IMPLEMENTATION OF NEW METHODS

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ABSTRACT: In case of accreditation, a laboratory has to use preferably established test procedures, such as official or standardised methods, published by referable technical scientific journals, or suggested by the apparatus manufacturer.
If such methods are not available, or if the laboratory concerned wishes to use more recent, quicker, economically more interesting test procedures, or which performances are superior, this laboratory is free to adopt, to develop and/or to design new methods, but these will have to be fully documented and validated before being used, i.e. their liability will be evaluated and accepted by accreditation authorities.

The following points will be developped in this presentation:

- Rules related to the selection of the method (Norm EN ISO, CEI 17025).
- Different types of methods supposed to be implemented in Forensic Laboratories, the circumstances in which these methods have to be validated.
- Rules to be applied to ensure the concerned laboratory has reached the level of performance required in the new implemented method (in the case of use of validated methods or others).
- General validation procedure for in-house designed or developped methods for qualitative or quantitative tests (how to document and evaluate the proper method).
- How to simplify the process for adopting a method issued from a simple adaptation of a validated method (verification of the efficiency of the modification, check the level of performance obtained by the laboratory).
- The problem of methods that cannot be validated.
- The problem of mutual acceptance of accreditated methods by European accreditation organisms.
- Ideas concerning the agreement of validation rules on a European scale and concerning the importance of publishing the methods established in mutual understanding within the ENFSI working groups.

KEY WORDS: New methods; Validation; Verification.

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INTRODUCTION

Every forensic expert is eager to get correct and valid results. Therefore one will have to pay attention to the correct selection of methods and the proper way of implementing them.

SELECTION OF METHODS

The ideas or criteria for the selection of a specific method, according to ISO 17025, are:

1. The performance of the method should meet the requirement of the customer or the client and the method should be appropriate for the intended use. It means that:
   – one really has to know the needs and intended use of the customer,
   – there should be an explicit agreement about these requirements.

The experience gained in the Netherlands shows that obtaining the right information from our customers is very time consuming. Therefore the experts sometimes make decisions on what they "think" the customer wants and this may not always be the real need.

2. Another criterion is that the method should be validated.
3. The last criterion is that a forensic expert also has to proof that he/she can properly operate this method.

TYPES OF METHODS

Generally, in Forensic Science we can distinguish tree types of methods:
– methods published in standards,
– laboratory adopted methods,
– laboratory developed methods.

Methods published in standards

The first group of methods, are those published in national or international standards like ASTM methods, ISO methods etc. These methods are not widespread Forensic Science. Although some examples exist like in Environmental science: the detection of heavy metals with ICP or techniques for the development of fingerprint.

If a method is published in an official standard, one does not have to validate it. It can be assumed, that the validation of a method has been done appropriately. However, each laboratory should confirm that it can operate

the method properly, and that it meets the performance characteristics of the standard. Of course these characteristics of a method should also meet the requirements of the customer.

Adopted methods

The second group of methods are those that have been developed in a laboratory or an institute and are later adopted by the others. A larger variety of these methods has been implemented in forensic laboratories or institutes like DNA methods or drug methods.

After adopting a method, one has to be sure that the validation of the method is appropriate. Therefore, one needs to have access to the data of this validation and has to verify this data. Obtaining it, one finally has to confirm that he/she can operate the method properly.

Developed methods

The third kind of methods are the so called "in-house developed methods". The introduction of these methods should be a planned activity. It should be assigned to qualified personnel equipped with adequate resources and managed like a project. The (project) documentation should include a clear specification of the client's requirements and the purpose of the method.

The method should be validated.

Last but not least, the method should be fully documented. This documentation should be in compliance with the criteria for standard operation procedures. For instance, it should contain: scope, procedure, apparatus and equipment but also environmental condition, safety measurement, presentation of data etc. Briefly, it should contain all aspects that are relevant for SOPS.

An example of an in-house developed method in the Netherlands, is breaking of the password of a specific electronic organiser.

In this case the police is only interested in the content of the organiser's memory. The purpose of the method is therefore to break the password without changing the data in the memory of the organiser. A new organiser of the same type has been bought to develop the method and to perform the validation tests. Before introduction, the method has been checked by another institute. They managed this process as a project and wrote down all relevant information. Later on, they made a SOP (standard operation procedure) for this method.

