

IECEE

CB-SCHEME

OD-CB2030-Ed.1.1

OPERATIONAL & RULING DOCUMENTS

**OPERATION OF SUPERVISED
MANUFACTURERS' TESTING (SMT)
LABORATORIES**

OD-CB2030-Ed.1.1

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

Foreword

SMT is a procedure by which personnel of an NCB or, at the request of that NCB a CBTL, supervises the quality management system and the laboratory testing processes and witnesses some part of each agreed testing program. The manufacturer's laboratory uses its own personnel and test equipment and takes responsibility for and signs the CB Test Report, which is reviewed by the NCB for acceptance.

The concept combines rigorous qualification of manufacturer's capabilities, a confidence building phase, extensive exchange of information between the NCB and the manufacturer, and a comprehensive supervision programme. The content of the supervision programme may evolve and change as confidence is built in the quality management and testing experience of the laboratory.

1. Introduction

- 1.1 General principles covering the use of manufacturers' testing laboratories for the purpose of third party assessment and certification are given in OD CB 2027.
- 1.2 An SMTL is a manufacturer's laboratory being used to test specified products for which the manufacturer has production responsibility, under the supervision of a NCB. Some part of each agreed testing program must be witnessed on site.
- 1.3 The NCB or CBTL wishing to use this procedure must have the relevant product category(ies) and standard(s) in their accepted IECEE scopes. The staff who supervise each testing programme and witness tests must have the necessary competence and expertise to carry out supervision and tests to the relevant standard(s).
- 1.4 The decision to conduct SMT must be approved beforehand by the relevant NCB.



2. Responsibilities

3.1 Responsibilities of the NCB

The NCB to whom the manufacturer has made application is responsible for:

- training the laboratory on an ongoing basis in the operation and procedures of the IECEE Schemes.
- establishing the technical competence of the laboratory.
- assessment, reassessment, and auditing of the laboratory in accordance with the requirements detailed in OD CB 2032.
- ongoing supervision of the SMTL through a continuing involvement covering quality management of the laboratory and its testing programme.
- the definition or validation of test programmes for which CB test reports are prepared.
- independent review of the test reports prepared by the SMTL.
- registration of the laboratory as a SMTL with the IECEE Secretariat, and the maintenance of the correct details in the register.
- issue of CB Certificates covering the test reports, once the SMTL is registered.
- the co-ordination of participation of SMTL in applicable CTL Proficiency Testing Programmes.
- Arranging all other required tests that are not performed at the SMTL.

3.2 Responsibilities of the SMTL

The SMTL is responsible for:

- demonstrating that the facilities are in compliance with all relevant requirements of ISO/IEC 17025 and the IECEE Schemes requirements;
- appointing an appropriate person to be responsible for the facilities and/or services provided to the NCB;
- ensuring that all tests are carried out in accordance with the applicable technical requirements and the instructions of the NCB;
- the preparation, signing and authorization of a CB test report prepared by the SMTL.
- participating in applicable CTL proficiency testing programmes.

3. References and General Provisions

3.1 The following document applies to the general arrangements for the use and operation of Manufacturers' Test Laboratories:

- OD CB 2027 General Principles covering the use of Manufacturers' Test Laboratories in the IECEE Schemes.



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- OD-CB 2034 Operation of Local Technical Representative (LTR)

3.2 The following documents apply to the assessment and auditing of SMTLs:

- ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories.
- OD CB 2032 Assessments Covering the Use of a Manufacturer's Test laboratory (SMTL or RMTL) within the IECEE Schemes.

3.3 The following document applies to the procedures of the NCB responsible for the operation of SMTLs:

- ISO/IEC Guide 65 General Requirements for Bodies Operating Product Certification Systems.

4.4 The technical competence to carry out testing activities is checked against the relevant IEC Standards or parts thereof for which the laboratory is seeking acceptance.

