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भाग 4 निर्भरणीयता कार्यक्रम प्रबंध की मार्गदर्शिका

Indian Standard

QUALITY MANAGEMENT AND QUALITY ASSURANCE STANDARDS

PART 4 GUIDE TO DEPENDABILITY PROGRAMME MANAGEMENT

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NATIONAL FOREWORD

This Indian Standard which is identical with ISO 9000-4 : 1993 'Quality management and quality assurance standards — Part 4 : Guide to dependability programme management', issued by the International Organization for Standardization (ISO), was adopted by the Bureau of Indian Standards on the recommendation of the Quality Management Sectional Committee (MSD 2), and approval of the Management and Systems Division Council.

The text of the ISO Standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

In the adopted standard, normative references appear to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their place are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
IEC 50 (191) : 1990	IS 1885(Part 39)[1)] Electrotechnical vocabulary — Part 39 : Dependability of electronic and electrical items (*second revision*)	Technically Equivalent
ISO 8402 : 1994	IS/ISO 8402 : 1994 Quality management and quality assurance — Vocabulary (*first revision*)	Identical
ISO 9001 : 1994	IS/ISO 9001 : 1994 Quality systems — Model for quality assurance in design, development, production, installation and servicing (*first revision*)	Identical
ISO 9002 : 1994	IS/ISO 9002 : 1994 Quality systems — Model for quality assurance in production, installation and servicing (*first revision*)	Identical
ISO 9003 : 1994	IS/ISO 9003 : 1994 Quality systems — Model for quality assurance in final inspection and test (*first revision*)	Identical
ISO 9004-1 : 1994	IS/ISO 9004-1 : 1994 Quality management and quality system elements — Part 1 : Guidelines (*fourth revision*)	Identical

The latest editions of referred standards, at the time of publication of this amendment, have been mentioned for the information of users of this standard, even though some of them were brought out after publication of this standard. However, till this standard is revised, specific clause references may tally with those in earlier editions.

In the adopted standard, normative reference has also been made to 'IEC 300-2 : XX, Dependability management — Part 2 : Dependability programme elements and tasks', which is under consideration for publication as an International Standard. The Committee would review the provisions of this International Standard as and when it is published and decide whether it may be adopted as Indian Standard.

[1)] to be published.

Indian Standard

QUALITY MANAGEMENT AND QUALITY ASSURANCE STANDARDS

PART 4 GUIDE TO DEPENDABILITY PRORAMME MANAGEMENT

1 Scope

This part of IEC 300/ISO 9000 provides guidance on dependability programme management. It covers the essential features of a comprehensive dependability programme for the planning, organization, direction and control of resources to produce products which will be reliable and maintainable. In management terms, it is concerned with what has to be done, and why, and when and how it has to be done, but it is not specific about who should do it and where, because organizations and projects vary widely.

This part of IEC 300/ISO 9000 is applicable to hardware and/or software products, where dependability characteristics are significant during the operation and maintenance phase. The requirements are aimed primarily at controlling influences on dependability at all product life-cycle phases from product planning to operation.

Any agreement using the guidance given in this part of IEC 300/ISO 9000 may use selected parts to fit particular circumstances. The parties involved shall agree upon and record the extent to which it is applied, including the guidance given in other parts of the IEC 300 series. Any selected clauses used in this way become requirements.

NOTES

1 The guidance given in this part of IEC 300/ISO 9000 primarily applies to a supplier with a small number of qualified customers but it can also be applied to the supply of consumer products.

2 The guidance given in this part of IEC 300/ISO 9000 addresses the life-cycle phases as defined and would also apply to any further subdivision of phases.

3 The masculine gender is used in this part of IEC 300/ISO 9000 to represent also the feminine gender where applied to persons.

4 In the context of this part of IEC 300/ISO 9000 the terms "document" and "documentation" are not restricted to paper media.

5 The term "customer" used in this part of IEC 300/ISO 9000 is synonymous with the term "purchaser".

2 Normative references

The following normative documents contain provisions which, through reference in this text constitute provisions of this part of IEC 300/ISO 9000. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this part of IEC 300/ISO 9000 are encouraged to investigate the possibility of applying the most recent editions of the normative documents listed below. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 50(191): 1990, *International Electrotechnical Vocabulary (IEV) – Chapter 191 – Dependability and quality of service*

IEC 300-2: XX, *Dependability management – Part 2: Dependability programme elements and tasks* (future publication under consideration)

ISO 8402: 1986, *Quality – Vocabulary*

ISO 9001: 1987, *Quality systems – Model for quality assurance in design/development, production, installation and servicing*

ISO 9002: 1987, *Quality systems – Model for quality assurance in production and installation*

ISO 9003: 1987, *Quality systems – Model for quality assurance in final inspection and test*

ISO 9004: 1987, *Quality management and quality system elements – Guidelines*

3 Definitions

For the purposes of this part of IEC 300/ISO 9000, the terms and definitions of IEC 50 (191) and ISO 8402 apply, together with the following particular terms and definitions:

3.1 **dependability:** The 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.

