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| | **PERMANENT DOCUMENT** | **PD 14** |

# Use of Manufacturers' Laboratories For Surveillance Testing

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## USE OF MANUFACTURER'S LABORATORIES FOR SURVEILLANCE TESTING

### 1. INTRODUCTION

1.1 This Permanent document describes the procedures to be followed when performing the surveillance tests of the HAR agreement at the Manufacturers premises.

1.2 Due to the special technicalities of the HAR agreement, this Permanent Document defines specific procedures and requirements for the purpose of performing surveillance testing. Mainly taking into account that the surveillance tests are only partially performed in the Manufacturer's Laboratory, therefore are necessary provisions to specify the tests to be performed, the handled of the samples and the evaluation of the results in case of controversy.

### 2. DEFINITIONS

2.1 Certification Body Testing Laboratory (CBTL): The laboratory (own or external) used by the HAR signatory for the purpose of third-party testing within the HAR agreement, according to the requirements for testing laboratories of Permanent Document PD 3.

2.2 Manufacturer's Laboratory: Hereinafter will be understood as the testing facilities which are effectively controlled by the manufacturer. For the purpose of surveillance testing the testing facilities must be located where the tested cables are produced. These testing facilities are the same required to the manufacturer by Permanent Document PD C.

2.3 Surveillance Testing at Manufacturer's Premises Laboratory (STMPL): A manufacturer's laboratory being used by CBTL staff.

2.4 Surveillance Witnessed Manufacturer's Testing Laboratory (SWMTL): A manufacturer's laboratory being used for 100% Witnessed Testing by CBs or CBTLs personnel duly qualified.

### 3. DOCUMENTS OF REFERENCE

- HAR PD C: Procedures for granting the HAR mark.
- HAR PD 3: Rules for assessment and recognition of signatories to the HAR Agreement.
- HAR PD 4: Surveillance procedures – Conditions for reduced sampling.
- HAR OD 106-1: Surveillance procedure for low production manufacturers
- HAR OD 106-3: Questionnaire on Surveillance
- ISO/IEC 17025 General requirements for the competence of testing and calibration Laboratories.

## 4. GENERAL REQUIREMENTS

The provisions of this Permanent Document are applicable for the specific use of the manufacturer's laboratories in the surveillance test of the HAR agreement.

- A Manufacturer's Laboratory can be considered as eligible for its use as STMPL or SWMTL for surveillance testing only when the manufacturer fulfils the requirements of "reduced sampling" as defined in document HAR PD 4.

- For the purpose of surveillance testing the laboratory should be in the same factory where the tested cable is produced. The testing facilities used for surveillance testing are the same ones as those required to the manufacturer by Permanent Document PD C.

- The visit to perform surveillance according to this PD could be combined with other activities (factory inspection, by instance). Anyhow the time necessary for the testing should be properly planned.

**Note**: A minimum of 2 days could be considered necessary due to the conditioning phase of some tests (like electrical resistance - the cable shall be kept in the test area for sufficient time to ensure that the conductor temperature has reached a level which permits an accurate determination of resistance using the correction factors provided). The audit duration has to be adapted in accordance with this request.).

- The discrepancies between the results of the tests performed in the Manufacturer's Laboratory and in the CBTL, should be investigated and solved. The actions depend on the investigation results. Anyhow the CB is always able to implement whatever action is deemed as necessary once the confidence is not guaranteed.

- The personnel representing the CB during the surveillance tests in the manufacturer's laboratory, must in all the cases specifically qualified to perform this task. When operating STMPL this personnel must be staff from the CBTL. When operating SWMTL this personnel could be staff from the CB or by delegation to CBTL.

