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Quality Management System – Policy and Programme Support Section					
VALIDATION METHODS					

1. PURPOSE

To specify the necessary steps in validating test methods used within the testing laboratory of the Section.

2. SCOPE

This procedure applies to all technical methods, regardless of their origin (standard, literature, self-developed), which are used in providing the services of the Section.

3. RESPONSIBILITIES

Service Group Leader

- To formulate the necessary requirements for each method
- To select the applicable validation method
- To define the needed records to document the validation process
- To inform the Quality Manager about the validation process.

Laboratory technician

- To perform and record the validation.

Quality Manager

- To keep a list of measurement methods and their validation dates and methods

	Function	Name	Signature and Date
Authorized	Section Head	K. Mrabit	2005/05/20
Approved	Unit Head	Pascal Deboodt	2005-05-05
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Approved	Service Group Leader	John Hunt	John Hunt 2005-03-08
Registered	Quality Manager	J. Zeger	2005-03-03

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 s:\quality management\quality management documentation\general technical procedures\ PR-13-OP_Method_validation_V1.doc

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4. ADDITIONAL INFORMATION

[EAL-P11](#) Validation of Test Methods

5. DESCRIPTION

Each method used within the testing laboratory of PPSS must be validated or follow closely a method description in an international standard. This validation process must provide evidence that the method can fulfil all requirements for its intended use.

Validation should cover:

- accuracy/total uncertainty
- limit of detection
- robustness/selectivity (free of disturbances)
- repeatability (immediately by the same person)
- reproducibility (e.g. by different persons).

The process of validation has to start with the **Service Group Leader** defining the special requirements that the method must fulfil.

As soon as these requirements are known, the **Service Group Leader**, if needed together with the laboratory technician concerned, will select one of the different methods of validation. The whole process of validation will be documented. The **Service Group Leader** will keep this documentation and send notification to the Quality Manager, stating the name of the validated method, a description of the procedure of validation and date of validation.

The different ways of validating a technical measurement method used in the testing laboratory are:

5.1.1 Calibration using standard reference materials.

Using a (extended) calibration as a validation method requires the definition of relevant measurement or environmental conditions observed during calibration (e.g. temperature, pressure).

5.1.2 Systematic investigation of parameters influencing the measurement method.

This process may be used when no certified reference materials exist. Parameters such as temperature, pressure, humidity, electrical and electromagnetic fields and chemical interferences could be used. Influences should be verified and quantified by systematical variation.

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5.1.3 Comparison with other testing methods.

A measurement method under development could be compared with one or more well established methods.

5.1.4 Laboratory intercomparison.

A group of recognized laboratories are organized to apply the newly developed measurement method to a set of identical samples.

5.1.5 A combination of these methods.

Different validation processes are applied to different steps of the measurement method.

A method may be regarded as validated only if it can be proven to fulfil all requirements established prior to the validation process.

6. RECORDS

Definition of the requirements for the method to be validated and documentation of the validation process, to be kept by the **Service Group Leader**.

Notification of the Quality Manager about the performed validation, to be kept by the Quality Manager.