3.2 **dependability programme:** The organizational structure, responsibilities, procedures, processes and resources used for managing dependability.

NOTE - A dependability programme covers all phases of a product's life cycle from planning to operation and possibly disposal. A dependability programme is composed of programme elements divided into tasks.

3.3 **dependability plan:** A document setting out the specific dependability practices, resources and sequence of activities relevant to a particular product, contract or project.

3.4 **product:** Any specified deliverable goods or service.

4 Management responsibilities

4.1 *Policy*

The supplier should establish and maintain a document expressing his policy and objectives regarding the dependability characteristics of his products and the related support services. This document may constitute a part of a quality policy document prepared in accordance with 4.1.1 of ISO 9001 and the guidance given in 4.2 and 4.3 of ISO 9004.

4.2 *Organization*

The supplier should establish and maintain programme elements and resources in his organization to achieve assurance of dependability. These elements can be product and project independent as well as project or product specific. They should be easily identifiable, and may be independent of but suitably interfaced with the organization responsible for performing quality assurance activities.

The functions to achieve assurance of dependability and quality assurance may have common organizational elements, in which case they may be integrated and executed in conjunction, but still remain identifiable.

4.3 *Quality system*

The supplier should establish and maintain a documented quality system in accordance with ISO 9001, ISO 9002 or ISO 9003, as applicable.

4.4 *Market research and product planning*

The supplier should establish and maintain procedures for market research to determine the needs of prospective customers for the dependability of products being considered for market introduction, and for converting these needs into specifications.

Early product planning activities, including feasibility studies, should be conducted on the basis of dependability specifications, based on market research.

4.5 *Management review*

The supplier should carry out reviews, at management level and with appropriate time intervals, of the dependability programme adopted in accordance with the guidance given in this part of IEC 300/ISO 9000. Records of such reviews should be maintained.

NOTE - These reviews should be coordinated with the management reviews done in accordance with 4.1.3 of ISO 9001.

4.6 *Dependability programme reviews*

The supplier should establish and maintain procedures for a systematic, recurrent and independent review of the adequacy of processes, procedures and tools used for his dependability programme, including;

- review of the dependability programme and its elements and tasks, including the rationale for their selection;
- review of all documents describing the programme, its elements, tasks and results;
- consideration of the effective performance and achievement of the dependability programme and approval of any changes;
- evaluation of the cost-effectiveness of the programme in terms of its benefits; higher dependability, lower maintenance cost, etc.

5 Product or project Independent programme elements

5.1 *Dependability programme implementation*

The supplier should be capable of implementing a dependability programme, with task selection based on IEC 300-2, to ensure that the specified dependability requirements are met.

The structure and elements of the dependability programme and the detailed descriptions of the procedures, analysis methods, tools and statistical principles used to define, control and evaluate dependability characteristics should be documented.

5.2 *Methods*

The supplier should establish and maintain access to effective statistical and other relevant qualitative and quantitative methods and models appropriate for prediction, analysis and estimation of dependability characteristics of his products. Education and training programmes should be issued and implemented for any personnel categories that will use the methods.

5.3 *Data banks*

The supplier should establish and maintain data banks to provide feedback on the dependability of its products, from testing and/or operation, in order to assist in product design, current product improvement, maintenance support planning, or as otherwise needed for the dependability programme.

5.4 *Dependability records*

All documents containing requirements for dependability and their allocation, dependability plans and results of dependability analyses and predictions, dependability test instructions and results, and field data analysis records should be retained for an appropriate period, defined with relation to the expected product life time. A master list of relevant documents, including their revision status, should be established and maintained in accordance with 4.5 of ISO 9001.

6 Product or project specific programme elements

6.1 *Planning and management*

The supplier should develop a dependability plan as a part of the general product plan or project plan.

The dependability plan should be reviewed, and if necessary revised, at project and product reviews. These reviews should also verify that the programme elements and tasks, analyses, and results conform to the plan and the specified dependability requirements.

The supplier should establish and maintain procedures for securing traceability, as defined in IEC 300-2, of dependability requirements.