## 5. RESPONSABILITIES

### 5.1 Responsibilities of the CB

The CB through which the CBTL operates in the HAR agreement is responsible for:

- Defining the surveillance program criteria in terms of number of samples per type of cable and tests to be conducted,
- Evaluation of the results of the tests and to implement the actions as defined in the relevant HAR PD´s,
- Investigating any major discrepancy in the results of the tests performed in the CBTL and in the Manufacturer's laboratory and the implementation of whatever action is deemed as necessary,
- Registration of the manufacturer's laboratory as a STMPL or SWMTL with the HAR Chairman, and the maintenance of the correct details in the register,
- Training of the CBTL in the Procedures which apply to STMPL or SWMTL (not applicable for SWMTL managed directly by the CB),
- Assessment and acceptance of the Quality Procedures of the CBTL applicable to the operation of STMPL or SWMTL (not applicable for SWMTL managed directly by the CB),
- Review of the documentation held by the CBTL covering assessment of the facilities and the contract arrangements (not applicable for SWMTL managed directly by the CB).

### 5. 2 Extended responsibilities of the CB

The CB wishing to use the STMPL or SWMTL Procedure for a surveillance test programme is responsible for:

- Providing qualified staff with the adequate training not only in test procedures but also in the relevant HAR procedures regarding the applicability of tests and the provisions of this PD,
- Holding Quality Procedures which adequately cover all aspects of working off-site,
- Quality auditing to ensure the correct application of off-site Quality Procedures,
- Assessment of the facilities and equipment of the manufacturer's laboratory,
- Defining the role of manufacturers' personnel in support of the qualified staff,
- Assessment, if necessary, of the competence of manufacturers personnel to perform the roles assigned to them,
- Holding an agreement with the manufacturer which describes the services to be provided by the manufacturer's laboratory,
- All testing carried out at the manufacturer's laboratory and for the content of the subsequent test report.

### 5.3 Responsibilities of the STMPL or SWMTL

The manufacturer's laboratory whose facilities are to be used by the CB is responsible for:

- Keeping the samples tested in its laboratory until the CB permission to destroy them (at least after the test are performed in the CBTL). By the time being the same rules applied for the CBTL should be applied by the Manufacturer's Laboratory,
- Demonstrating that the facilities are in compliance with the relevant requirements of ISO/IEC 17025,
- Appointing an appropriate person to be responsible for the facilities and/or services provided to the CBTL.

## 6. CB PROCEDURES FOR THE USE OF STMPL OR SWMTL

6.1 The CB shall ensure that STMPL or SWMTL is used in accordance with this Procedure.

6.2 The CB shall have provision that procedures covering all aspects of working off-site are compliant to ISO/IEC 17025 QMS, including:

- Assessment of suitability of the manufacturer's test facilities and test equipment in accordance with ISO/IEC 17025, and in particular:
  - Control of environmental conditions at the laboratory,
  - Stability of electrical power supplies,
  - Availability of acceptable test equipment and trained staff,
  - Test equipment calibration,
  - Arrangements for periodic auditing of its own off-site operations and re-assessment of the manufacturer's testing facility.
  - Risk to impartiality

6.3 The CB or by delegation to CBTL shall have a contract or agreement in place covering:

- The facilities and services being supplied by the manufacturer's laboratory,
- Use of data generated, including laboratory records,

- The supervisory role of the qualified staff (in case of STMPL, the qualified staff is coming from CBTL), and the right to audit and/or re-assess the facilities (SWMTL procedure only).

## 7. SELECTION OF SAMPLES

The samples to be tested must be selected at random as far as possible, following surveillance program criteria and procedures of the CB. The same forms used by the CB to record the samples selected must be used. When special cases are applicable ("put-by" or "on-call" procedures" as defined in document HAR OD 106-1) the "deviation" to the general method must be recorded.

## 8. CRITERIA FOR TESTING

The decision of which samples are going to be tested in the CBTL must be taken prior to knowing any results of the tests performed in the manufacturer's laboratory.

The samples selected must be submitted to the tests defined in the relevant table of PD-D, with the following criteria:

- All F100 and F50 tests are performed in the Manufacturer's Laboratory
- All F25 and F5 tests are performed in the CBTL. These samples are also submitted to F100 and F50 tests in the CBTL for comparison purposes.

