

HAR Agreement	PERMANENT DOCUMENT	PD 6
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**Operation of Supervised Manufacturer's
Testing, SMT**



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This document contains 10 Pages
Including appendix 1 and 2
Page 1 of 10

OPERATION OF SUPERVISED MANUFACTURER'S TESTING, SMT

1. INTRODUCTION

1.1. SMT is an alternative testing method to achieve third party certification and a development of the HAR Agreement. The Rules and decisions of the HAR scheme therefore apply to SMT as far as applicable. As the HAR is only applicable to manufacturers resident in the HAR countries, the same rule applies to the SMT within the HAR scheme.

1.2 SMT is applicable only for the type testing. Type testing could apply to the complete Standards or it may also apply to partial testing of approved products that are subject to modifications.

1.3 Definitions

Manufacturer's Laboratory: Hereinafter will be understood as the testing laboratories and facilities which are owned and effectively controlled by the manufacturer.

Supervision: Hereinafter will be understood as overall observation of the manufacturer's testing activities excluding intervention but including witnessing and assessment.

2. REQUIREMENTS FOR MANUFACTURER'S LABORATORIES

2.1 The quality system of the manufacturer's laboratory shall be managed according to EN 45001 or EN 17025 for the appropriate scope.

2.2 The complete test equipment necessary for the type testing shall be available and effectively used.

Note: The test equipment used for the test indicated as class B in tables 1 to 7 of the document PD-C may be available in another laboratory of the same manufacturer, provided that the same Quality System is applied.

Subcontracting of testing is allowed within the conditions indicated in EN 45001 or EN 17025 to a laboratory approved by the HAR group and provided that is previously informed to and agreed with the C.B.

2.3 The laboratory shall demonstrate experience in the tests for which the recognition is sought.

2.4 The laboratory shall possess and know the relevant HAR documents and Test Report Forms

3. ACCEPTANCE CRITERIA FOR MANUFACTURER'S LABORATORIES

3.1 The Certification Body shall check the requirements summarised in point 2 through an assessment visit prior to the acceptance of the laboratory. The following criteria are applicable in order to evaluate the fulfilment of the requirements.

- 3.2 The accreditation of the laboratory according to EN 45001 for the appropriate scope will be taken into consideration in order to fulfil the requirement 2.1
- 3.3 The certification of the Quality System of the manufacturer according to ISO 9001 or ISO 9002 (any versions) will be taken into account as a partial fulfilment of requirement 2.1.
- 3.4 The experience in testing products similar to those for which the recognition is sought (e.g. electrical cables not included in the HAR agreement) will be taken into consideration in order to fulfil the requirement 2.3

4. APPLICATION BY A MANUFACTURER

- 4.1 A manufacturer wishing to use its laboratory for SMT shall make the application to the appropriate Certification Body in accordance with the procedures of that Certification Body.
- 4.2 Information shall be provided to the Certification Body for evaluation in accordance with the procedures of the Certification Body.

5. ASSESSMENT

- 5.1 Prior to the acceptance of a laboratory, The C.B. shall carry out an assessment visit with appropriately qualified assessors to check the requirements indicated in point 2 taking into account the criteria of point 3. On the same visit supervision of product testing as indicated in 6.1 can also be carried out.

Note: Previous experience of the manufacturer held by the C.B. gained through the HAR scheme or similar arrangement shall be taken into account during the initial assessment

- 5.2 The results of the assessment visit shall be written down in a report in accordance with the procedures of the Certification Body.

6. SUPERVISION OF TESTING

- 6.1 Candidate laboratory acceptance

The Certification body shall as part of the initial assessment supervise, through the presence of its personnel, a representative selection of testing of a representative product or range of products prior to the acceptance of an SMT laboratory. Some of the selected tests must be related to a HAR licence.

Note: The degree of supervision may be limited by the C.B. taken into account previous experience of the manufacturer held by the C.B. gained through the HAR scheme or similar arrangement

6.2 Supervision of Testing for an Accepted SMT Laboratory

It is a requirement that supervision shall be carried out on some part of each product testing campaign. A testing campaign is defined as any test programme related to a product or a range of products when they are type testing to the complete Standards. It may also apply to partial testing of approved products that are subject to modifications.

