OPERATIONAL DOCUMENT	ENEC 312

ENEC+ Scheme:

Operation of Manufacturer's Performance Laboratories (MPL)

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Operation of Manufacturer's Performance Laboratories (MPL)

0. Foreword

This document is intended to describe the way of operating a test laboratory owned by a manufacturer for the purpose of performance testing supervised by a Certification Body.

A MPL is a manufacturer's laboratory being used to test specified products for ENEC+ for which the manufacturer has production responsibility, under the supervision of a CB.

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 ECS 032 under the same conditions as E-CTF Stage 3, except for the following:

- Presence of the CB/TL: It is not required for a CB or TL to be present during each performance testing program;
- Participation in CTL meetings is not relevant;
- Participation in IECEE CTL PTP is not required.

1.2 Testing using a MPL is using a procedure by which personnel of a Certification Body (CB) or, at the request of that CB a Testing laboratory (TL), supervises the quality management system and the laboratory testing processes and witnesses some part agreed testing programme. The manufacturer's laboratory uses its own personnel and test equipment and takes responsibility for and signs the Test Report, which is reviewed by the CB for acceptance.

The concept combines rigorous qualification of manufacturer's capabilities, a confidence building phase, extensive exchange of information between the CB 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.

1.4 The CB wishing to use this procedure shall have the relevant product category(ies) and standard(s) or EPR (ENEC+ Requirement) in their accepted ECS scopes. The staff checking the manufacturer's parameters shall have the necessary competence and expertise to carry out the tests to the relevant standard(s).

1.5 The decision to conduct MPL testing shall be approved beforehand by the relevant CB.

2. Responsibilities

2.1 Responsibilities of the CB

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

- training the MPL on an ongoing basis in the operation and procedures of the ENEC+ Scheme;
- establishing the technical competence of the MPL;
- assessment, reassessment, and auditing of the MPL in accordance with the requirements detailed in OD ECS 032 (consistent with OD-2048 of IECEE);
- ongoing supervision of the MPL through a continuing involvement covering quality management system of the MPL 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 MPL;
- registration of the laboratory as a MPL with the ETICS Secretariat, and the maintenance of the correct details in the register;
- arranging all other required tests that are not performed at the MPL but in the TL;
- arranging the monitoring tests to validate the results of the MPL.

2.2 Responsibilities of the MPL

The MPL is responsible for:

- demonstrating that the facilities are in compliance with all relevant requirements of EN ISO/IEC 17025 and the ENEC+ Scheme requirements;
- appointing an appropriate person to be responsible for the facilities and/or services provided to the CB;
- ensuring that all tests are carried out in accordance with the applicable technical requirements and the instructions of the CB;
- preparing, signing and approving of a CB test report prepared by the MPL;
- delivering the tested samples to the CB/TL for the purpose of the monitoring tests, if required by them.

3. References and General Provisions

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

- OD ECS 032: "Use of Customers' Testing Facilities in the European Certification Schemes (E-CTFs)" with the exception described in 1.1.

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

- EN ISO/IEC 17025: "General requirements for the competence of testing and calibration laboratories";
- OD ENEC 312 Annex C "MPL Assessment Report".

3.3 The following document shall be applied to the procedures of the CB responsible for the operation of MPLs:

- EN ISO/IEC 17065: ”Conformity assessment - Requirements for bodies certifying products, processes and services”.

3.4 The technical competence to carry out testing activities is checked against the relevant Standards or parts thereof or ENEC+ Requirements for which the laboratory is seeking acceptance.

4. Application by a Manufacturer

4.1 A manufacturer is eligible to apply to a CB to operate a MPL provided that the manufacturer is ultimately responsible for the product and its continued compliance with the relevant requirements (as per PD ECS 050).

4.2 An application shall be made to the appropriate CB in accordance with the Procedures of that CB and of the ECS Schemes, the most significant of which are listed in OD ECS 032. 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 CBs

5.1 A MPL shall be permitted to participate in the ENEC+ Scheme for more than one CB in the same product category.

CB responsibilities including supervision and traceability requirements shall be applied independently by each CB.

6 Qualification of the Manufacturer’s Performance Laboratory

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

- initial evaluation of the Quality Management System and Procedures employed by the MPL, including verification of the information provided with the application;
- evaluation of the general competence of the MPL in testing for conformity assessment, and design of an appropriate training programme;
- training of technical staff;
- endorsement of proposals by the MPL for the competence of staff to perform tests within specified areas;

7. Assessment by the CB

7.1 A formal assessment and reassessment of the MPL shall be carried out by the CB in accordance with EN ISO/IEC 17025 and OD ECS 032 and taking into account the elements of 6.1.

