

### Gestion de la sûreté de fonctionnement

Partie 1 : Gestion du programme de sûreté de fonctionnement

E : Dependability management – Part 1 : Dependability management systems

D : Zuverlässigkeitsmanagement – Teil 1 : Zuverlässigkeitsmanagementsysteme

### Norme française homologuée

par décision du Directeur Général d'afnor le 5 novembre 2004, pour prendre effet à compter du 5 décembre 2004.

Remplace la norme homologuée NF EN 60300-1, de juillet 1994.

### Correspondance

La norme européenne EN 60300-1:2003 a le statut d'une norme française. Elle reproduit intégralement la publication CEI 60300-1:2003 qui n'existe actuellement qu'en version anglaise (voir avant-propos national).

### Analyse

Le présent document décrit les concepts et principes des systèmes de gestion de la sûreté de fonctionnement.

dow : 2006-09-01

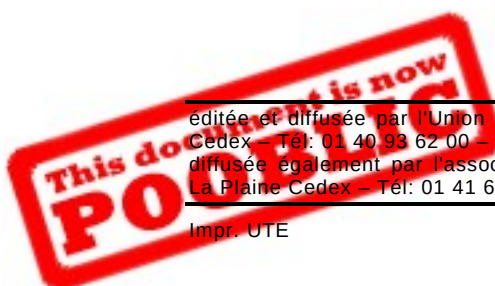
### Descripteurs

Sûreté de fonctionnement, qualité, caractéristique de fonctionnement, gestion, planification, disponibilité, fiabilité, logistique, maintenance, relation client fournisseur.

### Modifications

Par rapport au document remplacé, publication d'une nouvelle édition.

### Corrections



## AVANT-PROPOS NATIONAL

*Le corps du présent document est composé du texte intégral de la norme européenne EN 60300-1:2003 en reprenant le texte de la publication CEI 60300-1:2003. La nature de ce document n'a pas permis d'en faire une traduction complète. Seuls l'introduction et le domaine d'application ont été traduits.*

*Le présent document décrit les concepts et principes des systèmes de gestion de la sûreté de fonctionnement. Il identifie les processus génériques d'un programme de sûreté de fonctionnement en termes de planification, d'affectation des ressources, de contrôle et d'adaptation nécessaires à la réalisation des objectifs de sûreté de fonctionnement.*

*Les modifications du CENELEC (dans le présent document, l'annexe ZA uniquement) sont signalées par un trait vertical dans la marge gauche du texte.*

*Après consultation de son Conseil d'Administration et enquête probatoire, l'Union technique de l'Électricité et de la Communication a voté favorablement au CENELEC sur le projet de EN 60300-1, le 19 mai 2003.*

### Correspondance entre les documents internationaux cités en référence et les documents CENELEC et/ou français à appliquer

| Document international<br>cité en référence                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Document correspondant |                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|---------------------------------------------|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | CENELEC (EN ou HD)     | français (NF ou UTE)                        |
| CEI 60300-2 (2004)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | EN 60300-2 (2004)      | NF EN 60300-2 (2004)<br>(indice C 20-300-2) |
| ISO 9000 (2000)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | EN ISO 9000 (2000)     | NF EN ISO 9000 (2000)<br>(indice X 50-130)  |
| ISO 9001 (2000)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | EN ISO 9001 (2000)     | NF EN ISO 9001 (2000)<br>(indice X 50-131)  |
| ISO 9004 (2000)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | EN ISO 9004 (2000)     | NF EN ISO 9004 (2000)<br>(indice X 50-122)  |
| <p><i>Note : Les documents de la classe C sont en vente à l'Union technique de l'Électricité et de la Communication – BP 23 – 92262 Fontenay-aux-Roses Cedex – Tél. : 01 40 93 62 00 ainsi qu'au service diffusion de l'Association française de normalisation – 11, avenue Francis de Pressensé – 93571 Saint-Denis La Plaine Cedex – Tél. : 01 41 62 80 00.</i></p> <p><i>Les documents CEI sont en vente à l'UTE.</i></p> <p><i>Les documents de la classe X et les documents ISO sont en vente à AFNOR.</i></p> |                        |                                             |



## Introduction

La sûreté de fonctionnement est un facteur essentiel de l'environnement commercial global actuel. Elle affecte en effet le coût et les processus de production. Cette propriété, inhérente à la conception du produit, en affecte les performances. On obtient un produit sûr en mettant en œuvre des disciplines de sûreté de fonctionnement dès le lancement des phases concept et conception du cycle de vie du produit afin d'assurer l'économie des opérations qui le concernent. Comme les autres disciplines techniques et d'ingénierie, la sûreté de fonctionnement doit être gérée afin de fournir aux clients des produits à forte valeur ajoutée. Au sens le plus large, la sûreté de fonctionnement est le reflet de la confiance de l'utilisateur dans l'aptitude à l'emploi du produit, qui se manifeste par sa capacité à fonctionner correctement, par sa disponibilité au service sur demande et par la réduction de ses coûts d'acquisition et de possession tout au long de son cycle de vie.

