

IECEE

CB-SCHEME

OD-CB2031-Ed.1.0

OPERATIONAL & RULING DOCUMENTS

**OPERATION OF RECOGNISED
MANUFACTURERS' TESTING (RMT)
LABORATORIES**

OD-CB2031-Ed.1.0

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1. Introduction

- 1.1 The general principles covering the use of a manufacturer's testing laboratory(ies) for the purpose of third-party assessment and certification are given in OD-CB 2027.
- 1.2 A Recognized Manufacturer's Testing Laboratory (RMTL) is a manufacturer's testing laboratory being used by a NCB to conduct agreed upon testing of products, falling under the accepted scope of the responsible NCB and the relevant standard(s), for which the manufacturer has design and production responsibility.
- 1.3 The recognition of a RMTL applies only to its work in association with the responsible NCB. This Operational Document describes the detailed procedures that apply to RMT.

2. Concept

- 2.1 The RMT concept combines rigorous qualification of the manufacturer's capabilities, a confidence building phase, extensive exchange of information between the NCB and the RMTL, verification of reports and a specified laboratory surveillance programme.
- 2.2 RMT is a procedure by which an NCB assesses initially and on an on-going basis the capability and expertise of the manufacturer's laboratory(ies) according to ISO/IEC 17025 and any other relevant IECEE Operational Documents, including the laboratory's quality management system and the laboratory's testing processes.
- 2.3 In this procedure, the NCB is not required to witness or supervise all or portions of individual test programmes as is required for SMT.
- 2.4 The RMTL uses its own personnel and test equipment, takes responsibility for, and signs the test report, which is verified by the NCB prior to issuing a CB Test Certificate.



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3. Responsibilities

3.1 Responsibilities of the NCB

The NCB is responsible for:

- (a) Training the laboratory initially and on an on-going basis on the relevant IECEE Operational Documents,
- (b) Ensuring on an on-going basis the technical competence of the laboratory according to ISO/IEC 17025,
- (c) Carrying out supervision of the RMTL's operations according to Clause 11 of this OD .
- (d) Assessing, reassessing, and auditing of the laboratory according to the requirements in OD-CB2032,
- (e) Validating/endorsing test programmes for which IECEE CB Test Reports are prepared,
- (f) Carrying out independent reviews of the CB Test Reports prepared by the RMTL,
- (g) Issuing CB Test Certificates based on the RMTL's CB Test Reports,
- (h) Registering each of its RMTLs with the IECEE Secretariat, and maintaining the correct details in the register,
- (i) Coordinating the participation of RMTLs in the CTL Proficiency Testing Programmes,
- (j) Arranging with the CBTL(s) for which the NCB is responsible to carry out required tests* that are not performed by the RMTL, and
- (k) Reporting annual statistics on the number of CB Test Certificates issued according to this OD to the IECEE Secretariat.

*Extent (and nature) of these tests is under consideration

3.2 Responsibilities of the RMTL

The RMTL is responsible for:

- (a) Demonstrating that the RMTL's facilities are in compliance with all relevant requirements of ISO/IEC 17025 and the relevant IECEE Operational Documents,
- (b) Appointing a person and a deputy having a clearly defined responsibility and authority with respect to the RMTL's operations,
- (c) Ensuring that the tests are carried out in accordance with the applicable technical requirements and the instructions of the NCB,



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- (d) Preparing, reviewing and authorizing (by signing) the RMTL's CB Test Reports,
- (e) Participating in applicable CTL Proficiency Testing Programmes as directed by the NCB(s).

4. Application by a Manufacturer to become a RMTL

4.1 Definitions

manufacturer

an organization, situated at a stated location or stated locations, that carries out or controls such stages in the manufacture, assessment, handling and storage of a product that enables it to accept responsibility for continued compliance of the product with the relevant requirements and undertakes all obligations in that connection

manufacturer's testing laboratory

an integral part of the manufacturer, such as a department, division, under the complete technical and legal control of the relevant Manufacturer

factory

the location at which the product is produced or assembled and follow-up service is established by the NCB

- 4.2 The RMTL's scope per product category/per standard shall be fully defined, but may be limited to the testing of specific products. The NCB may arrange for specific tests that are outside of the capability of the RMTL (e.g. those within the scope of the applicable product standard that are designated as either "S" or "R" in the CTL Equipment Lists) to be carried out by one of the CBTLs for which the NCB is responsible.

