

Rule of procedure 14

Quality assessment procedures

Part 1. Approval of manufacturers and other organizations

The European Standard EN 100114-1 : 1994 has the status of a British Standard

Cooperating organizations

The European Committee for Electrotechnical Standardization (CENELEC), under whose supervision this European Standard was prepared, comprises the national committees of the following countries:

Austria	Italy
Belgium	Luxembourg
Denmark	Netherlands
Finland	Norway
France	Portugal
Germany	Spain
Greece	Sweden
Iceland	Switzerland
Ireland	United Kingdom

This British Standard, having been prepared under the direction of the Electrotechnical Sector Board, was published under the authority of the Standards Board and comes into effect on 15 September 1994

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The following BSI references relate to the work on this standard:
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Amendment No. 1
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Rule of Procedure 14 Quality assessment procedures
Part 1. Approval of manufacturers and other organizations

NOTE. This amendment implements EN 100114-1 : 1994/A1 : 1994.
A consequent amendment to the national foreword has also been made.

This amendment together with the European Standard
EN 100114-1 : 1994 has the status of a British Standard.

Revised text

National foreword

In paragraph 1, line 4, after 'organizations,' insert 'as amended by amendment A1 : 1994,'.

AMD 8444/February 1995

EN addendum page

Insert, after the foreword of EN 100114-1 : 1994, the attached addendum to the title page and amend the text in accordance with the details given on the addendum page.

AMD 8444/February 1995

Rule of Procedure : Quality Assessment Procedures
Part I : Approval of Manufacturers and Other Organizations

ADDENDUM

The following amendments (1 to 5) shall be made

- 1) Add on the title page after the document number EN 100 114 - 1 '+ **A1**'
- 2) Add to the 'CONTENTS' list on page 4 the following:
'Annex B (Informative): Guide to the application of ISO 9001 : 1987 requirements within the CECC System'
- 3) At the end of the first paragraph of § 1.1.3(1) on page 11 add the following: '(See Annex B)'
- 4) At the end of the first paragraph of § 3.1.3 on page 18 add the following: '(See Annex B)'
- 5) At the end of the first paragraph of § 7.1.3(1) on page 29 add the following: '(See Annex B)'
- 6) After Annex A insert the new ANNEX B attached (pages 36 to 45).

Secretariat Note:

Annex B to EN 100 114 - 1 : 1994 is based on documents ECQAC/SG 6(Sec)75B and CECC/WG QAP(Secretariat)255.

The text was discussed and accepted by the CECC Special Editing Group (SEG) for publication as an annex to RP 14 Part I. As the information contained in this addendum is urgently requested and French and German translations are not available it is published in English only.

Since this amendment concerns a 'Guide to the application of ISO 9001 : 1987 requirements within the CECC System' and bearing in mind ISO 9001 : 1994 is scheduled to be published within the next few weeks it is important that this amendment be published as soon as possible. In view of this the SEG approved its publication as recommended by WG QAP without voting. The reasons being:

- a) If, as originally planned, the information was published as a Guide in the CECC 00 800 series it would not have been circulated for voting.
- b) If the amendment was circulated for voting it would not be published until early 1995 by which time it will be out of date due to the publication of ISO 9001 : 1994.

ANNEX B
(Informative)

**GUIDE TO THE APPLICATION OF ISO 9001 : 1987
REQUIREMENTS WITHIN THE CECC SYSTEM**

Note:

All the clause numbers given in this Annex B correspond to the clause numbers contained in ISO 9001 : 1987

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ANNEX B

GUIDE TO THE APPLICATION OF ISO 9001 : 1987
REQUIREMENTS WITHIN THE CECC SYSTEM

1. Scope and field of application

1.1 Scope

If a manufacturer, distributor or specialist contractor operating in the field of electronic components (hereafter "eligible organization") applies for approval in accordance with RP 14 Part I, in order to receive CECC : pproval, the requirements of EN 29 00X/ISO 900X are applicable, as prescribed in RP 14 for the design/development, production, distribution, etc., of electronic components. RP 14 shall prevail in cases of apparent conflict.

