

**Rule of Procedure - Quality Assessment  
Procedures - Part 1: CECC  
requirements for the approval of an  
organization**

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN 100114-1:2002 sisaldab Euroopa standardi EN 100114-1:1996 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 18.12.2002 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN 100114-1:2002 consists of the English text of the European standard EN 100114-1:1996.</p> <p>This document is endorsed on 18.12.2002 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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ICS 03.120.10, 31.020

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EUROPEAN STANDARD

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English version

**Rule of procedure  
Quality Assessment Procedures  
Part 1: CECC requirements for the  
approval of an organization**

Règle de procédure  
Procédure d'assurance de la qualité  
Partie 1: Exigences CECC pour  
un agrément d'organisation

Verfahrensregel  
Qualitätsbewertungsverfahren  
Teil 1: Anforderungen des CECC zur  
Anerkennung von Unternehmen

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

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## FOREWORD

This document is a revision of EN 100114-1:1994. The revision was due to implement the requirements of EN ISO 9001:1994, EN ISO 9002:1994 and EN 45001:1989.

The document has been re-worked by CECC Working Group ECQAC/QAP SG6.

The text of the draft was submitted to the Unique Acceptance Procedure (UAP) and was approved by CENELEC as EN 100114-1 on 1996-02-01.

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) 1996-12-01
- latest date by which the national standards conflicting  
with the EN have to be withdrawn (dow) 1997-12-01

<b>CONTENT</b>		<b>page</b>
<b>Section I:</b>	<b>Organization approval of manufacturers, distributors and specialist contractors</b>	<b>4</b>
	(Section I follows the clause numbering of EN ISO 9001:1994)	
0	Introduction	4
1	Scope	4
2	Normative Reference	4
3	Definitions	5
4	Quality-system requirements	5
4.2	Quality system	5
4.3	Contract review	6
4.4	Design control	6
4.6	Purchasing	6
4.7	Control of customer-supplied product	7
4.8	Product identification and traceability	7
4.9	Process control	7
4.10	Inspection and testing	7
4.11	Control of inspection, measuring and test equipment	7
4.12	Inspection and test status	8
4.13	Control of non-conforming product	8
4.15	Handling, storage, packaging, preservation and delivery	8
4.16	Control of quality records	9
4.19	Servicing	9
4.20	Statistical techniques	9
<b>Section II:</b>	<b>Organization approval of independent test laboratories</b>	<b>10</b>
	(Section II follows the clause numbering of EN 45001:1989)	
0	Introduction	10
1	Object and field of application	10
2	Definitions	10
5	Technical competence	10
5.1	Management and organization	10
5.4	Working procedures	11
<b>Annex A:</b>	<b>Requirements for Organizations' CECC System Managers</b>	<b>13</b>
<b>Annex B:</b>	<b>Subcontracting in the CECC System</b>	<b>15</b>
B.1	Introduction	15
B.2	Subcontracting to manufacturers or specialist contractors with CECC approval	15
B.3	Subcontracting to a remote site which is part of the same parent organization (EMA)	15
B.4	Use of unapproved subcontractors	16
B.5	Sharing of test facilities	16
<b>Annex C:</b>	<b>CECC Policy on Uncertainty of Measurement and inset limits</b>	<b>18</b>
C.1	Objective	18
C.2	Definitions	18
C.3	Calculation of Measurement Uncertainty	18
C.4	Policy	19
C.5	Calculation of Inset and Outset Limits	19
C.6	Examples	20
C.7	References (Information only)	20

## **Section I: Organization approval of manufacturers, distributors and specialist contractors**

### **0 Introduction**

The CECC System bases its requirements for the approval of the organization of a manufacturer, distributor or specialist contractor (supplier approval) on those of the ISO 9000 family of standards (now implemented as EN ISO 900X:1994 and, in earlier versions, variously implemented as EN 2900X and as EN 300XX). To reflect the status of the CECC System as a European activity, reference is made throughout this standard to EN ISO 900X:1994, except in those cases where it is specifically intended to broaden the reference beyond the restrictions implied by the invocation of EN ISO 900X.