4. **Application by a Manufacturer**

4.1 A manufacturer is eligible to apply to an NCB to operate an SMTL provided that the manufacturer is ultimately responsible for the product and its continued compliance with the relevant requirements (as per IECEE 02, Clause 3.7).

4.2 An application shall be made to the appropriate NCB in accordance with the Procedures of that NCB and of the IECEE Schemes, the most significant of which are listed in OD CB 2032. In addition, the application documents shall:-

- provide evidence that the laboratory operates independently of other departments of the Organisation (e.g. production, marketing).
- provide evidence that the staff employed in testing at the laboratory have no conflict of interest within the Organisation.

5. **Relationships with Multiple NCBs**

5.1 An SMTL shall be permitted to participate in the IECEE Schemes for more than one NCB in the same product category

5.2 An SMTL shall not be permitted to participate in the IECEE Schemes for more than one NCB for the same product model

NOTE: an SMTL shall not be permitted to address a test report for the same model to more than one NCB.



- 5.3 NCB responsibilities including supervision and traceability requirements shall be applied independently by each NCB

6 Qualification of the Manufacturer's Laboratory

- 6.1 Following receipt of an application the NCB shall initiate a Qualification Phase, which typically should include the following steps:-

- initial evaluation of the Quality System and Procedures employed by the laboratory, including verification of the information provided with the application (see clause 5.3).
- evaluation of the general competence of the laboratory in testing for conformity assessment, and design of an appropriate training programme.
- training of technical staff.
- endorsement of proposals by the SMTL for the competence of staff to perform tests within specified areas.
- the conducting of comparison tests based on a programme defined by the NCB, in which the same product is tested, and a report prepared, by both the candidate laboratory and a CBTL.
Note: Appropriate means have to be taken if e.g. test equipment is only available at the manufacturers lab or the test samples cannot be easily moved to the CBTL.
- witnessing of critical aspects of the comparison test programme.

7 Assessment by the NCB

- 7.1 A formal assessment and reassessment of the laboratory shall be carried out by the NCB in accordance with ISO/IEC 17025 and OD CB 2032 and taking into account the elements of 6.1.
- 7.2 The assessment or reassessment report of the laboratory shall be fully documented by the NCB utilising the appropriate IECEE Assessment Report Form, and records maintained for a minimum ten years.

8 Agreement between the NCB and the Manufacturer

- 8.1 When the NCB is satisfied that the laboratory meets the requirements for the operation of SMTLs a formal agreement shall be signed covering the provision of testing services by the SMTL under this OD. An NCB may use its own form of Agreement, but the essential elements for inclusion in such an Agreement are given in Annex A to this OD.



9 Notification to the IECEE

- 9.1 Each NCB wishing to register a laboratory as an SMTL accepted within the IECEE Schemes shall inform the IECEE Secretariat giving details of the Agreement as shown in Annex B to this OD. NCBs shall also inform the IECEE Secretariat when the reported details of the Agreement change, or the Agreement is cancelled.
- 9.2 Each NCB shall provide the completed Assessment and Reassessment Report(s) to the IECEE Secretariat in accordance with the rules and procedures.
- 9.3 The IECEE Secretariat shall keep OD CB2019 duly updated giving details of SMTLs accepted within the IECEE Schemes and operating in accordance with this OD.

