

European Committee for Electrotechnical Standardization (CENELEC)
Cenelec Electronic Components Committee

CECC



Système Harmonisé d'Assurance de la Qualité
des Composants Electroniques

SPECIFICATION DE BASE:
EXIGENCES D'ETALONNAGE
DANS LE SYSTEME CECC

Harmonized System of Quality Assessment for
Electronic Components

BASIC SPECIFICATION:
CALIBRATION REQUIREMENTS
FOR THE CECC SYSTEM

Harmonisiertes Gütebestätigungssystem für
Bauelemente der Elektronik

GRUNDSPEZIFIKATION:
EICHANFORDERUNGEN
FÜR DAS CECC-SYSTEM

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FOREWORD

The CENELEC Electronic Components Committee (CECC) is composed of those member countries of the European Committee for Electrotechnical Standardization (CENELEC) who wish to take part in a harmonized System for electronic components of assessed quality.

The object of the System is to facilitate international trade by the harmonization of the specifications and quality assessment procedures for electronic components, and by the grant of an internationally recognized Mark, or Certificate of Conformity. The components produced under the System are thereby accepted by all member countries without further testing.

This specification has been formally approved by the CECC, and has been prepared for those countries taking part in the System who wish to issue national harmonized specifications for CALIBRATION REQUIREMENTS FOR THE CECC SYSTEM. It should be read in conjunction with document CECC 00 100: Basic Rules (1974).

At the date of printing of this document the member countries of the CECC are Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, the Netherlands, Norway, Sweden, Switzerland and the United Kingdom, and copies of it can be obtained from the addressees shown on the inside cover.

PREFACE

This basic specification was prepared by the Special Editing Group (SEG) of the CECC.

In accordance with the requirements of document CECC 00 100 it is based on the publications of the International Electrotechnical Commission (IEC).

The text of this specification was circulated to the CECC for voting in the documents listed below and was approved by the CECC Management Committee for publication as a CECC Specification:

<u>Document</u>	<u>Voting Date</u>	<u>Report on the Voting</u>
CECC(Secretariat)1082	November 1981	CECC(Secretariat)1151 and 1151A

1. INTRODUCTION

The CECC System requires that all measuring equipment and standards used in the production and testing of electronic components of assessed quality be checked periodically by an approved calibration service.

2. SCOPE

This basic specification prescribes the calibration requirements to be met as part of the quality assessment procedures given in CECC 00 107: RP 7, Part I: Quality assessment procedure for general usage, for the approval of manufacturers and independent test laboratories. This specification is to be implemented only when specifically required by the relevant CECC specification.

3. RULES OF PROCEDURE

The following are the relevant extracts from CECC 00 107: RP 7, Part I (Issue 3) governing the calibration requirements:

RP 7 § 1

and § 1.3 : The manufacturer shall demonstrate in respect of all activities relevant to the System, that his measuring instruments are periodically checked by an approved calibration service.

RP 7 § 5

and § 5.2 : When a laboratory wishes to have recognized its fitness to carry out tests on components within the System, it shall demonstrate that its staff possesses the necessary competence, that its test facilities are completely adequate for its purpose and that its measuring instruments are checked at regular intervals by an approved calibration service.

4. REQUIREMENTS

4.1 General

A manufacturer or an independent test laboratory wishing to be approved under the CECC System shall establish and maintain an effective organization for the control and calibration of all the measuring equipment and standards relevant to the approval. This organization shall ensure that the measurement facilities have the capability to perform measurements to the required degree of accuracy. It shall provide for prompt detection of deficiencies and timely action for their correction.

It is not necessary for a manufacturer or an independent test laboratory to establish or maintain a complete measurement or calibration capability if these services are obtained from sources which meet this requirement.

4.2 Periodic review and surveillance

The calibration organization shall be reviewed by the manufacturer or independent test laboratory in accordance with 4.3 to 4.15. Evidence that the organization is effective shall be available to the National Supervising Inspectorate (ONS), who may, in the case of dissatisfaction, suspend or withdraw approval in accordance with § 6 of RP 7, Part I.

4.3 Measuring equipment and standards

The calibration organization shall ensure that measuring equipment and standards have the accuracy, repeatability of measurement and range appropriate to the requirements of the specification for which these equipments are used.

4.4 Traceability

All measuring equipment shall be calibrated against standards which are traceable to a national standard except where the standards have been derived from accepted values of natural physical constants or derived by the ratio type of self-calibration techniques. Standards held by manufacturers or independent test laboratories need not be calibrated directly against national standards, but may be calibrated against intermediate standards provided that the requirement for traceability to national standards is satisfied. However, the number of stages for calibration shall be limited to the minimum consistent with the requirement for accuracy. All standards used for calibration shall be authenticated by certificates, reports or data sheets attesting to the date, accuracy and conditions under which the results were obtained.