La sûreté de fonctionnement est le terme collectif qui décrit la disponibilité d'un produit simple ou complexe. Les facteurs qui influencent la disponibilité d'un produit sont les caractéristiques de conception de la fiabilité et de la maintenabilité, ainsi que la logistique de maintenance. L'Annexe A montre les relations de la sûreté de fonctionnement. La fiabilité, la maintenabilité et la disponibilité sont les performances les plus importantes pour le client à la recherche d'un fonctionnement économique. La fiabilité et la maintenabilité sont des caractéristiques intrinsèques à la conception du produit. La logistique de maintenance reflète la capacité de l'organisation de maintenance à fournir les ressources nécessaires au maintien d'un niveau de maintenance permettant d'atteindre les objectifs de disponibilité.

La présente norme internationale fournit les directives générales nécessaires à l'établissement d'un système de gestion de la sûreté de fonctionnement permettant de répondre aux besoins de la plupart des entreprises ou projets. La structure des normes relatives à la sûreté de fonctionnement référencées est basée sur un concept de type "boîte à outils". Les recommandations sont non descriptives afin de faciliter l'adaptation et la mise en œuvre efficace des disciplines de sûreté de fonctionnement dans la gestion. La norme de gestion de la sûreté de fonctionnement de niveau supérieur CEI 60300-1 s'appuie sur la CEI 60300-2 qui fournit la référence de guides d'application et de méthodes. Ce concept de type "boîte à outils" aide les utilisateurs des normes à trouver les guides d'application de la sûreté de fonctionnement spécifiques et les méthodes correspondantes pour atteindre les objectifs de leurs projets propres.

La présente norme internationale encourage l'innovation et la flexibilité dans la gestion et la conception en vue de l'optimisation de produits à contraintes et limitations technologiques connues. Elle est alignée sur la structure des systèmes de gestion de la qualité (QMS, Quality Management System) des normes ISO 9001:2000 et ISO 9004:2000 afin de faciliter l'intégration d'activités de sûreté de fonctionnement au système global de gestion. Les activités de sûreté de fonctionnement viennent compléter les processus de QMS pour atteindre les niveaux souhaités de fiabilité, de maintenabilité et de logistique de maintenance des produits. L'alignement de la CEI 60300-1 sur les normes ISO 9001:2000 et ISO 9004:2000 est nécessaire afin de relier les recommandations spécifiques de sûreté de fonctionnement aux processus QMS correspondants. Les principales clauses de la CEI 60300-1 renvoient aux normes ISO 9001:2000 et ISO 9004:2000 bien que certains libellés de clauses ne soient pas nécessairement les mêmes. Elles traitent de sujets relatifs à la qualité similaires du point de vue de la sûreté de fonctionnement.



## Domaine d'application

La présente norme internationale décrit les concepts et principes des systèmes de gestion de la sûreté de fonctionnement. Elle identifie les processus génériques d'un programme de sûreté de fonctionnement en termes de planification, d'affectation des ressources, de contrôle et d'adaptation nécessaires à la réalisation des objectifs de sûreté de fonctionnement.

La présente norme traite des questions de sûreté de fonctionnement au cours des phases du cycle de vie d'un produit des points de vue de la planification, de la conception, des mesures, de l'analyse et de l'amélioration. La sûreté de fonctionnement comprend la disponibilité et ses facteurs déterminants : fiabilité, maintenabilité et logistique de maintenance.

L'objet est de faciliter la coopération entre toutes les parties concernées (fournisseur, entreprise et client) et favoriser la compréhension et la valeur des besoins de sûreté de fonctionnement afin d'atteindre l'ensemble des objectifs de sûreté de fonctionnement.