10 Supervision of SMTL Operations

- 10.1 The involvement of the NCB on site at the SMTL is regarded as essential for the credibility of this Procedure. However, specifically nominated personnel from an independent CBTL having an Agreement with the NCB may be authorised to carry out the witnessing of testing and other specific tasks of supervision at the request and on behalf of the NCB. There shall be a written agreement between the NCB and CBTL covering any delegation of the responsibility of the NCB under this clause. Where the CBTL is integrated with the NCB, internal Procedures shall clearly define the delegated responsibility on a case- by- case basis.
- 10.2 Supervision within this Procedure is intended to cover not only witnessing of testing, but also all other elements that contribute to the establishment of confidence in the laboratory quality processes, and in the design of the product under test.
- 10.3 It is a requirement that supervision shall be carried out on some part of each product testing programme. A testing programme is defined as any series of tests related to a product or a family of products which constitutes type testing to complete Standards. It may also apply to partial testing of approved products that are subject to modifications. Products of similar construction, for which it is reasonable to define a test programme package, may be considered to be a family.
- 10.4 As the experience of the SMTL develops, and confidence in the management of the laboratory grows, the focus of supervision visits by the NCB may move gradually away from the witnessing of tests and towards the examination and improvement of the quality process under-pinning the design, production, and testing of the product in question.
- 10.5 The frequency of visits by the NCB will depend on the volume of test work carried out by the SMTL. During such visits, in addition to review of the test work in progress the following are examples of issues which should be covered:



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- construction review of products.
- review of designs.
- review of partially completed test reports.
- use of Standards.
- use of interpretations.
- information and training on the IECEE Schemes, and National Differences in Standards.
- calibration of test equipment.
- participation in applicable CTL Proficiency Testing Programmes.

10.6 Visits by the NCB will normally be announced, but may also be unannounced. The SMTL has the responsibility to provide all necessary information to the representative of the NCB.

10.7 SMTLs shall participate fully in the Proficiency Testing Programmes arranged by the IECEE Committee of Test Laboratories (CTL) for programmes which cover test methods within the scope of the SMTL.

11 Laboratory Auditing and Verification of Competence

11.1 There shall be an ongoing verification by the NCB of the competence of the laboratory and its compliance with the requirements for the duration of the Agreement, in accordance with OD-CB2032. Audit findings shall be fully documented, and the documentation shall be available for scrutiny at any subsequent peer reassessment of the NCB.

11.2 A minimum of one visit per year is required to audit the SMTL's procedures against the requirements of relevant clauses of ISO/IEC 17025. On the same visit, supervision of product testing can also be carried out.

12 Test Reports and CB Test Certificates

12.1 Test reports prepared by an SMTL shall use the relevant CB Test Report Forms. After completion and authorisation by the SMTL, the test reports shall be countersigned by the representative of the NCB who provided supervision of the test programme.

12.2 Test Reports prepared using SMT shall record the name and address of the manufacturer's laboratory used, and indicate what tests have been carried out by the manufacturer.

12.3 When a CB Test Certificate or a Conformity Assessment Certificate is based on a report from an SMTL, a reference to the SMTL origin of the report shall be included under "Additional Information". Annual Statistics on the number of



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Certificates granted under this Procedure shall be provided by the relevant NCB to the IECEE Secretary.

Annexes

- A. Essential contents of the Formal Agreement between Manufacturer and NCB concerning an SMTL.
- B. Rules for Reports about SMTLs.



**ESSENTIAL CONTENTS OF THE FORMAL AGREEMENT BETWEEN
MANUFACTURER AND NCB ABOUT SMT**

1. The Agreement shall cover the SMT rules and procedures according to the applicable IECEE clauses and Operational Documents approved by the CMC of the IECEE Schemes.
2. The applicable rules of the NCB shall be included or referred to in the Agreement.
3. The manufacturer, product categories and types, standards and/or parts of standards shall be clearly specified. This implies that the Agreement shall be updated every time changes occur in these respects.
4. The manufacturer shall inform the NCB about changes in the facilities covered by the Agreement.
5. The manufacturer shall give access for duly qualified experts from the NCB to the premises covered by the Agreement at any time during working hours without appointment and shall provide all information requested by the NCB representative relating to the operation of the laboratory.
6. The NCB shall be entitled to obtain samples for following up and comparative testing purposes
7. The NCB shall keep the manufacturer informed about decisions and recommendations relevant to the operations covered by the Agreement, and shall provide the relevant CTL decisions and the relevant harmonized TRFs. The manufacturer shall keep this information as controlled documentation and follow it in the operations covered by the Agreement. However, the manufacturer himself has the responsibility to follow and to keep himself well informed of the development of the relevant standards.
8. The operations according to the Agreement shall be covered by the same confidentiality rules as for the other operations of the NCB. Confidentiality shall be observed also after termination of the Agreement.
9. It shall be made clear that the Agreement and its application does in no way exempt the manufacturer from the full and final responsibility for the products which are marketed after testing under the SMT Procedure.
10. It shall be stated that the manufacturer or client may not use its status as an SMTL for promotional or advertising purposes (reference IECEE 02).
11. There shall be a termination clause in the Agreement covering both the normal routine with a stipulated time for notice by either party and those measures which may be necessary if the manufacturer does not fulfil the basic conditions (immediate termination).



