplier's PA plan shall be maintained throughout the programme life cycle.

d) The supplier shall report on a regular basis as specified in the business agreement on the status of the PA programme implementation.

e) The supplier shall plan and perform quality audits of the PA programme, processes and/or products using established and maintained procedures.

5.3.4 Contractual aspects

At any contractual level, the applicable PA programme shall provide evidence that:

a) all contracts include suitable PA provisions based upon the knowledge of the products and on the customer's requirements;

b) the PA function is involved in the preparation and negotiations of the PA provisions;

c) the PA function participates in the detailed review of the contract;

d) the PA function is involved in the assessment and review of all changes to the contractual requirements.

5.3.5 Risk assessment and control

5.3.5.1 PA shall provide inputs to the overall programme risk management process defined in ISO 14300-1. In the implementation of the process, the following PA aspects shall be considered systematically:

a) the likelihood and severity of risks or their uncertainties expected in demonstration of design performance, and with items having small design margins;

b) the risk identified by dependability and safety analyses;

c) the likelihood and severity of risks or their uncertainties expected in the development of new products, components, parts, materials, processes and critical technologies;

d) the likelihood and severity of risks or their uncertainties expected in the procurement, manufacturing, assembly, inspection, testing, handling, storage and transportation, which may lead to unacceptable degradations in the quality of the product;

e) the likelihood and severity of risks anticipated in product utilization or service implementation;

f) the risk identified by suppliers at lower levels;

g) the risk of product quality degradation as a result of cost and schedule constraints imposed on the programme;

h) the effectiveness of risk reduction and control measures;

i) the acceptability of residual risks.

5.3.5.2 Critical items shall be identified as a result of risk assessment. It is a programme responsibility to define the specific criteria for critical item identification, taking into account the capability for detection and control of risk occurrence.

5.3.5.3 In terms of dependability and safety, the following apply.

a) The dependability and safety concept of technical risk identification, reduction and control is part of the "risk management process", which shall be a continuous and iterative process throughout the programme life cycle. The dependability and safety-related technical risk reduction and control process are joint activities within engineering domains.

b) The process of risk identification may be performed by applying two principles of approach simultaneously: the top-down approach and the bottom-up approach.

c) The dependability and safety-related technical risk reduction and control process shall be applied to all identified hazards and failure modes, which have unacceptable consequences at any time in the programme.

d) In the identification of failure modes and hazards, and associated technical risks, due consideration shall be given to past experience, studies, ground and flight tests, reviews, the industrial process, as well as the operational use.

e) Risk-reduction measures as proposed for dependability and safety shall be assessed at system level in order to select the optimum solution to reduce the system-level risk.

5.3.5.4 The process of risk identification and assessment employs both qualitative and quantitative approaches.

a) All identified technical risks shall be assessed primarily for the severity classification of their consequences and categorized according to the appropriate programme severity class. Corresponding controls shall be implemented.

b) After qualitative risk reduction is applied, the residual risks, including probability, shall be evaluated. The acceptability of these residual risks shall be justified according to defined criteria.

6 Quality assurance

6.1 Objective

The objective of quality assurance is to provide adequate confidence to the customer that the end product or service satisfies the requirements.

6.2 Policy and principles

The quality assurance policy is to ensure, in conjunction with other integrated programme and PA functions, that the required quality is specified, designed-in and is incorporated, verified and maintained in the relevant hardware, software and associated documentation throughout all programme phases, by applying a programme where:

a) assurance is provided that all requirements are adequately specified;

b) design and development rules, methods and standards are consistent with the programme requirements;

c) each applicable requirement is verified through a verification programme, which includes one or more of the following methods:

   1) analysis;

   2) inspection;

   3) testing;

4) review of design;

5) audits;

d) design and performance requirements, including the specified margin and design traceability, are demonstrated through a qualification and acceptance process;

e) inputs to the risk-management process are provided;

f) assurance is provided that the design is producible and repeatable, and that the specification of the resulting product can be verified (including requirements verification control) and operated within the required operating limits;

g) assurance that the operations, including post-flight and disposal, are carried out in a controlled way and in accordance with the relevant requirements;

h) assurance is provided that suitable quality systems covering design, development, production, installation, servicing, final inspection and testing are in place and implemented by all participants in the programme;

i) fabrication, integration, testing and maintenance are conducted in a controlled manner, such that the end item conforms to the applicable baseline;

j) a non-conformance control system is established and maintained in order to track non-conformances systematically and to prevent reoccurrence;

k) quality records are maintained and analysed to report and detect trends in due time for preventive/corrective actions;

l) inspection, measurement and testing equipment and tools in use on the contract are controlled to be accurate for their application;

m) procedures and instructions are established, which provide for the identification, segregation, handling, packaging, preservation, storage and transportation of all items.