EUROPEAN STANDARD

**EN 60300-1**

NORME EUROPÉENNE

EUROPÄISCHE NORM

September 2003

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Supersedes EN 60300-1:1993

English version

**Dependability management**  
**Part 1: Dependability management systems**  
(IEC 60300-1:2003)

Gestion de la sûreté de fonctionnement  
Partie 1: Gestion du programme  
de sûreté de fonctionnement  
(CEI 60300-1:2003)

Zuverlässigkeitsmanagement  
Teil 1: Zuverlässigkeits-  
managementsysteme  
(IEC 60300-1:2003)

This European Standard was approved by CENELEC on 2003-09-01. CENELEC 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 Central Secretariat or to any CENELEC 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 CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

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**CENELEC**

European Committee for Electrotechnical Standardization  
Comité Européen de Normalisation Electrotechnique  
Europäisches Komitee für Elektrotechnische Normung

**Central Secretariat: rue de Stassart 35, B - 1050 Brussels**

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## Foreword

The text of document 56/856/FDIS, future edition 2 of IEC 60300-1, prepared by IEC TC 56, Dependability, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60300-1 on 2003-09-01.

This European Standard supersedes EN 60300-1:1993.

The following dates were fixed:

- latest date by which the EN has to be implemented  
at national level by publication of an identical  
national standard or by endorsement (dop) 2004-06-01
- latest date by which the national standards conflicting  
with the EN have to be withdrawn (dow) 2006-09-01

The main changes with respect to EN 60300-1:1993 are listed below:

- Dependability management system seen as part of the organization's overall management system.
- Structural and terminological alignment with EN ISO 9000:2000 standards.
- Focus on systems.

Annexes designated "normative" are part of the body of the standard.

Annexes designated "informative" are given for information only.

In this standard, annex ZA is normative and annexes A and B are informative.

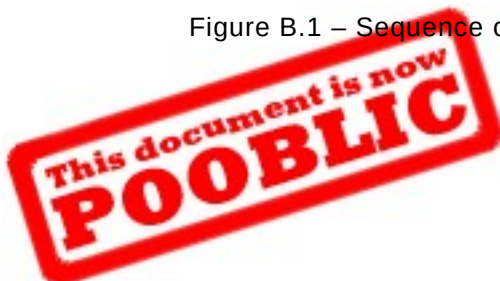
Annex ZA has been added by CENELEC.

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## INTRODUCTION

Dependability is a key decision factor in today's global business environment. Dependability affects product costs and processes. It is an inherent product design property influencing product performance. A dependable product is achieved through the implementation of dependability disciplines in the early concept and design phases of the product life cycle to provide cost-effective product operations. Like other technical and engineering disciplines, dependability needs to be managed in order to deliver high-value products to customers. In the broadest sense, dependability reflects user confidence in fitness for use by attaining satisfaction in product performance capability, delivering service availability upon demand, and minimizing the costs associated with the acquisition and ownership throughout the life cycle.

Dependability is the collective term describing the availability performance of any simple to complex product. The factors influencing the availability performance of a product are the reliability and maintainability design characteristics and the maintenance support performance. Annex A provides the dependability relationships. In many products, reliability, maintainability, and availability rank amongst the dominant performance characteristics of importance to the customers seeking cost-effective operation. Reliability and maintainability are performance characteristics inherent in the product design. Maintenance support is external to the product, and will affect its dependability. Maintenance support performance reflects the ability of the maintenance organization to provide the necessary resources to sustain a level of maintenance support effort to achieve system availability performance objectives.

This part of IEC 60300 provides general guidelines in establishing a dependability management system to meet most organization or project needs. The structure of the referenced dependability standards follows a "tool-box" concept. The recommendations are non-prescriptive to facilitate tailoring and effective implementation of dependability disciplines in management. The top-level dependability management standard IEC 60300-1 is supported by IEC 60300-2 providing references to application guidelines and methods. This "tool-box" concept helps standards users locate specific dependability application guidelines and relevant methods to accomplish their respective project objectives.

This standard encourages innovation and flexibility in management and design for product optimization with known constraints and technology limitations. It is aligned with ISO 9001:2000 and ISO 9004:2000 Quality Management Systems (QMS) structure to facilitate incorporation of dependability activities in the overall management system. Dependability activities complement QMS processes to achieve the desired levels of reliability, maintainability, and maintenance support performance of products. The alignment of IEC 60300-1 to ISO 9001:2000 and ISO 9004:2000 is necessary to link specific dependability recommendations to relevant QMS processes. The major clauses in IEC 60300-1 are cross-referencing ISO 9001:2000 and ISO 9004:2000 although some clause headings may not be exactly the same. They address similar quality topics from a dependability perspective.



## DEPENDABILITY MANAGEMENT –

### Part 1: Dependability management systems

#### 1 Scope and object

This part of IEC 60300 describes the concepts and principles of dependability management systems. It identifies the generic processes in dependability for planning, resource allocation, control, and tailoring necessary to meet dependability objectives.

