Validation of methods under Flexible Scope

1 Scope

In the frame of its accreditation, the ESTI laboratory normally uses methods defined in international standards. The laboratory, only under the field of accreditation, may identify the needs of developing newer methods, more modern, faster, more economical or more technically advanced, or to adapt/modify existing methods.
These methods shall be introduced and used by the laboratory under flexible scope only upon validation, that is, the verification and acceptance of their performances and obtainable results.
This Instruction describes how methods are validated by the laboratory before they can be used for valid measurements.

2 Field of Application

Development of new methods; introduction, adaption and modification of internal methods or methods validated at international level.

3 History of changes

Version b (Jan 2006)	reviewed; new header and footer; added history of changes
Version c (Feb 2009)	reviewed; minor changes to header and footer
Version d (Mar 2015)	reviewed; new header, revised par. 1, par 4.1, 4.4, 4.5
Version d-rev1 (Jan 2019)	reviewed; new header
Version d-rev2 (Jul 2019)	new title; clarification of the scope
Version d-rev3 (Jul 2019)	in 4.4. "new method case" has been added; in 4.4 and 4.5. "statistical EN comparison of the tests shall result in EN ≤ 1" added.
Version d-rev4 (Jul 2022)	Reviewed; minor editorial changes.

4 Description

4.1 Introduction

When introducing a method, developing a new method or modifying a method special attention must be given to the competence of the staff and the technical capabilities of the laboratory: for ESTI this is guaranteed by:

- Formal education of staff ;
- Experience in the field;
- Deep knowledge in the domain;
- Knowledge about risks the clients are dealing with and how they intend to use the results;
- Knowledge about the procedures applied, about their reliability, including the associated uncertainties;
- Participation in research/development projects;
- Participation in standardisation committees;
- Participation in scientific or authoritative committees;
- Participation to inter-laboratory comparison with world top reference laboratories.

4.2 Appointment of staff for development and modification of methods

The ESTI staff undertaking development and modification of methods shall have the necessary technical understanding of the method and the technology used. They shall be able to judge the suitability of methods and the quality of the results obtained.

4.3 Documentation of the Method

All new methods shall be identified and sufficiently described to allow its subsequent use, under the same conditions, in a reproducible way.

The following information shall be safeguarded (preferably as part of the operating instruction):

1) Scope (Field of application: product or equipment, type of sample,
2) References (Exact definitions of norms, standards, internal methods already in use and complimentary documentation supporting the method (if available));
3) Terminology (when needed: definition of the specific terms, description of symbols and abbreviations used);
4) General principles of the test (summary or short description of the method);
5) Equipment (Instruments required and additional requirements);
6) Consumables to be used (if required);
7) Samples (number of required samples and sample preparation);
8) Preparation, calibration, check, conditioning of the instruments and possible environmental condition specification;
9) Procedure for the execution of the measurement;
10) Results (Calculations and interpretation; estimation of the uncertainties);
11) Limits or extensions of measurements.

The following additional information shall also be safeguarded together with the raw data, the calculations, and the conclusions:

12) Performances of the methods as detected during the validation phase.
13) Scientific evidences, when available.

4.4 Validation of method

A staff member of proven experience and competence is appointed as "Responsible for validation of methods" (RVM); they have the responsibility to define how validation shall be carried out, and then to verify and accept the validation results.

When the circumstances and the relevance of the new methods require it, the method may (where possible) be submitted for verification to other laboratories with a recognized competence in the photovoltaic field (for example NMI's or other ISO/IEC 17025:2017 laboratories) and statistical EN comparison of the tests shall result in $EN \leq 1$.

Where the method is entirely new and no other comparable method is available for comparison, judgment will be made with some or all of the following: similarity to existing methods; evidence of peer reviewed scientific publications, documented reports of the method and results obtained in this case statistical tests may not be possible.

Results obtained from these verifications will be taken into account in the process of validation of the method and safeguarded as described above.

4.5 Adaption of methods

A method already implemented in the laboratory might need to be adapted for usage with a different measurement station, or a different product, or range of measurement, or due to revision of the reference International standard.

If the principle of measurement remains the same and is done under similar operating conditions, the validation process shall consist in the documented verification of the efficacy of the modification introduced including a statistical EN test shall result in $EN \leq 1$.