- 4.3 The application shall be made to the appropriate NCB in accordance with the administrative procedures of that NCB and according to the relevant IECEE Operational Documents, the most significant of which is OD-CB2032. In addition, the application documents shall provide:

(a) Evidence that the laboratory operates independently of other departments of the Manufacturer's organizational structure (e.g. production, sales, marketing, business development, etc.).

(b) Evidence there are provisions to ensure that RMTL staff have no conflict of interest within the manufacturer's organizational structure.



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5. Conditions Concerning a RMTL's Choice of NCB

- 5.1 A manufacturer's testing laboratory shall be permitted to be a RMTL for more than one NCB in the same product category.
- 5.2 A RMTL shall not be permitted to use multiple NCBs for the same model of the product (i.e. shall not submit a test report for the same model of the product to more than one NCB).
- 5.3 When a RMTL is operating with multiple NCBs, each NCB shall independently apply the requirements of this Operational Document.
- 5.4 When a RMTL is operating with multiple NCBs, the NCBs may optionally choose to have one of the NCBs coordinate a specific CTL Proficiency Testing Program. If this is the case, the results shall be shared among the involved NCBs.

6. Qualification of the Manufacturer's Laboratory

- 6.1 Following receipt of an application, the NCB shall initiate a Qualification Phase, that shall include the following prerequisites:
 - (a) The candidate RMTL has been operating as a SMTL with its NCB(s) during two years immediately prior to the application.
 - (b) The candidate RMTL has designed and carried out three full testing programs and fully prepared the associated test reports as a SMTL for the NCB following which the NCB issued CB Test Certificates based on those CB Test Reports (as registered by the IECEE Secretariat) for each accepted product category/standard.
- 6.2 For those candidates that meet the prerequisites, the Qualification Phase will continue and will include as a minimum the following steps:
 - (a) Initial RMTL assessment according to ISO/IEC 17025 and the relevant IECEE Documents.
 - (b) The assessment report is provided to the IECEE Secretariat, is posted in a specific restricted area of the IECEE Website accessible only to the Assessment Advisory Group, and is processed according to the IECEE assessment report technical review procedure.
 - (c) Evaluation of the appointed person and the deputy having a clearly defined responsibility and authority with respect to the RMTL's operations,
 - (d) Evaluation and acceptance of the competence of the RMTL staff to perform the tests for which the acceptance is sought.
- 6.3 When a registered RMTL wishes to operate under the responsibility of another NCB, the RMTL shall have operated under the SMT procedure with that NCB for a minimum of one year, and furthermore the requirements of Sub-clause 7.1 b) shall be fulfilled.



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7. Assessments and Re-Assessments

- 7.1 There shall be an ongoing verification by the NCB of the competence of the RMTL and its compliance with the requirements for the duration of its Agreement with the RMTL
- 7.2 Assessment findings shall be fully documented, and the documentation shall be available for review at any subsequent peer assessment or reassessment of the NCB.
- 7.3 The NCB shall use OD-CB2005-MTL for recording the assessments and reassessments of the RMTL. In addition, assessment and reassessment reports shall be maintained for a minimum of ten years.
- 7.4 RMTLs are subjected to a re-assessment every three years carried out by an assessment team composed of one assessor from the responsible NCB and one Lead Assessor appointed by the IECEE Secretariat.
- 7.5 Assessment findings (see Sub-clause 8.2) shall be fully documented, and the documentation shall be available for review at any peer assessment or reassessment of the RMTL.
- 7.6 The reassessment report is provided to the IECEE Secretariat, is posted in a specific restricted area of the IECEE Website accessible only to the Assessment Advisory Group, and is processed according to the IECEE reassessment report technical review procedure.

8. Agreement between the NCB and the Manufacturer

When the NCB is satisfied that the manufacturer's testing laboratory meets the requirements for operation as a RMTL, a formal agreement shall be signed covering the provision of testing services by the RMTL 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 Secretariat

- 9.1 NCBs wishing to register a laboratory as an accepted RMTL shall inform the IECEE Secretariat giving details of the Agreement as shown in Annex A to this OD, and confirm that records of assessment are available at the NCB and RMTL for review if required during any assessment or reassessment. The NCB shall also inform the IECEE Secretariat when the Agreement changes, or the Agreement is cancelled.
- 9.2 The IECEE Secretariat shall maintain OD-CB 2019 up-to-date giving details of accepted and registered RMTLs.