This standard deals with the dependability performance issues in the product life-cycle phases concerning planning, design, measurements, analysis and improvement. Dependability includes availability performance and its influencing factors: reliability performance, maintainability performance, and maintenance support performance.

The object of this standard is to facilitate co-operation by all parties concerned (supplier, organization and customer) and foster understanding of the dependability needs and value to achieve the overall dependability objectives.

#### 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.

IEC 60300-2, *Dependability management – Part 2: Guidelines for dependability programme management*<sup>1</sup>

ISO 9000:2000, *Quality management systems – Fundamentals and vocabulary*

ISO 9001:2000, *Quality management systems – Requirements*

ISO 9004:2000, *Quality management systems – Guidelines for performance improvements*

#### 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

NOTE Certain terms come from IEC 60050(191) and, where this is the case, the concept from that publication is referenced in square brackets after the definition. ISO 9000:2000 is used as referenced to quality vocabulary.

##### 3.1

##### **dependability**

collective term used to describe the availability performance and its influencing factors: reliability performance, maintainability performance and maintenance support performance

NOTE Dependability is used only for general descriptions in non-quantitative terms.

[IEC 60050, 191-02-03]



<sup>1</sup> Second edition to be published.

### 3.2

#### **dependability management**

coordinated activities to direct and control an organization with regard to dependability

NOTE Dependability management is part of an organization's overall management.

### 3.3

#### **dependability management system**

management system to direct and control an organization with regard to dependability

NOTE 1 The dependability management system of an organization is part of its overall management system.

NOTE 2 The organizational structure, responsibilities, procedures, processes and resources used for managing dependability are often referred to as dependability programme.

### 3.4

#### **dependability plan**

document setting out the specific dependability practices, resources and sequences of activities relevant to a particular product, contract or project

### 3.5

#### **product**

result of a process

NOTE 1 There are four generic product categories, as follows:

- services (for example, transport);
- software (for example, computer program, dictionary);
- hardware (for example, engine mechanical part);
- processed materials (for example, lubricant).

Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed material depends on the dominant element. For example the offered product "automobile" consists of hardware (for example, tyres), processed materials (for example, fuel, cooling liquid), software (for example, engine control software, driver's manual), and service (for example, operating explanations given by the salesman).

NOTE 2 Service is the result of at least one activity necessarily performed at the interface between the supplier and customer and is generally intangible. Provision of a service can involve, for example, the following:

- an activity performed on a customer-supplied tangible product (for example, automobile to be repaired);
- an activity performed on a customer-supplied intangible product (for example, the income statement needed to prepare a tax return);
- the delivery of an intangible product (for example, the delivery of information in the context of knowledge transmission);
- the creation of ambience for the customer (for example, in hotels and restaurants).

Software consists of information and is generally intangible and can be in the form of approaches, transactions or procedures.

Hardware is generally tangible and its amount is a countable characteristic. Processed materials are generally tangible and their amount is a continuous characteristic. Hardware and processed materials often are referred to as goods.

NOTE 3 Quality assurance is mainly focused on intended product.

[ISO 9000, 3.4.2]

NOTE 4 In the context of dependability, a product may be simple (for example, a device, a software algorithm) or complex (for example, a transportation system or an integrated network comprising of hardware, software and human elements and support facilities and activities).

### 3.6

#### **system**

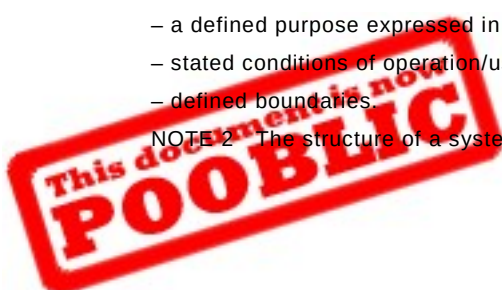
set of interrelated or interacting elements

[ISO 9000, 3.2.1]

NOTE 1 In the context of dependability, a system will have

- a defined purpose expressed in terms of intended functions;
- stated conditions of operation/use (191-01-12);
- defined boundaries.

NOTE 2 The structure of a system may be hierarchical.



## 4 Dependability management system

### 4.1 Application

This standard is applicable for organizations wishing to establish and maintain a dependability management system. It provides generic guidance for effective dependability management of products, which may consist of a combination of hardware, software, and human interactions and support activities. The objective is to ensure achievement of the dependability of the product under consideration by addressing the essential dependability management processes. These processes are generic and applicable to all organizations, life-cycle phases, and contract situations, regardless of type, size and product provided.