The following table explains the criteria for a case of 20 samples per inspection.

| Table 1- Criteria for testing **Sample Nº** | **Manufacturer Laboratory** (Witnessed or performed by CBTL personnel) | | | | **CBTL** | | | |
|---|---|---|---|---|---|---|---|---|
| | **F100** | **F50** | **F25** | **F5** | **F100** | **F50** | **F25** | **F5** |
| **1** | X | | | | | | | |
| **2** | X | X | | | | | | |
| **3** | X | | | | | | | |
| **4** | X | X | | | X | X | X | |
| **5** | X | | | | | | | |
| **6** | X | X | | | | | | |
| **7** | X | | | | | | | |
| **8** | X | X | | | X | X | X | |
| **9** | X | | | | | | | |
| **10** | X | X | | | | | | |
| **11** | X | | | | | | | |
| **12** | X | X | | | X | X | X | |
| **13** | X | | | | | | | |
| **14** | X | X | | | | | | |
| **15** | X | | | | | | | |
| **16** | X | X | | | X | X | X | |
| **17** | X | | | | | | | |
| **18** | X | X | | | | | | |
| **19** | X | | | | | | | |
| **20** | X | X | | | X | X | X | X |

Note: Some F50 and F100 tests are necessary in order to perform and evaluate F5 and F25 tests.

## 9. CONDUCT OF TESTING

### 9.1 Surveillance Testing at Manufacturer's Premises Laboratory (STMPL)

Under STMPL testing is carried out by CBTL personnel with own or manufacturers test equipment. Manufacturer's personnel may assist in the preparation for and in the conduct of tests, but full responsibility rests with the CBTL.

### 9.2 Surveillance Witnessed Manufacturer's Testing Laboratory (SWMTL)

Under SWMTL, testing is carried out by the manufacturer's personnel but full responsibility for the testing rests with the CB or by delegation to CBTL. Qualified staff shall be present whenever tests are conducted, and shall supervise, check, and witness all critical aspects of the tests. This includes but is not limited to:

- Preparing a product test plan and providing it to the manufacturer's laboratory,
- Checking the test set-up, instrumentation and the relevant calibration,
- Directing proper placement and attachment of thermocouples,
- Witnessing the final data acquisition or read-out and conducting its validation where necessary.

## 10. NOTIFICATION TO HAR SECRETARIAT

The CB wishing to register on behalf of a CBTL a manufacturer's testing facility under this PD shall inform the Chairman of the HAR Group giving details of the agreement as shown in Annex B to this PD, and confirm that records of assessments are available for scrutiny if required. The CB shall also inform the Chairman of the HAR Group when the reported details of the agreement change, or the agreement is cancelled.

The CB shall identify in the yearly reporting of surveillance activities (as defined in document HAR OD 106-3), the manufacturers whose laboratory has been accepted to as STMPL or SWMTL for surveillance purposes.

## 11. ASSESSMENT AUDITING AND VERIFICATION OF COMPETENCE

11.1 Responsibility for the initial assessment of the manufacturer's test facility rests with the CB. Additionally, at each visit to the manufacturer's laboratory for STMPL or SWMTL, the initial assessment results shall be re-validated to ensure the ongoing suitability of the facility. Both the initial assessment and any re-assessments are to be documented, and the documentation shall be available for audit by the CB and for scrutiny at any subsequent European Scheme re-assessment of the CBTL.

11.2 During the HAR Agreement re-assessment of the CB, the responsibilities of the CB in respect of any STMPL or SWMTL arrangements of its CBTLs shall be reviewed.

11.3 When assessing and reassessing the testing facilities of the Manufacturer's Laboratory against the relevant clauses of ISO/IEC 17025, the qualified staff must take into account the directions given in annex A.

## 12. TEST REPORTS

Test Reports prepared by a CB or by delegation to CBTL using STMPL or SWMTL arrangements shall record the details of the manufacturer's laboratory used and indicate what tests have been carried out by the manufacturer.

The Surveillance tests must be recorded in a form defined by the CB.