RULES FOR REPORTS ABOUT SMTLS

Each NCB shall report to the IECEE Secretary SMTLs which have been approved by the NCB and have signed an SMT Agreement. The IECEE Secretary will keep a register containing details of SMTLs for all NCBs.

The report from the NCB to the IECEE Secretary shall contain information as follows:

1. **Standard Agreement**

An NCB shall lodge with the IECEE Secretary a sample of its standard form of Agreement for the operation of an SMTL, and shall advise the IECEE Secretary of amendments to it.

2. **Report on each SMTL**

For each laboratory which has been accepted and has signed the Agreement, the following information shall be reported by the NCB to the IECEE Secretary

- 2.1 Date of the Agreement.
- 2.2 Manufacturer's name and address of the headquarters.
- 2.3 Name and address of each accepted laboratory*.
- 2.4 Products and Standards covered by the Agreement.

Note: () Participation of a laboratory having a different legal identity from the Applicant (Manufacturer) is allowed only if it is demonstrated that the Applicant has the ownership and/or full control of the laboratory..*

For the reports, the enclosed form (Appendix 1) shall be used.

Changes in the content of the Agreement referring to the above mentioned information shall be reported.

3. **Record of Operations**

The NCB shall keep records containing information as follows:

- 3.1 Dates and hours of performed supervision and the elements of supervision addressed.
- 3.2 When testing has been supervised, details of those tests and the relevant clauses from the Standard.
- 3.3 Observations made and advice given to the laboratory during supervision visits.



Report on Supervision

Statistics of supervision visits to clients shall be reported by the NCB to the IECEE Secretary annually in January covering the past year.

Records on supervision visits (Appendix 2) shall be kept and shall be made available for re-assessment of the NCB.

4. List of SMTLs

The IECEE Secretary shall compile a list of all accepted SMTLs and distribute it to the IECEE Members as OD CB2019.

5. Numbering of SMTL Reports

The numbering of SMTL reports forwarded by the NCBs according to Annex B, clause 2 and when listed by the IECEE Secretary according to Annex B, clause 5 is described by the following rules.

NCB-xxx - y

(1) (2) (3)

Explanations

- (1) The name or abbreviation of the NCB, e.g.: SEMKO; UL, IMQ, JQA, PSB.
- (2) Number indicating client. The first SMTL of the NCB will be given Nr 001/SMT, the second No 002/SMT etc. If an SMTL ceases to operate in the IECEE Schemes, the free number may not be used for another client.
- (3) When the SMTL Agreement between an NCB and a client is modified, a letter will be introduced indicating the modification. When (3) is empty, the first Agreement is still valid.



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**ANNEX B
Appendix 2**

SUPERVISION OF Supervised Manufacturers Test laboratory (SMTL)

NCB : _____

Manufacturer : _____

SMTL: _____

Date of Initial Agreement: _____

Number of CB Test Reports issued in Year: _____

DURING YEAR _____

Report n° : _____

Date : _____

Name : _____

Signature : _____

DATE OF VISIT	SUPERVISION CARRIED OUT	QUALITY PROCESSES REVIEWED/AUDITED