Dependability is one of the driving factors in the configuration management procedure, which should be established and maintained by the supplier in accordance with guidance given in 8.8 of ISO 9004.

NOTE - The programme tasks are defined in 6.1 of IEC 300-2 (dependability plans; project decision management; traceability management; configuration management).

6.2 *Contract review and liaison*

The supplier should establish and maintain procedures for contract review, performed in accordance with 4.3 of ISO 9001, in order to ensure that the dependability requirements and the conditions and constraints for definition of dependability requirements are adequately specified and documented, that any dependability requirements differing from those in the tender are resolved, that operations and maintenance support conditions are adequately defined by the customer and that acceptance testing criteria are specified. Records which include decisions taken at these reviews should be maintained.

The supplier should appoint a management representative to interface with the customer.

NOTE - The programme tasks are defined in 6.2 of IEC 300-2 (contract review; management representative).

6.3 *Dependability requirements*

The supplier should prepare specifications which contain qualitative and quantitative requirements for availability performance, reliability performance and maintainability performance. The maintenance support assumptions should be clearly stated, taking into account any customer-provided information.

The supplier should perform a requirements review activity prior to the start of design. This review should ensure that any incomplete, ambiguous or conflicting dependability requirements are clarified or modified. The overall dependability requirements should, as appropriate, be allocated to the various parts of the product to be designed.

NOTES

1 Dependability requirements may need to be redefined during the product's life cycle.

2 The programme tasks are defined in 6.3 of IEC 300-2 (specification of dependability requirements; requirements interpretation; requirements allocation).

6.4 *Engineering*

The supplier should establish and maintain guidelines and practices for design of the product and its maintenance support to ensure that the desired dependability will be achieved.

NOTE - The programme tasks are defined in 6.4 of IEC 300-2 (reliability engineering; maintainability engineering; maintenance support engineering; testability engineering; human factors engineering).

6.5 *Externally provided products*

The supplier should establish and maintain procedures to specify dependability requirements for externally provided products.

The supplier should require and ensure that all requirements of the dependability programme are fulfilled by any subcontracted hardware or software parts of the final product.

NOTE - The programme tasks are defined in 6.5 of IEC 300-2 (subcontracted products; customer provided products).

6.6 *Analysis, prediction and design review*

The supplier should identify and perform dependability analysis, prediction and formal design review activities (programme tasks) adequate for the product or project.

NOTE - The programme tasks are defined in 6.6 of IEC 300-2 (fault mode and effects analysis; fault tree analysis; stress and load analysis; human factors analysis; predictions; trade-off analysis; risk analysis; formal design review).

6.7 *Verification, validation and test*

The supplier should establish and maintain procedures for effective and adequate verification and validation of dependability requirements.

NOTE - The programme tasks are defined in 6.7 of IEC 300-2 (verification, validation and test planning; life testing; dependability testing; reliability growth testing; production testing; acceptance testing; reliability stress screening).

6.8 *Life-cycle cost programme*

The supplier should establish and maintain procedures for assessing the life-cycle cost elements for the product or project.

NOTE - The programme element is defined in 6.8 of IEC 300-2 (life-cycle cost programme).

6.9 *Operation and maintenance support planning*

The supplier should provide the customer with information needed for the operation of the product.

The supplier should identify and advise the customer on the maintenance support requirements for the product, including recommendations on spare parts (range and scale), test equipment, special tools, maintenance personnel skill levels, etc.

NOTE - The programme tasks are defined in 6.9 of IEC 300-2 (maintenance support planning; installation; support services; support engineering; spares provisioning).

6.10 *Improvements and modifications*

The supplier should establish and maintain procedures for a systematic identification and implementation of any necessary improvement of the reliability performance and maintainability performance of the product and of the maintenance support performance, in order to ensure conformity to dependability requirements.

The supplier should establish and maintain procedures to ensure that changes or modifications of the product or changes to data related to its dependability characteristics will result in a review and, as necessary, revision of all analyses and predictions previously done in order to determine the possible influence on dependability and the possible need to initiate and implement product improvements.

NOTE - The programme tasks are defined in 6.10 of IEC 300-2 (improvement programmes, modification control).

6.11 *Experiences feedback*

The supplier should establish and maintain procedures for handling, storage and analysis of failure and fault data from testing and manufacturing and of operational dependability information received from the customer.

The supplier should define and communicate to the customer information on his need for field data and cooperate with the customer in the establishment of appropriate procedures for field data collection, storage and analysis.

NOTE - The programme tasks are defined in 6.11 of IEC 300-2 (data acquisition; data analysis).