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10. Supervision of RMTL Operations

- 10.1 Direct involvement of the NCB on site at the RMTL is regarded as essential for the credibility of the entire RMT Procedure. However, specifically nominated personnel from a CBTL for which the NCB is responsible may be authorized to carry out specific tasks of supervision at the request of and on behalf of the NCB.
- 10.2 Where the CBTL is integrated with the NCB, internal Procedures shall clearly define the delegated responsibility on a case- by- case basis to fulfill the responsibility of the NCB under this Clause.
- 10.3 For an independent CBTL, there shall be a written agreement between the NCB and CBTL covering any assignment of the responsibility of the NCB under this Clause.
- 10.4 Supervision within this Procedure is intended to cover all elements that contribute to the establishment and continuance of confidence in the RMTL's quality management system and the RMTL's testing processes.
- 10.5 The frequency of supervisory visits by the NCB will depend on the volume and complexity of test work carried out by the RMTL, however a minimum of two supervisory visits per year are required. One of the supervisory visits may be combined with the required annual audit.
- 10.6 The following are issues which shall , as a minimum, be covered during the supervisory visits:
- (a) Review of any test work in progress, construction review of products under evaluation and review of partially completed test reports,
 - (b) Review of product designs scheduled to be tested in the near future,
 - (c) Review of staff awareness of current IECEE information,
 - (d) Review of training carried out on the IECEE Basic Rules, Rules of Procedure and Operational Documents,
 - (e) Review of the availability and the use of appropriate IEC Standards.
 - (f) Review of capability to identify and use published National Differences to IEC Standards as published in IECEE documents and on the IECEE Website.
 - (g) Review the availability, awareness and use of CTL Decisions.
 - (h) Review of any CTL Proficiency Testing underway.
- 10.7 Supervisory visits by the NCB will normally be announced, but may also be unannounced. The RMTL has the obligation, in accordance with the agreement as per Clause 9., to provide the representative of the NCB access to the RMTL's staff and facilities and all necessary information.



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11. IECEE Test Reports and IECEE Test Certificates

- 11.1 The RMTL shall use the current versions of the relevant IECEE CB Test Report Forms.
- 11.2 After completion and authorization by the RMTL, the CB Test Reports shall be validated* by the representative of the NCB prior to the NCB issuing the CB Test Certificate.

*The Convenor of WG 3 (MT) to check the consistency of the terminology with the new TRF terminology..
- 11.3 When a CB Test Certificate is based on a report from a RMTL, a reference to the RMTL origin of the report shall be included under "Additional Information".

Annexes

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



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ANNEX A

ESSENTIAL CONTENTS OF THE FORMAL AGREEMENT BETWEEN MANUFACTURER AND NATIONAL CERTIFICATION BODY ABOUT MTL PROCEDURE

1. The Agreement shall cover the RMTL 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 RMT Procedure.
10. It shall be stated that the manufacturer or client may not use its status as an RMTL 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).



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ANNEX B

RULES FOR REPORTS ABOUT RMTLS

Each NCB shall report to the IECEE Secretary RMTLs which have been approved by the NCB and have signed an RMT Agreement. The IECEE Secretary will keep a register containing details of RMTLs 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 RMTL, and shall advise the IECEE Secretary of amendments to it.

2. Report on each RMTL

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 approved 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.



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4. 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.

5. List of RMTLs

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

6. Numbering of RMTL Reports

The numbering of RMTL 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, eg SEMKO; UL, IMQ, JQA; PSB.
- (2) Number indicating client. The first RMTL of the NCB will be given Nr 001/RMT, the second No 002/RMT etc. If an RMTL ceases to operate in the IECEE Schemes, the free number may not be used for another client.
- (3) When the RMTL 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.

Example:

UL-001	First and basic agreement of UL with RMTL number 001
SEMKO-009-c	3rd modification of SEMKO's agreement with RMTL 009



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**ANNEX B
Appendix 2**

SUPERVISION OF Recognised Manufacturers Test Laboratory (RMTL)

DURING YEAR _____

NCB : _____

Report n° : _____

Manufacturer : _____

Date : _____

RMTL: _____

Name : _____

Date of Initial Agreement: _____

Signature : _____

Number of IECEE Test Reports issued in Year: _____

DATE OF VISIT	SUPERVISION CARRIED OUT	QUALITY PROCESSES REVIEWED/AUDITED