- 1.2 Field of application
- RP 14, Part I, Paragraphs 1.1.3(1), 3.1.3 and 7.1.3(1), explicitly requires that the relevant requirements of EN 29 00X/ISO 900X have to be met. EN 29 00X/ISO 900X are therefore applicable as far as relevant for the product or activity concerned.
2. References
- Details of standards, specifications and other requirements applicable within the CECC System, including ECQAC Permanent Documents, are given in CECC 00 300 and CECC 00 301.
3. Definitions
- Definitions used within the CECC System are given in CECC 00 401.
4. Quality system requirements
- 4.1.2.3 Management representative
- The CECC System Manager (previously "Chief Inspector"), who may also be the "management representative", provides a formal contact point for the ONS to enable the resolution of questions related to quality. (See RP 14 Part I §§ 1.2, 3.2, 5.2 and 7.2).
- 4.2 Quality system
- The quality system for the product or services concerned should be defined and documented by means of a quality manual, as prescribed in ECQAC-2100. The quality manual may be a

main document supported by one or more levels of subsidiary documents, each level being progressively more detailed. For example, there may be an overall quality manual and one or more procedural manuals.

4.3

Contract review

The purchaser's requirements, as reflected in the contract, should include as a minimum all requirements of the relevant CECC specification. This should be verified by means of a defined procedure.

4.4

Design control

4.4.1

General

Requirements for design are also to be found in RP 14 Parts II to VI and in CECC documents relevant to the approval.

4.4.5

Design verification

In the case of Capability Approval, design verification may be covered in the Capability Manual. Qualification tests and demonstrations may be used as a form of design verification, for hardware, software, services or processed material.

4.6

Purchasing

4.6.1

General

To ensure that all purchased sub-contracted materials (including services) conform to a specified requirement, purchasing should be planned and carried out under a defined

procedure, which should take account of the specific product or service being provided.

This should include the assessment and selection of sub-contractors, who should preferably fulfil the requirements of RP 14 Part V.

4.6.2 Assessment of sub-contractors

The eligible organization should additionally either invoke the requirements of the relevant parts of RP 14, including RP 14 Part V, or establish his own procedure to assess sub-contractors to ensure that they meet sub-contracting requirements.

The fulfilment of this requirement does not diminish the responsibility of the CECC System Manager in respect of incoming materials.

4.6.3 Purchasing data

Purchasing data should be clearly defined technically (e.g. in a Customer Detail Specification) in order to ensure the quality of purchased product (including services).

4.6.4 Verification of purchased product

Except as covered in RP 14 Part V, if specified in the contract, the eligible organization should verify that the purchased product conforms to specified requirements. In such cases, the verification should include the facilities of the sub-contractor, product verification and processes.

- 4.7 Purchaser supplied product
- Purchaser (i.e. customer supplied product is material (e.g. raw or part-processed materials, piece parts, software, testing or production equipment) owned by the purchaser and which is necessary to complete the product in accordance with the contract. The eligible organization is responsible for the prevention from damage, identification, maintenance, handling, use and storage of the purchaser supplied product. If not specified in the contract, the supplier should establish his own procedure to meet the contract requirement.
- The purchaser supplied product may also be a service provided by the purchaser (e.g. transportation, consultancy, etc....).
- Purchaser supplied product should be subjected to standard rules and procedures for relevant incoming inspection, periodic inspection, etc....
- 4.8 Product identification and traceability
- In accordance with RP 14 Part I §§ 1.2.3(14) and RP 14 Part IV, product identification and traceability is a requirement of the CECC System.
- 4.9 Process control
- 4.9.1 General
- Process control may use statistical methods, and may be supplemented by procedures to maintain software or in-process material and

activity needed for appropriate storage, handling and segregation. Attention is drawn to the procedures contained in CECC 00 016, which provides guidance on the use of statistical process control.

These requirements may be satisfied for Capability Approval or Process Approval by compliance with RP 14 part III or RP 14 Part V, as appropriate.

4.9.2 Special processes

Special processes may be undertaken by a manufacturer as part of a CECC Qualification Approval in accordance with RP 14 Part II §§ 1.2.1 and 1.2.2. Special processes undertaken by an independent specialist contractor should be in accordance with RP 14 Part V.

4.10 Inspection and testing

4.10.3 Final inspection and testing

Final inspection and testing requirements, where applicable, are defined in the relevant detail specification, as required by the appropriate CECC generic specification or process assessment schedule.

Note: Final inspection and testing may not be applicable e.g. in respect of Process Approval or Technology Approval under RP 14 Parts V and VI respectively.

4.10.4 Inspection and test records

Acceptance criteria are defined in the relevant detail specification, where the detail