It is recognized that, in certain circumstances, it may be inappropriate to include all the clauses of this standard within a project or a contract. Accordingly, this standard should only be considered as forming part of a contract – however that contract may be formed – if the parties to that contract explicitly call upon and refer to this standard (or parts thereof) and require it to be included within the contract.

This standard describes the fundamentals of dependability management systems and provides general principles for organizations aiming to

- a) establish a dependability management system to achieve product dependability objectives;
- b) determine the customer's dependability needs and expectations and how to meet them;
- c) assist in the development of dependability plans;
- d) measure and improve the effectiveness of the dependability management system;
- e) facilitate communications on dependability activities.

### 4.2 General recommendations

The organization should establish and maintain a dependability management system to direct and control the dependability activities. The dependability management system of an organization should be an integral part of its overall management system. Annex B provides generic process steps for managing dependability.

The organization should

- a) identify the dependability activities related to the needs of the organization's business;
- b) establish dependability objectives and plan product life-cycle phases as appropriate to specific projects;
- c) ensure timely implementation of relevant time-phased dependability activities during all applicable project phases;
- d) determine criteria and methods for dependability assessment, evaluation and acceptance of the product;
- e) provide available resources and information necessary to support product realization by implementation of relevant dependability activities in projects;
- f) monitor the dependability activities, and measure and analyse the results for continual improvement;
- g) encourage collaboration of process applications (design, product realization, service provision, etc.) to maintain cost-effective operations;
- h) promote supplier-organization-customer relationships to achieve overall project objectives and customer satisfaction.



### 4.3 Documentation recommendations

The dependability management system documentation should include

- a) documented statement of dependability policy and objectives;
- b) dependability plans;
- c) dependability methods relevant to the organization's project or business;
- d) dependability records.

## 5 Management responsibility

### 5.1 Management function and commitment on dependability

The management function on dependability should be identified. A dependability management system should be an integral part of the overall management system. Specific management roles and dependability objectives should be clarified in relation to quality and other technical disciplines as necessary for the organization or project. This is to achieve business needs and customer objectives, and continual improvement of the organization. The management function on dependability should include

- strategic planning for dependability;
- definition of a suitable organizational structure, including definition of responsibilities and authorities for dependability activities;
- allocation of dependability resources;
- communication of dependability objectives and the benefits arising out of the dependability activities;
- identification of responsibilities and authorities for dependability management and activities;
- establishment of dependability policy, programmes and associated processes;
- implementation and control of dependability activities;
- assessment of dependability performance results;
- continual improvements of product dependability;
- systematic review of above.

Top management should provide evidence of its commitment and involvement in the dependability management system to ensure its effectiveness and continual improvement.

### 5.2 Customer focus on dependability

Top management should ensure that customer needs and expectations for dependability are determined, understood, and met by focusing on the objective of enhancing customer satisfaction. Supplier and customer dialogue should be sustained to ensure that dependability problems are promptly resolved and the dependability of product is continually improved.

### 5.3 Dependability policy

Top management should establish a policy aimed at achievement of product dependability objectives and customer value. The dependability policy may form part of the management policy, or be incorporated in the quality policy.



## 5.4 Dependability planning

Top management should ensure that dependability planning is linked to the strategic business plan and form part of the overall management plan. Dependability should be viewed as a key business decision factor and technology enabler to deliver added value to customers. The dependability plan should encompass customer feedback mechanisms to determine product dependability performance. Dependability planning should examine some of the following issues as appropriate:

- market needs and timing for dependability initiatives;
- dependability as a value-added attribute of products providing a market advantage or leverage;
- interactions between dependability management and other management processes;
- dependability design trade-off to optimize cost-effective solutions;
- regulatory and contract stipulations affecting cost-effective dependability performance;
- dependability competence development and maintenance of the organization's resources;
- retention of knowledge base and intellectual properties;
- dependability information dissemination and feedback mechanisms;
- implementation of dependability plan and strategy;
- social benefits and environmental impact.

## 5.5 Responsibility, authority and communication

Top management should ensure that the responsibilities and authorities for dependability are defined, communicated, and provided with sufficient resources. Specific dependability functions and assignments to projects should be identified, and their interrelation with quality and other technical disciplines should be communicated within the organization.

Where necessary, the role of a management representative for dependability issues should be designated to ensure customer needs and expectations on dependability are adequately addressed. Internal and external communications on dependability issues should be identified as part of the dependability planning process.