7 Safety assurance

7.1 Objective

The objective of safety assurance is to ensure that all safety risks associated with the design, development, production and operations of space products are identified, assessed, minimized, controlled and finally accepted.

The safety requirements for space systems are defined in ISO 14620-1.

7.2 Policy and principles

7.2.1 Policy

The safety policy shall ensure that space systems do not involve unacceptable hazards to (in order of priority):

a) human life;

b) the environment;

c) public and private property;

d) spacecraft and launcher;

e) ground support equipment and facilities.

7.2.2 Implementation principles

The safety policy shall be implemented by applying a safety programme which shall ensure that:

a) safety is integrated into the design of the system;

b) safety control measures are adequately verified;

c) safety requirements, including launch centre safety regulations, are met;

d) hazards are identified and eliminated or, where this is not possible, minimized, ranked and controlled in accordance with programme objectives in a manner acceptable to the customer and to the safety organizations involved in the implementation of the mission.

Furthermore, the safety policy shall be fully compatible and associated with the dependability programme.

7.2.3 Safety programme

The safety programme shall comprise:

a) the identification and control of all safety-related risks with respect to the design, development and operations of space products;

b) the assessment of the risks based on qualitative and quantitative analysis, as appropriate;

c) the application of a hazard-reduction precedence and of control measures of the residual risks;

d) resolution of all accidents and incidents;

e) cognizance of ISO 14620-1.

8 Dependability assurance

8.1 Objective

The objective of the dependability assurance is to ensure that dependability risks associated with the design, development, production and operation of space products are adequately identified, assessed, minimized, controlled and finally accepted.

8.2 Policy and principles

8.2.1 General

The dependability policy is to ensure that space systems are available to achieve a successful mission at minimum life cycle costs.

8.2.2 Dependability programme

The dependability programme shall comprise:

a) the identification of all technical risks with respect to functional needs which can lead to non-compliance with dependability requirements;

b) the application of suitable analysis and design methods to ensure that dependability targets are met;

c) the minimization of overall cost and schedule by making sure that

   1) design rules, dependability analyses and risk reducing actions are tailored with respect to a suitable criticality categorization, and

2) risk-reducing actions are implemented continuously from the early phase of a programme and especially during the design phase;

d) the provision of suitable inputs to the integrated logistics support activities.

The dependability policy shall be implemented by applying a dependability programme, fully compatible and coordinated with the safety programme.

9 Parts, materials and processes

9.1 Objective

The objective of the PA activities associated with parts (EEE components, mechanical, etc.), materials and processes is to ensure that their use satisfies the mission performance requirements during the complete life cycle.

The parts management and the control programme requirements for EEE parts are defined in ISO 14621-1 and ISO 14621-2.

9.2 Policy and programme

9.2.1 Policy

The policy covering the objective in 9.1 is to select those items which are capable of meeting the functional performance, design, lifetime, environmental, dependability, safety and quality requirements.

The policy shall be implemented by applying a programme, which ensures that:

a) the best use of all available and space-proven technology is made;

b) technical risks are minimized by relying on available space-proven technologies or are properly validated prior to their use;

c) programmatic risks resulting from technology unavailability or obsolescence are minimized. The use of suitable design or procurement strategies is recommended.

9.2.2 Programme

This programme shall comprise:

a) a description and justification of the selection, evaluation, qualification and validation status of all items, in due time prior to their intended use and procurements;

b) the procurement plan, including type reduction, standardization, monitoring, control and reporting steps whenever appropriate, of these items;

c) the assurance that the selected parts, materials and processes are capable of meeting the applicable requirements and the design engineering rules and standards.

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