4.5 Cumulative effect of errors

The cumulative effect of errors at each stage of calibration shall be taken into account for each successive measuring equipment or standard calibrated. When the total error is such as to undermine confidence in the ability to make measurements within the permitted tolerances, corrective action shall be taken.

The basis for the calculation of the cumulative effects shall be recorded and shall be to the satisfaction of the ONS.

4.6 Environmental conditions

Measuring equipment and standards shall be calibrated and used in an environment controlled to the extent necessary to ensure the required accuracy. Consideration shall be given to temperature, rate of change of temperature humidity, lighting, vibration, dust control and cleanliness and other controllable factors affecting accuracy of measurement. When pertinent, these factors shall be continuously monitored and recorded. When essential, compensating corrections shall be applied to measurement data obtained in a non-controlled environment. Records shall contain both the original and the corrected data.

4.7 Intervals between calibration

Measuring equipment and standards shall be calibrated at periodic intervals established on the basis of their stability, purpose or degree of usage. These intervals shall be shortened when required to ensure continued accuracy dependent on the results of preceding calibrations, and may be lengthened when the results of previous calibration provide definite indications that such action will not adversely affect confidence in the accuracy of the measuring equipment or standard.

4.8 Faulty equipment

The calibration organization shall provide for immediate removal or, if not movable, conspicuous labelling or marking to prevent use of any measuring equipment or standard which

- has not been calibrated in accordance with the established schedule
- has failed in operation
- shows evidence of damage
- is, or is suspected to be, outside the required accuracy.

Any such event shall be recorded and previous results may be re-examined, to ascertain whether re-testing is necessary. Repaired measuring equipment and standards shall be calibrated before use.

4.9 Calibration labelling

The calibration status of measuring equipment and standards shall be indicated by labelling or marking or by recording in a log book. Any limitation of calibration or restriction of use shall be clearly indicated.

4.10 Documentation of calibration procedures

Documented procedures shall be prepared and used for the calibration of all measuring equipment and standards. The procedures may be a compilation of published standard practice, locally developed procedures or instrument manufacturers' written instructions. Calibration procedures shall include those step-by-step instructions necessary to enable personnel performing calibration functions to determine that the measuring equipment and standards are within their prescribed accuracy.

4.11 Records

The calibration organization shall maintain a complete set of records that document the reference standard, calibration methods, and history of all measuring equipment and standards. Where the calibration is carried out by a third party a set of records, or reference to records that give the reference standard, calibration methods and history of all measuring equipment and standards shall be maintained by the calibration organization.

These records shall demonstrate that each measuring equipment or standard is capable of performing measurements within the required accuracy. When measuring equipment or standards are found to be outside these requirements, the extent of the error shall be recorded for appropriate action (see 4.8).

The data to be recorded is dependent on the nature of the measuring equipment and standards in use and their application.

As a minimum, the records shall include the following:

- 1) description of equipment and unique identification
- 2) dates on which each calibration was performed
- 3) calibration interval
- 4) date of next calibration
- 5) calibration procedure
- 6) reference standard and traceability data
- 7) measured values obtained
- 8) the environmental conditions for calibration and corrections that may be applied
- 9) a statement of the cumulative effects of errors on the data obtained in calibration
- 10) details of any adjustment, repair or maintenance. When measuring equipment and standards are adjusted or repaired, the results of calibration before and after such work shall be included.

Records shall be available for review as required by the ONS.

4.12 Sealing of means of adjustment

Access to means of adjustment, which are fixed at the time of calibration, shall be sealed or otherwise safeguarded to prevent tampering by unauthorized persons. Seals shall be so designed that tampering will destroy them.

4.13 Sub-contracting by the manufacturer

When a manufacturer sub-contracts parts of his production, he shall ensure that his sub-contractors have an organization which meets the requirements of this specification.

4.14 Handling, transport and storage

The manufacturer or independent test laboratory shall take steps to prevent abuse, misuse, damage, or change in characteristics during handling, transport and storage of all measuring equipment and standards.

4.15 Visits by the ONS

The ONS has the right to visit the premises of the manufacturer or independent test laboratory to determine that the calibration organization fulfills the requirements of this specification. The manufacturer or the independent test laboratory may be required to undertake measurements for this purpose.

Adequate facilities shall be provided for the ONS for the proper accomplishment of its work. The ONS shall have the right of access to all areas of a manufacturer or of an independent test laboratory relevant to the measurement or calibration function, except where these are stated to be commercially confidential. In such cases, adequate demonstration shall be provided to the satisfaction of the ONS that all the requirements of this specification have been fulfilled.