EFLM Committee on Quality and Regulations

WG on IVD Directive (WG-IVD)

WG Chair: Prof. Christos Kroupis (GR)

Terms of reference

1. Interpretation and harmonization of the use of the EU IVD Directive in laboratory practice and during accreditation of laboratories in Europe.

2. Improvement of information given by IVD manufacturers to their customers (laboratories).

3. Guidance and recommendations for laboratories, vendors or distributors of IVD equipment and assessors on the requirements for the documentation (needed in the scope of accreditation) for the documentation of installation and preventive maintenance of equipment.

4. Guidelines for method validation/verification reports in different fields of laboratory medicine.

5. Influencing the EU regulatory frameworks related to IVDs.

Short-term goals

Re: ToR2. Improvement of information given by IVD manufacturers to their customers

The WG wishes to contribute to an improvement of information given by the IVD manufacturers to laboratories and consumers, who purchase IVD instruments and devices, in order to enhance quality and safety of *in vitro* medical devices and analytical instruments used in clinical practice.

Directive 79/98/EC (annex I, essential requirements 8) defines the information to be supplied by the manufacturer. The WG critically evaluates the requirements and highlights those items that currently have shortcomings. The weaknesses identified will be addressed in more depth and suggestions will be made for modifications, in collaboration with EDMA. The WG will propose solutions to the problems identified in form of guideline recommendations which intend to improve the information given by IVD manufacturers.

Re: ToR3. Recommendations for the documentation of installation and preventive maintenance of equipment.

Directive 79/98/EC requires information to be supplied by the manufacturer on the traceability of the calibration of the device.

ISO 15189 audits often identified nonconformities in different countries pointing to the lack of *transparency* and *traceability* of installation reports and preventive maintenance reports of instruments. Certificates of calibrations and verifications are often lacking transparency (item 5.3.4 of ISO 15189). Moreover, measurement results (also those used for calibration of instruments) must be designed and performed so as to ensure that those are traceable to SI units or by reference to a natural constant (item 5.6.3 of ISO 15189).

In relation to the above, accreditation bodies currently assess compliance with these standards in variable ways in different European countries. For quality, comparability and transferability, a more harmonised approach is therefore needed all across Europe.

In collaboration with EDMA and UNAMEC, the WG will prepare concrete guidelines for:

- The deployment and installation of instruments in the laboratory of the customer: i.e. type and content of documents to be provided by manufacturers for the laboratory.
- Preventive maintenance: i.e. contract content, documentation of performed verifications, documentation of performed measurements in relation with the required specifications, proofs of traceability of used measurement equipment and types of certificates required.
- Policy for the delivery of batch release certificates by IVD reagent providers.

Long-term goals

The WG-IVD plans the following activities:

Re ToR4: Guidelines for method validation/verification reports in different fields of laboratory medicine

Validation reports
Elaboration of a general template that can be used for the presentation of a validation report according to ISO 15189 (in collaboration with the EA Health Care WG).

Validation guidelines
In 2007, Rabenau *et al* published a guideline with specific recommendations for the verification and validation of diagnostic tests in clinical virology *(Journal of Clinical Virology 40 (2007) 93-98)*. In this paper, a distinction was made in the requirements for validation/verification of manufacturer provided IVD kits or methods, modified methods or protocols, and in-house tests. This paper is often used now as a reference for auditors in this field.

The WG-IVD plans to set up similar guidelines for other laboratory fields, such as clinical chemistry, coagulation, cell counting, etc.

Re ToR5: Influencing the EU regulatory frameworks related to IVDs.

The European Commission (EC) has set up an Exploratory Process on the future challenges of the medical devices sector in 2009, which might have implications for the IVD industry and its users, i.e. medical laboratories, clinicians and their patients in Europe. EFLM, together with EDMA, have been invited by the EC to take part in these discussions and in the three key work stream groups of this exploratory process focusing on: (1) future challenges and opportunities for public health and medical technologies developments, (2) balance between patients' needs and financial sustainability, and (3) competitiveness and innovation of the medical devices industry. The aim of the discussions was to map the existing public health and industrial challenges in the sector and investigate possible topics of reflection at European level.

The WG is involved in these consultations and wishes to influence EU policy on this topic and to take part actively in the future revisions of the EU IVD Directive.

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