## 5.6 Management review

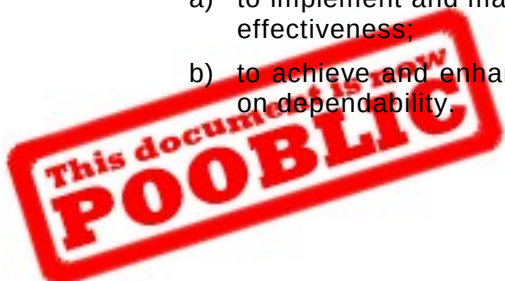
The dependability management system should be reviewed regularly to ensure its continuing suitability, adequacy, and effectiveness. Management review may be combined with other continual improvement activities. Top management should conduct the management review to determine if the organization's dependability policy and objectives are met. Relevant dependability information should be made available at the management review meetings for decision-making. Recommendations on dependability improvements and proposed changes in the dependability management system should be presented for the review. Decision and action items resulting from the management review meetings should be recorded for reference and follow-up.

# 6 Resource management

## 6.1 Provision of resources

The organization should determine and provide the resources needed:

- a) to implement and maintain the dependability management system and continually improve its effectiveness;
- b) to achieve and enhance customer satisfaction by meeting customer needs and expectations on dependability.



## 6.2 Human resources

Personnel assigned to dependability projects or performing specific dependability activities should be competent, based on appropriate education, training, skills and experience.

Personnel responsible for dependability should be encouraged and provided with the opportunity to continuously improve their knowledge and competence through training and education. Their dependability knowledge and competence should be kept current and up-to-date to enable adaptation to business and market changes. A human resource review process should be in place to determine the need for appropriate competence enhancement, personal development, and to prepare the employees for assuming additional responsibilities.

## 6.3 Infrastructure

The organization should determine, provide and maintain the infrastructure needed to achieve long-term dependability goals and short-term project objectives reflecting the organization's dependability policy.

Infrastructure includes, for example,

- a) workplace, facilities and utilities to support dependability activities;
- b) information systems to facilitate dependability data capture, dissemination and archiving, and use of data;
- c) security systems to protect information and intellectual properties;
- d) processes for contracting out non-core support activities.

## 6.4 Work environment

The organization should establish and maintain a work environment to encourage continual learning, leadership training and team building, and continual process improvement according to the organization's business needs. Dependability as a key business factor should be taken into consideration in the work environment.

# 7 Product realization

## 7.1 Planning of product realization

The organization should plan and develop the processes affecting dependability consistent with the product objectives or specification. Appropriate dependability activities should be implemented in each product life-cycle phase. These should be integrated with other elements of the product development and production processes and the operational activities of the organization for cohesive project effort. The extent and contents of a dependability plan should be governed by the particular needs of the project. This content includes the specific constraints and the criticality of dependability application of the actual product.

NOTE Guidance for developing a dependability plan is provided in IEC 60300-2.

In planning for product realization, the organization should determine where appropriate:

- a) the dependability objectives for the product;
- b) the methods and processes to be applied to meet the dependability objectives;
- c) the need to establish specific processes affecting dependability due to technology limitations and application constraints;
- d) the verification and validation methods and relevant criteria for product dependability evaluation and acceptance;
- e) the need for dependability documentation and records.

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## **7.2 Customer-related processes**

The organization should determine

- a) the dependability needs and objectives in conjunction with the customer reflecting the market or business strategy;
- b) the statutory and regulatory requirements governing the use and applications of the product;
- c) the expected end-use conditions and application environments affecting the dependability performance of the product.

The organization should ensure that dependability objectives are defined and the organization's ability in meeting those objectives is assessed. A dependability review process should be put in place and reviews conducted at specific product life-cycle phases to facilitate evaluation and acceptance of the product.

Dependability records should be maintained for product validation and acceptance. Relevant information associated with the product dependability should be communicated to the customer on a timely basis. Customer feedback on dependability issues should be reviewed for problem resolution and continual improvement. Customers should be advised of any planned product discontinuance.

## **7.3 Design and development**

The organization should plan and control the design and development activities affecting dependability of the product. Design inputs and outputs should be reviewed, evaluated and records maintained. Design changes or modifications should be controlled. Dependability issues impacting production, service operations, maintenance support, and product disposal or possible reuse should be identified, documented and resolved as early as possible. Project risk assessment and life-cycle cost analysis should be initiated where applicable and appropriate to ensure dependability performance is optimized with given life-cycle cost constraints.

## **7.4 Purchasing and subcontracting**

The organization should ensure that purchased and subcontracted product conforms to specified dependability criteria. Supplier selection should be initiated. Supplier qualification should form part of the purchasing and subcontracting process. Where necessary, relevant dependability data and history of the product should be obtained and assessed to validate that its dependability could meet end-use environment. Supplier communications should be established to ensure a collaborative effort and sharing of dependability information relating to the purchased and subcontracted product.