Once an application to the HAR mark is received from a manufacturer with a laboratory already accepted for SMT, the manufacturer shall propose a test programme for the product or range of products applied for and the C.B. shall review and approve the programme indicating a minimum of:

- Test to be performed by the SMT laboratory and witness by the C.B. personnel
- Test to be performed by the SMT laboratory without witnessing of C.B. personnel (if any).
- Test to be performed by the C.B. laboratory (if any).

Note: The degree of test which need to be witness by the C.B. is likely to be few for manufacturers where substantial previous experience is held by the C.B. gained through the HAR scheme or similar arrangement

It is important that the C.B. is able to resource the plan and is ready to send an inspector to the manufacturer at reasonably short notice, arrangements are agreed with the manufacturer in advance. The SMT laboratory manager has the responsibility to provide all necessary information to the inspector witnessing the tests.

7. MAINTENANCE AND REASSESSMENT OF ACCEPTED SMT LABORATORIES

7.1 The C.B. shall perform on yearly basis a routine surveillance visit to verify the continuous fulfilment of the requirements indicated in point 2 taking into account the criteria of point 3 by the accepted SMT laboratory. On the same visit supervision of product testing as indicated in 6.2, or any other certification activity can also be carried out.

A reassessment against all requirements of point 2 shall be performed every three years.

7.2 The results of these visits shall be written down in reports in accordance with the procedures of the Certification Body.

8. CONTRACT BETWEEN THE CERTIFICATION BODY AND THE MANUFACTURER

When the C.B. is satisfied that the SMT laboratory meets the requirements, a formal agreement or contract shall be arranged to cover the operation of the Scheme. A C.B. may use its own form of contract, but Guidelines for the contents of such a contract are given in Appendix 1 to this PD.

9. NOTIFICATION TO THE HAR GROUP

- 9.1 The C.B. shall inform the Chairman of the HAR Group of the details of the contract. Rules for reports to the Chairman are given in Appendix 2 to this PD. The C.B. shall also inform the HAR Group Chairman of contracts which are withdrawn or modified. The HAR Group Chairman shall keep the Member CB's informed about contracts in force by amendments to, and distribution of, the list of accepted SMT manufacturers to the HAR Group.
- 9.2 Appendix 2 also gives details of statistics concerning supervision visits to be reported by the C.B. to the HAR Group Chairman annually.

10. TEST REPORTS

- 10.1 Test reports prepared by an SMT laboratory shall use the relevant Test Report Forms (TRF), agreed by the C.B. which shall be made available by the C.B.
- 10.2 When a Test Report is based on SMT, a reference to the SMT origin of the report shall be included.
- 10.3 The C.B. shall inform the other members of the HAR agreement of Certificates granted via SMT in the communication required in article 10 of the HAR agreement
- 10.4 Statistics on the number of Certificates granted via SMT shall be provided by the C.B. to the HAR Group Chairman on request.

**CONTENTS OF THE FORMAL AGREEMENT BETWEEN MANUFACTURER AND
CERTIFICATION BODY ABOUT SMT**

- (1) The contract should cover the SMT rules.
- (2) The applicable national rules of the C.B. should be included or referred to in the contract.
- (3) The manufacturer shall be well defined, as per its legal foundation documents, and the product types and categories shall be clearly specified in terms of the harmonised documents. This implies that the contract shall be updated every time changes occur in these respects.
- (4) The manufacturer shall inform the C.B. about changes in the facilities covered by the contract, including any change of the accreditation or certification status
- (5) The C.B. shall agree to send inspectors at reasonably short notice to inspect tests on the manufacturer's site.
- (6) The manufacturer shall give access for duly authorised inspectors from the C.B. to the premises covered by the contract at any time during working hours without appointment and give all information needed for the inspector to prepare the inspection.
- (7) The C.B. shall be entitled to request or select test samples free of charge for following up and comparison purposes.
- (8) The C.B. shall keep the manufacturer informed about decisions and recommendations relevant to the operations covered by the contract. The manufacturer should keep this information filed and follow it in the operations covered by the contract. However, the manufacturer himself has the responsibility to follow and to keep himself well informed of the development of the relevant standards.
- (9) The operations according to the contract shall be covered by the same confidentiality rules as for the other operations of the C.B... Confidentiality shall be observed also after termination of the contract.
- (10) It shall be made clear that the contract and its application does in no way exempt the manufacturer from the full and final responsibility for the products which are marketed after application of SMT.
- (11) It shall be stated that the manufacturer or client may not use SMT for promotional or advertising purposes.
- (12) There shall be a clause in the contract covering both the normal termination routine with a stipulated time for notice by either party and termination in the event of not fulfilment of conditions (e.g. immediate cancelling).