ANNEX A

## APPLICATION OF RELEVANT CLAUSES OF ISO/IEC 17025 FOR MANUFACTURERS´S LABORATORIES ELIGIBLE FOR SURVEILLANCE TESTING AS STMPL OR SWMTL

This annex is a guidance in order to apply in a common and harmonised way the relevant clauses of ISO/IEC 17025 to apply to Manufacturers laboratories seeking its acceptance as STMPL or SWMTL for surveillance testing within the HAR agreement.

Table A.1 – Criteria for testing

| CLAUSE | STMPL | SWMTL |
|---|---|---|
| **4. General requirements** | --- | --- |
| 4.1 Impartiality | Fully applicable | Fully applicable |
| 4.2 Confidentiality | Fully applicable | Fully applicable |
| **5 Structural requirements** | --- | --- |
| 5.1 | Fully applicable | Fully applicable |
| 5.2 | Fully applicable | Fully applicable |
| 5.3 | Not applicable | Fully applicable |
| 5.4 | Only applicable to internally provided laboratory activities | Only applicable to internally provided laboratory activities |
| 5.5 | Fully applicable | Fully applicable |
| 5.6 | Fully applicable | Fully applicable |
| 5.7 | Fully applicable | Fully applicable |
| **6 Resource requirements** | --- | --- |
| 6.1 General | Fully applicable | Fully applicable |
| 6.2 Personnel | Not applicable | Fully applicable |
| 6.3 Laboratory facilities and environmental conditions | Fully applicable | Fully applicable |
| 6.4 Equipment | Fully applicable | Fully applicable |
| 6.5 Metrological traceability | Partially applicable (with the exception of provisions for calibration laboratories) | Partially applicable (with the exception of provisions for calibration laboratories) |
| 6.6 Externally provided products and services | Fully applicable | Fully applicable |
| **7 Process requirements** | --- | --- |
| 7.1 Review of requests, tenders and contracts | Only applicable to the contract with the CBTL | Only applicable to the contract with the CBTL |
| 7.2 Selection, verification and validation of methods | Not applicable | Fully applicable |
| 7.3 Sampling | Not applicable | Not applicable |
| 7.4 Handling of test or calibration | Fully applicable | Fully applicable |
| 7.5 Technical records | Fully applicable | Fully applicable |
| 7.6 Evaluation of measurement uncertainty | Fully applicable | Fully applicable |

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| 7.7 Assuring the quality of results | Fully applicable | Fully applicable |
| 7.8 Reporting of results | Fully applicable | Fully applicable |
| 7.9 Complaints | Applicable to the relation with the CBTL | Applicable to the relation with the CBTL |
| 7.10 Management of nonconforming work | Partially applicable (test equipment, supplies, preparation of samples) | Fully applicable |
| 7.11 Control of data – Information management | Fully applicable | Fully applicable |
| **8 Management requirements** | --- | --- |
| 8.1.2 Option A - including 8.2 to 8.9 | --- | --- |
| 8.1.3 Option B - including 8.2 to 8.9 | --- | --- |
| 8.2 Management system documentation | --- | Fully applicable |
| 8.3 Control of management system documents | --- | Fully applicable |
| 8.4 Control of records | --- | Fully applicable |
| 8.5 Actions to address risks and opportunities | --- | Fully applicable |
| 8.6 Improvement | --- | Partially applicable. 8.6.2 only in case of external customers |
| 8.7 Corrective actions | --- | Fully applicable |
| 8.8 Internal audits | --- | Fully applicable |
| 8.9 Management reviews | --- | Fully applicable |

ANNEX B

**Use of a Manufacturer's Testing Laboratory for surveillance testing under PD-14**
**Report to the HAR Chairman**

**CB:** _____ **Report Ref:** _____ _____

Date: _____

Name: _____

Sign: _____

**CBTL using the Manufacturer's Facility**

Name: _____

Address: _____

Type of agreement (STMPL or SWMTL): _____

Date of initial agreement: _____ Name: _____

Latest revision of agreement: _____ Sign: _____

**Manufacturer's Test Laboratory**

Name: _____

Address: _____

HD/EN Standards/Tests covered by the Agreement

| HD/EN Standard | Tests Covered (by clause number) |
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