## **7.5 Production and service provision**

The organization should plan its production and service provision processes for control of dependability performance. Where applicable, dependability testing and validation of the product at specific stages of assembly and product integration should be conducted to ensure product conformance prior to release or delivery. Product identification should be initiated where appropriate for control of product versions to ensure product traceability. The organization should establish a supply-chain management process to facilitate procurement, and contracting of the project work. Where applicable, customer property should be identified and protected against damage, misuse or loss. All incidents related to the customer property should be reported to the customer for action and resolution on a timely basis. Where the product has degradation or shelf-life limitation, a preservation process should be initiated to monitor and record its status and conditions.



## 7.6 Control of monitoring and measuring devices

Dependability testing and measurement relies on the accuracy of instrumentation and measuring devices. The organization should establish processes as part of the QMS for control and calibration of monitoring and measuring devices. Primary test equipment and software test algorithms for product dependability evaluation and performance validation should be calibrated and traceable to established standards. Calibration records for monitoring and measuring equipment should be maintained.

## 8 Measurement, analysis and improvement

### 8.1 General

The organization should plan and implement processes to monitor, measure, analyse and improve the effectiveness of the organization's dependability management system and the dependability of its products. Early focus on design for dependability should be initiated as appropriate to the product life-cycle phases.

NOTE Guidance for quality management system performance improvement is provided in ISO 9004. Guidance for product dependability improvement is provided in IEC 60300-2.

### 8.2 Monitoring and measurement

The organization should initiate processes for

- a) determining customer satisfaction by monitoring customer feedback and complaints;
- b) validating the status and effectiveness of the dependability plan by suitable assessment or survey methods;
- c) measuring the product performance for acceptance at various phases of the product life cycle to determine design adequacy, yield and throughput, effectiveness in operation and maintenance, as well as efficiency in logistic support. Typical product performance data needed for dependability assessment include the following:
  - system configuration;
  - reliability evaluation and verification;
  - systems integration test results;
  - product acceptance records;
  - system operational records on failures, malfunction, or degradation;
  - maintenance service records;
  - logistics support.

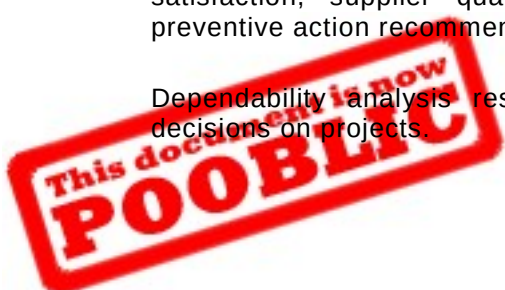
### 8.3 Control of nonconforming product

The organization should establish a process for controlling nonconforming product. Nonconforming products such as products with excessive early failures, design defects, or abnormal wear-out should be identified and controlled for dependability management review and resolution.

### 8.4 Analysis of data

The organization should establish a process for data collection, analysis and reporting. The analysed data should be interpreted to provide information on items such as customer satisfaction, supplier quality, product dependability, performance trends and corrective/preventive action recommendations as appropriate.

Dependability analysis results should be documented and used to support management decisions on projects.



## 8.5 Improvement

The organization should continually improve the effectiveness of the dependability management system through implementation of dependability policy and strategic plans, use of suitable assessment or survey methods and the analysis of relevant dependability data, management of nonconformity through preventive and corrective actions and review processes. Improvement records should be maintained to establish trends.



## Annexe A (informative)

### Dependability relationships

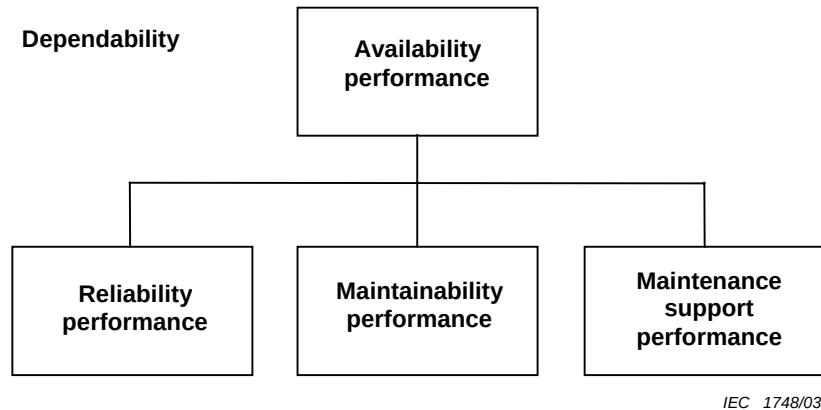


Figure A.1 – Dependability relationships

**Dependability** is a collective term used to describe the availability performance and its influencing factors: reliability performance, maintainability performance and maintenance support performance.