The following text provides details of CECC requirements which implement the provisions of EN ISO 9000:1994, with specific reference to EN ISO 9001:1994. Organisations seeking approval under the CECC System should additionally refer to CECC 00 700, which provides administrative procedures. CECC 00 114 Part 0 provides information on types of approval available under the CECC System.

**This section follows the clause numbering of EN ISO 9001:1994.** Where EN ISO 9001:1994 clauses are not specifically invoked, the provisions of those clauses apply without modification. Where EN ISO clauses are referenced, the additional CECC requirements are given.

### **1 Scope**

This section is intended for use by manufacturers, distributors and specialist contractors operating in the field of electronic components, who wish to obtain quality system approval for an organization under the CECC System. This EN shall prevail in cases of apparent conflict.

Application of EN ISO 9001/9002 reliability aspects to electronic components is covered by the CECC Guidance Document "CECC 00 804:1996, Interpretation of EN ISO 9000 - Reliability aspects for electronic components".

### **2 Normative References**

A "normative document" is defined in ISO/IEC Guide 2:1986, as a document that provides rules, guidelines and characteristics for activities or their results.

Notes:

- 1) The term "normative documents" is a generic term that covers such documents as standards, technical specifications, codes of practice and regulations.
- 2) A document is to be understood as any medium with information recorded on or in it.
- 3) The terms for different kinds of normative documents are defined considering the document and its content as a single entity.

Normative documents within the CECC System are: the EN ISO 9000:1994 family, including specifically:

EN ISO 9001:1994 (ISO 9001:1994), Quality systems - Model for quality assurance in design/development, production, installation and servicing,

EN ISO 9002:1994 (ISO 9002:1994) Quality systems - Model for quality assurance in production, installation and servicing,

ISO 10012-1:1992 (EN 30012-1) Quality assurance requirements for measuring equipment - Part 1: Metrological confirmation system for measuring equipment,

EN 45001:1989: General criteria for the operation of test laboratories,

ISO 8402: 1994 (EN 28402: 1994): Quality management and quality assurance - vocabulary,

CECC 00 401:1991: Glossary of abbreviations, terms and definitions of the CECC System.

Details of standards, specifications and other requirements applicable within the CECC System, including ECQAC Permanent Documents, are given in CECC 00 300: List of CECC European Standards (ENs), CECC Publications and related national documents, and CECC 00 301: List of CECC Specifications and related detail specifications.

### 3 Definitions

In addition to definitions given in ISO 8402 (EN 28402): Quality concepts and terminology. Part One: Generic terms and definitions, definitions used within the CECC System are given in CECC 00 401: Glossary of abbreviations, terms and definitions of the CECC System.

### 4 Quality-system requirements

The relevant provisions of EN ISO 900X:1994 shall be met. Implementation of this requirement means that EN ISO 9002:1994, shall be applicable as far as relevant for the component(s) or the range(s) of activity, technology(ies), process(es) and or technical service(s) concerned. An applicant claiming design/development capability shall meet the requirements of EN ISO 9001:1994.

#### 4.1.2.3 Management representative

The "CECC System Manager", who may also be the "management representative", provides a formal contact point for the ONS to enable the resolution of issues related to quality. See Annex A: for additional CECC provisions related to the activities of the "CECC System Manager".

#### 4.2 Quality system

##### 4.2.1 General

The quality system shall be defined and documented by means of a quality manual and supporting documentation. For CECC product/process-related approvals, requirements also exist for a Capability Manual, Process Manual or Technology Approval Declaration Document (TADD) (see CECC 00 114 Parts III, V and VI respectively).

Compliance with this EN shall be confirmed by the ONS periodically. The period between such confirmations shall not exceed two years. Within this period all requirements shall be verified by the normal periodic auditing process.

The organization shall notify the ONS in advance of any changes to the location of its approved facilities, or any part thereof. If there is reason to suppose that there have been any changes affecting the approval at the new location, the ONS may require revalidation of the approval prior to the release of products processed, tested or distributed at the new location.