7.2 At the initial start-up phase, a sample from each product which is being presented for the ENEC+ Mark, already tested by the MPL, will be re-tested at the TL in order to monitor the outcome.
When the recorded differences to the initial values being claimed by the MPL are not higher than the tolerances permitted by the relevant standard and/or EPRS, the monitoring schedule "normal" can start.

If general acceptance criteria are not sufficient, specific initial acceptance criteria of MPLs are defined in the relevant EPRS document.

Note 1 – Situations where a MPL under-claims the performance measured by the TL, are acceptable regardless of the actual difference.
Note 2 – When considering a measurement difference, the TL may also need to include some allowance for its own uncertainty of measurement.

7.3 The assessment or reassessment report of the MPL shall be fully documented by the CB utilising the appropriate Assessment Report Form OD ENEC 312 Annex C, and records maintained for a minimum of ten years.

8. Agreement between the CB and the MPL

8.1 When the CB is satisfied that the laboratory meets the requirements for the operation of MPLs a formal agreement shall be signed covering the provision of testing services by the MPL under this OD. A CB 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 ETICS Secretariat

9.1 Each CB wishing to register a laboratory as an MPL accepted within the ENEC+ Scheme shall inform the ETICS Secretariat giving details of the Agreement as shown in Annex B to this OD. The CBs shall also inform the ETICS Secretariat when the reported details of the Agreement change, or the Agreement is cancelled.

9.2 If required, each CB shall provide the completed Assessment and Reassessment Report(s) to the ETICS Secretariat in accordance with the rules and procedures.

9.3 The ETICS Secretariat shall keep AD ECS 036 duly updated giving details of MPLs accepted within the ECS Schemes and operating in accordance with this OD.

10. Supervision of MPL Operations

The CB may delegate its tasks to its TL.

10.1 The involvement of the CB on site at the MPL is regarded as essential for the credibility of this Procedure. However, specifically nominated personnel from an

independent TL having an Agreement with the CB may be authorised to carry out the monitoring of testing and other specific tasks of supervision at the request and on behalf of the CB. There shall be a written agreement between the CB and TL covering any delegation of the responsibility of the CB under this clause when the TL is not in the same corporate structure. Where the TL is integrated with the CB, internal Procedures shall clearly define the delegated responsibility.

10.2 Supervision within this Procedure is intended to cover not only monitoring of testing, but also all other elements that contribute to the establishment of confidence in the MPL quality processes and in the design of the product under test.

10.3 Visits by the CB will normally be announced, but may also be unannounced. The MPL has the responsibility to provide all necessary information to the representative of the CB.

11. MPL Monitoring and Verification of Competence

11.1 There shall be an ongoing monitoring by the CB of the competence of the MPL and its compliance with the requirements by means of surveillance.
Surveillance test findings shall be fully documented, and the documentation shall be available for scrutiny at any subsequent peer reassessment of the CB.

11.2 The following schedule shall be used to monitor the validity of the results of the MPL after the initial start-up phase (§7.2). The percentage figure given in the table is the sample size of test reports submitted by the MPL from which a surveillance test sample should be selected for measurement by CB or its TL for comparison. Where the MPL is testing to more than one standard the surveillance samples selected by the CB should be representative of the full range standards being used by the MPL. In all cases at least one set of comparative measurements shall be made between the MPL and the CB each year.

Schedule	Number of standards for which licences are being issued per MPL		
	1-4 different standards	5-8 different standards	> 8 different standards
Reduced	5 %	10 %	15 %
Normal	10 %	20 %	25 %
Increased	20 %	25 %	30 %
Extended	40 %	50 %	50 %

11.3 After 1 deviation from the conditions from §7.2, corrective actions are required.
After 2 deviations from the conditions from §7.2 the monitoring schedule will go to "Increased"
After 4 deviations from the conditions from §7.2 the schedule will go to “Extended”.
In all cases corrective actions are needed to ensure that correct data will be published for the corresponding product.

11.4 Each consecutive series of 4 correct monitoring data will lead to go to one schedule level better until the level "Reduced" has been reached.