**Availability performance** is the ability of an item to be in a state to perform a required function under given conditions at a given instant of time or over a given time interval, assuming that the required external resources are provided [see IEV 191-02-05].

**Reliability performance** is the ability of an item to perform a required function under given conditions for a given time interval [see IEV 191-02-06].

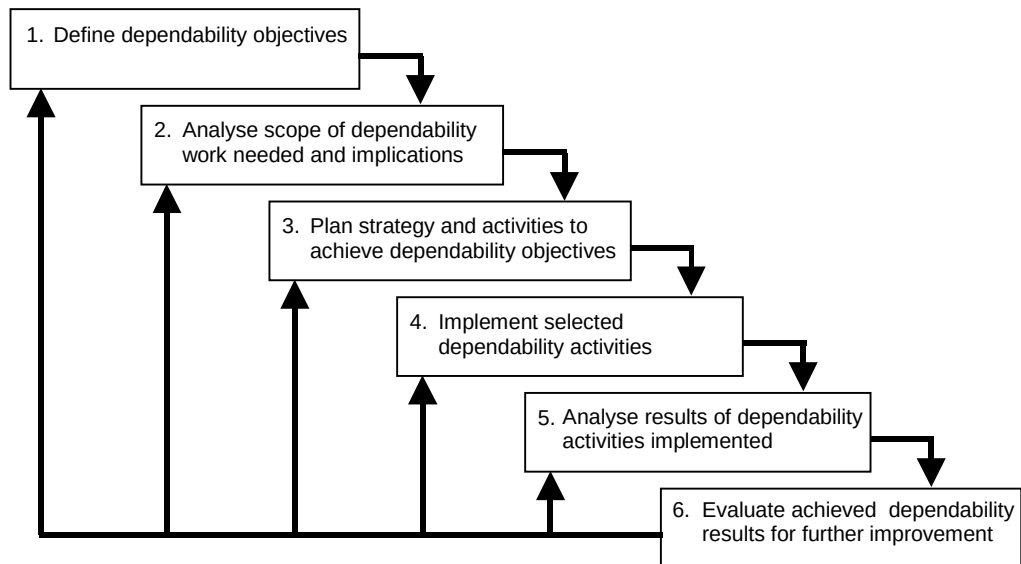
**Maintainability performance** is the ability of an item under given conditions of use, to be retained in, or restored to a state in which it can perform a required function, when maintenance is performed under given conditions and using stated procedures and resources [see IEV 191-02-07].

**Maintenance support performance** is the ability of a maintenance organization, under given conditions, to provide upon demand, the resources required to maintain an item, under a given maintenance policy [see IEV 191-02-08].



## Annexe B (informative)

### Process steps for managing dependability



IEC 1749/03

**Figure B.1 – Sequence of activities**

The process steps for managing dependability consist of a sequence of activities that could be applied to any phase of a product life cycle. The feedback loop to the various process steps permits continual improvement where appropriate.

A product life cycle consists of the following phases:

- concept and definition;
- design and development;
- manufacturing;
- installation;
- operation and maintenance;
- disposal.

NOTE Applicable dependability standards to each process step are provided in IEC 60300-2.



## Bibliography

IEC 60050-191:1990, *International Electrotechnical Vocabulary (IEV) – Chapter 191: Dependability and quality of service*

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## Annex ZA (normative)

### Normative references to international publications with their corresponding European publications

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).

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

| <u>Publication</u> | <u>Year</u>     | <u>Title</u>                                                                 | <u>EN/HD</u> | <u>Year</u>     |
|--------------------|-----------------|------------------------------------------------------------------------------|--------------|-----------------|
| IEC 60300-2        | - <sup>1)</sup> | Dependability management<br>Part 2: Guidance for dependability<br>management | EN 60300-2   | - <sup>1)</sup> |
| ISO 9000           | 2000            | Quality management systems<br>Fundamentals and vocabulary                    | EN ISO 9000  | 2000            |
| ISO 9001           | 2000            | Quality management systems -<br>Requirements                                 | EN ISO 9001  | 2000            |
| ISO 9004           | 2000            | Quality management systems<br>Guidelines for performance<br>improvements     | EN ISO 9004  | 2000            |

