

IECEE

CB-SCHEME

OD-CB2032-Ed.1.1

OPERATIONAL & RULING DOCUMENTS

**Assessments covering the use of a
Manufacturer's Test Laboratory (SMTL or
RMTL) within the IECEE Schemes**

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IEC System for Conformity Testing and Certification of Electrotechnical Equipment and Components CB Scheme

1. Concept

A manufacturer's laboratory must be assessed and formally accepted by the NCB which will be responsible for the operation of the laboratory in the IECEE Schemes under the SMT or RMT Procedures. An accepted laboratory is notified to the secretariat of the IECEE for registration. The NCB is responsible for the initial and follow-up assessments and audits which are carried out by the NCB or, with the agreement of the NCB, by the CBTL.

A candidate laboratory is assessed by the NCB against ISO/IEC 17025 and other relevant documents in relation to the Certification Scheme that is applied. When accepted, the laboratory signs an agreement with the NCB.

During the assessment, reassessment, or audit of an NCB the arrangements made for the management of Manufacturers' Laboratories are verified.

2. Assessment and Auditing of Manufacturers' Laboratories by NCBs

2.1 General Principle

The assessment and auditing of manufacturer's laboratories shall be carried out to the same level of compliance as CBTLs within the defined scope of the manufacturer's laboratory, and all the relevant guidelines developed for peer assessment purposes apply equally to assessment of manufacturers' laboratories

2.2 Initial Assessment and Acceptance of Candidate Laboratories by NCBs

In general the assessments should be based on the following Operational Documents

OD-CB 2017	Check List for Testing and Calibration Laboratories
OD-CB 2005	Test Laboratory Assessment Report
OD-CB 2006	Guidelines and Information for IECEE Assessors related to IECEE Peer Assessment

These forms shall be used until more dedicated forms are developed.



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The above mentioned documents were designed for use when making assessment of CBTLs. The documents provide a framework for the assessment and acceptance of a manufacturer's laboratory, but may need some modification when a variation from the peer assessment procedure is appropriate because the manufacturer owns the laboratory, or because the NCB is responsible for the assessment.

These documents and reports are to be available for scrutiny when the NCB is assessed, as described in section 3 below.

2.3 Follow-up Auditing and Reassessment of Accepted Manufacturers' Laboratories

- Follow-up auditing is carried out at least annually and may be combined with the supervision of testing where required.
- NCB reviews test Reports issued by manufacturers' laboratories.
- A follow up audit is still required whether or not supervised tests are carried out.
- Further comparative tests may be made with a CBTL used by NCB.
- A re-assessment is carried out every three years.

3. Assessment of NCBs on the Application of SMT and RMT Procedures

As an integral part of the peer assessment or reassessment of an NCB the assessor must verify how the manufacturer's laboratory has been accepted, and how its operation within the IECEE Schemes is managed. Provision for a report on the assessment of NCBs in respect of the management of manufacturers' laboratories is made at clause 1.12 of the Assessment Report OD-CB2004.

Particular requirements to be covered during the peer assessment of the NCB are listed at Annex A.



Particular Requirements to be covered during the Peer Assessment or Reassessment of an NCB Responsible for the Operation of a Manufacturer's Test Laboratory (SMTL or RMTL) within the IECEE Schemes

Records relating to the initial assessment and supervision of the SMTL / RMTL shall be verified, including any administrative matters (conformity with ISO/IEC 17025 agreements with manufacturers, etc). The documents listed in section 2.2 above shall be made available.

The following particulars shall be checked by the assessors with regard to the procedures followed by the NCB for acceptance and supervision of manufacturers' laboratories, in order to confirm that the candidate laboratory has been satisfactorily qualified before being accepted as an SMTL or RMTL, and that auditing takes place on a continuing basis:

1. Has confidence in the candidate laboratory been gained by witnessing fully the testing of a number of products, and by examination or other documented evidence of competence, to the satisfaction of the NCB?
2. Has the Quality System of the laboratory been evaluated against the requirements of ISO/IEC 17025? Are the results of the evaluation recorded and are the records kept in file?
3. Has the competence of the staff been evaluated?
4. Is it verified that the staff of the laboratory is trained at regular intervals?

NOTE: Training involves general laboratory practice, testing methods, knowledge of standards within the scope of the laboratory.
Additionally it is the responsibility of the NCB to forward current information on the certification scheme, such as TRFs, Decisions of Current Interest, and CTL Decisions.

5. Has it been verified that the laboratory uses a reliable method to update its standards to be used for testing? Does the NCB check systematically that the correct version of the standard is being used?
6. Has the knowledge of the testing personnel on the interpretation of standards (CTL Decisions) been verified?
7. Is there a calibration plan in force in the laboratory?



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8. Are comparative tests organised by the NCB with an accepted CBTL
 - prior to the qualification of the laboratory?
 - subsequent to acceptance within the Certification Scheme?

9. Is the extent of supervision carried out by the NCB in accordance with the general principles given in the relevant operational documents covering the SMT and RMT Procedures?

10. Is a reliable system in force for the distribution of the TRFs to the laboratory (within its scope of recognition).

11. Is the laboratory using the current version of TRFs to report on Testing results?

12. Is there a formal agreement between the NCB and the laboratory to cover the operation of the Scheme?

13. Is the quality system of the laboratory audited by the NCB after initial acceptance? How frequently? Are audit records available?

14. Does the NCB prepare and keep records on supervision and system verification?