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

12. Test Reports

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

12.2 Test Reports prepared using the MPL 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 Test Report is based on a report from an MPL, a reference to the MPL origin of the report shall be included under "Additional Information". Annual Statistics on the number of Certificates granted under this Procedure shall be provided by the relevant CB to the ETICS Secretariat.

12.4 The evaluation work of the CB in accepting the previous data based on the results of the assessment of the MTL must be trusted. The proposed 'age' of test results for accepting data is 2 years maximum. The CB has the option when judged necessary to perform a new testing of a limited sample of luminaires from a family as the basis to demonstrate the accuracy of older data already established for the same family. It would be necessary as well for the manufacturer to prove to the CB that no subsequent changes in design or component have been made that could affect any already made measurements.

Essential information and data shall include:

- Full traceability of the measurement data, equipment used and engineers performing the tests,
- Calibration history of the equipment used to perform the testing,
- Comparable results from the spot check measurements.

Annexes

A. Essential contents of the Formal Agreement between Manufacturer and CB concerning an MPL.
B. Rules for Reports about MPLs.

C. MPL Assessment Report

ANNEX A

ESSENTIAL CONTENTS OF THE FORMAL AGREEMENT BETWEEN MANUFACTURER AND CB ABOUT MPL

1. The Agreement shall cover the rules and procedures according to the applicable ECS clauses and ECS Operational Documents.

2. The applicable rules of the CB 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 CB about changes in the facilities covered by the Agreement.

5. The manufacturer shall give access for duly qualified experts from the CB to the premises covered by the Agreement at any time during working hours without appointment and shall provide all information requested by the CB representative relating to the operation of the laboratory.

6. The CB shall be entitled to obtain samples for the monitoring schedule as described in this OD.

7. The CB shall keep the manufacturer informed about decisions and recommendations relevant to the operations covered by the Agreement and shall provide the relevant TRFs.
   The manufacturer shall keep this information as controlled documentation and follow it in the operations covered by the Agreement. However, the manufacturer has the responsibility to follow and to be 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 CB. Confidentiality shall be observed also after termination of the Agreement.

9. It shall be made clear that the Agreement and its application do in no way exempt the manufacturer from the full and final responsibility for the products which are marketed after testing under this MPL Procedure.

10. It shall be stated that the manufacturer or client may not use its status as an MPL for promotional or advertising purposes.

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).

ANNEX B

RULES FOR REPORTS ABOUT MPLs

Each CB shall report to the ETICS Secretariat MPLs which have been approved by the CB and have signed an MPL Agreement. The ETICS Secretariat will keep a register containing details of MPLs for all CBs.

The report from the CB to the ETICS Secretariat shall contain information as follows:

1. Report on each MPL

For each MPL which has been accepted and has signed the Agreement, the following information shall be reported by the CB to the ETICS Secretariat:

1.1 Date of the Agreement
1.2 Manufacturer's name and address of the headquarters
1.3 Principal contact person at the accepted MPL laboratory
1.4 Name and address of each accepted MPL (*)
1.5 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.

2. Record of operations

The CB shall keep records containing information as follows:

2.1 Information on performed monitoring and the elements of supervision addressed (in the enclosed Appendix 2 form)
2.2 Overview of granting Schedule levels

3. List of MPLs

The ETICS Secretariat shall keep AD ECS 036 duly updated on the basis of the information reported by the CBs (§9.3).

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ANNEX B
Appendix 1

European Certification System (ECS)

Manufacturer's Performance Laboratories (MPL)
Report to the ETICS Secretariat

CB: _____ **Report Ref:** _____

Address: _____ Date: _____

Country: _____ Name: _____

Date of initial Agreement: _____ Sign: _____

Latest revision of Agreement: _____

Manufacturer

Name: _____
Address of
headquarters: _____

Accepted MPL

Name: _____

Address: _____

Products/Standards covered by the Agreement

EPRS	Products Covered

ANNEX B
Appendix 2

SUPERVISION OF **Manufacturers Test laboratory (MPL)**	**DURING YEAR: _____**
CB: _____	**Report n°: _____**
Manufacturer: _____	**Date: _____**
MPL: _____	**Name: _____**
Date of Initial Agreement: _____	
Number of CB Test Reports issued in the year: **_____**	**Signature: _____**

DATE OF evaluation	**MONITORING CARRIED OUT**	**QUALITY PROCESSES REVIEWED/AUDITED**