THE IMPLEMENTATION PROCESS

First of all, one needs the requirements of the client, the user of the results of the method.

Then one has to translate these requirements into language and specifications that can be understood by staff members responsible for the development. The next step is to set acceptance criteria to satisfy the specifications. Then one has to design the validation tests

The validation starts. Finally after the validation one has to verify the process in casework.

VALIDATION

Validation means that one should confirm that the particular requirements for a specific intended use are fulfilled.

Validation requires at least the following:

1. The performance characteristics for the methods have been determined and these characteristics should meet the requirements of the customer. Also, the critical aspects of the method have to be identified and the limitations have to be defined.
2. It should be demonstrated that the methods, the material and the equipment are fit for the purpose.
3. There should be appropriate quality control and quality assurance procedures for monitoring the performance.
4. The individuals using the method should have demonstrated that they are competent to use it.
5. The method should be fully documented. The validation data should be recorded and the validation documentation should contain a statement on the validity of the method.

The characteristic of the method has to be determined. Table I gives an overview of the most common characteristics one has to determine in case of analytical methods. Of course, it depends on the type of method (qualitative, quantitative) and the requirements of the customer, and whether a characteristic is relevant or not.

TABLE I. PERFORMANCE CHARACTERISTICS FOR ANALYTICAL METHODS

Performance characteristic	Qualitative method	Quantitative method (high concentration)	Quantitative method (low concentration)
Trueness	–	+	+
Limit of repeatability	–	+	+
Limit of reproducibility	–	+	+
Detection limit	+	–	+
Linearity	–	+	–
Sensitivity/selectivity	–	+	+
Robustness	+	+	+
Estimation of a method uncertainty	–	+	+
Distribution of the component among the relevant population			

For analytical methods these characteristic are clear and it is not too difficult to develop validations test. There are some guidance documents and standards to help. Relevant documents could be:

– Eurachem guides on validation and the expression of uncertainty,
– ISO standards,
– Guides or standards related to the specific field of expertise,
– National guidelines and standards (for example: in the Netherlands the Accreditation Body has a standard on validation).

On the other hand for difficult areas like handwriting, shoeprints, toolmarks, voice analysis etc. it is not so easy to validate the method.

The validation of these methods should (among others) contain at least:

– identification of aspects that can influence the method and the results,
– independent assessment or peer review,
– competency tests.

UNIQUE CASES & UNVALIDATED METHODS

The policy of the Netherlands Forensic Laboratory is that all methods that are performed have to be validated, if possible. This can be done for methods performed on regular basis. For unique or special requests however, sometimes they have no choice than to use unvalidated methods.

Sometimes for investigation purposes sometimes the customer really needs a result at once. Then they are less interested in the validity of the method. It is once called quick and dirty.

For example, the police found a strange white substance on the scene of crime. They came with the request: Can you give an indication on what could it be?

The policy is that this is done only on explicit request of the customer. In such cases the customer must be informed that the results can not be authorised. They are just results from a quick research exercise. It is not allowed to use them for legal or evidential purposes.

The customers are always asked if they want a full validation afterwards. In most cases they do not.

COMPUTERS AND AUTOMATED EQUIPMENT

The question might come up if the validation of software is necessary. Can the computer be wrong? The policy in the Netherlands is that if software is involved in a casework it also should be validated before implementation.

This means:

– validation of an in house developed software,
– demonstration that an associated software is validated,
– checking of new versions of software before introduction.

For instance before using a new version of a integration programme for gas chromatography in casework the software has been checked with determination of control samples, standards and blanks.

COLLABORATION WITHIN ENFSI

If one really wants to get correct and valid results, he/she will have to pay attention to the validation and the way of implementing new methods. Though we all know that if one wants to do that properly, it costs a lot of time and effort. Therefore if we could spread out the validation part and publish the validation data we will do a great favour to our communities.

But this means:

– standardisation of technical methods within ENFSI working groups,
– agreement on the standards for validation within the working groups,
– the willingness of publication of our validation data.

There are a lot of political and technical barriers in doing this but the wall, the Berlin Wall, was much higher.