RULES FOR REPORTS ABOUT SMT

Each C.B. shall report to the Chairman of the HAR Group manufacturers who have been accepted by the C.B. and signed a contract for SMT. The Chairman of the HAR Group will keep a register containing SMT manufacturers for all CB`s.

The report from the C.B. to the Chairman of the HAR Group shall contain information as follows.

1. Standard contract

Prior to accepting the first SMT manufacturer, the C.B. has to submit to the HAR group, a copy of the standard contract, which is used between the C.B. and its manufacturer. (The copy shall be an example without the specific conditions from any manufacturer.) When the standard contract is changed, a copy of the new version shall be sent to the HAR Group.

2. Report on each SMT manufacturer

For each manufacturer/each laboratory who has been accepted and has signed the contract, the following information shall be reported by the C.B. to the HAR Group:

2.1 Date of the contract.

2.2 Manufacturer's name and address of the headquarters.

2.3 Name and address of each involved manufacturing factory.

2.4 Name and address of each accepted laboratory.

2.5 Products covered by the contract as defined by harmonisation documents.

For the reports, the enclosed form shall be used.

Changes in the content of the contract referring to the above mentioned information shall be reported to HAR group.

3. Records of Operations

The C.B. shall keep records in accordance with its procedures containing information as follows.

3.1 The intended minimum level of supervision, as contained in the test programme, expressed as clauses in the corresponding harmonised documents.

3.2 Dates and hours of performed supervision and which clauses in corresponding harmonised documents have been supervised.

4. Report on supervision

Statistics of supervision visits to manufacturers shall be reported by the C.B. to the HAR Group annually in January covering the past year. For the reports, the enclosed form shall be used.

5. List of accepted SMT manufacturers

The secretariat of HAR Group shall compile a list of all accepted manufacturers and distribute it to signatories of the HAR scheme.

6. Numbering of SMT contract

The numbering of contract with accepted SMT manufacturers as reported by the C.B.'s according to item 2 above and when listed by the HAR Group secretariat according to item 5 above is described by the following rules.

C.B.-xxx-y

(1) (2) (3)

Explanations

(1) The name of abbreviation of the C.B., eg KEMA, IMQ, SEMKO.

(2) Number indicating manufacturer. The first SMT manufacturer of the C.B. will be given N° 001, the second N° 002, etc. If an SMT manufacturer ceases, the free number may not be used for another manufacturer.

(3) When the SMT contract between a C.B. and a manufacturer is modified, a letter will be introduced, indicating the modification. When (3) is empty, the first contract is still valid, A indicates the first modification, B the second, etc.

SMT MANUFACTURER
(Report to the HAR Group)

C.B.: _____ Report n° _____

Address : _____ Date : 20____ - ____ - ____

Country : _____ Name :

Date of initial contract : _____ Signature : _____

Latest revision : _____

manufacturer name and
address of headquarter: _____

Approved laboratories
name and address : _____

Manufacturing factories,
name and address : _____

Products covered by
the contract : _____

SUPERVISION OF MANUFACTURER TO SMT DURING 20 _____
 (Report to the HAR Group)

C.B.: _____ Report n° _____
 : _____

MANUFACTURER: _____ Date : 20 _____

SMT LABORATORY : _____ Name : _____

Signature

: _____

ITEM	PRODUCT CATEGORY (*1)	PURPOSE OF VISIT (*2)	DATES AND DURATION	PARTS OF TEST WITNESSED CLAUSE N ^{OS}	TRF N° ISSUED (IF APPLICABLE)

END OF REPORT

(*1) Please indicate in detail, eg H05VV-F. If more than one laboratory per manufacturer, please use one form per laboratory

(*2) Please indicate supervision of test, assessment,...