



European
Diagnostic
Manufacturers
Association

STANDARDISATION

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Benefits of standards

Standards have a positive impact on the in-vitro diagnostic industry, in particular harmonized standards in the context of the requirements of the IVD-Directive. In this function they provide the basis for the free trade in the European Member States and the European Economic Area. At the same time they assure quality and safety of products and processes. Revisions are necessary to reflect changes in the social, technological and regulatory environment.

The standardisation process involves the participation of experts from all interested constituencies, i.e. competent authorities, medical laboratories, industry and other interest groups (e.g. patient organizations). The outcome of this process, i.e. the standards, should reflect a balance of interests, and should take into account also cost-benefit considerations, not only of the standard development process as such, but of the impact on industry and society as a whole. Therefore it is legitimate for industry to represent its interests during the standardization process.

IVD-industry needs to take a position at the time of a proposal of new standards, assessing the potential benefit of the endeavour, and balancing it against the cost for development and implementation of the standard. No projects should be supported with questionable gain in safety and quality, or when they put undue burdens on manufacturers.

Nomination of experts

While the standards are developed, it is necessary for industry to commit the appropriate experts to these processes. Concerning the qualifications of these persons, it is not sufficient to have the necessary knowledge in their field, but they need also to take into account, what financial, regulatory and organizational consequences the proposed standard will have. The best experts in their field may not be the best persons to be delegated to participate in these processes. In several situations the representatives will need to strive for compromises. Also skill for negotiations and a feeling for "hidden agendas" by other parties are very useful.

Harmonization, Communication and Networking

Industry needs to consolidate its position and assume a common position. This is accomplished by monitoring the processes regularly, identifying problematic issues and harmonizing industry's input by meetings prior to the discussions at the standardisation working group's level. It is also helpful, if industry representatives take up the chair of relevant Technical Committees or act as convener of Working Groups.

In several situations work in one Technical Standardisation Committee is influenced by activities in other Committees. In these cases it is necessary to align industry's input across these Committees. Industry associations like EDMA offer the appropriate platform to achieve such harmonized

positions. The ideal situation is to have the same experts participating in both or all Committees. It is also essential to establish an efficient informal communication network with other interested parties, e.g. users, chairpersons of other TCs, members of other industries, etc.

At the same time it is indispensable to keep informed those manufacturers, who are not directly involved in standardization. This is done by regularly updated information by EDMA (Standards News) as well as by direct information of the participating experts through their National Members Associations. Industry should also be encouraged to participate at

standardization work in national mirror groups for CEN, CENELEC and ISO and IEC activities.

Industry needs to take an active role in standardization, supporting only projects which are meaningful, contributing to the process by nominating the right persons and harmonizing its position versus the other interest groups. Otherwise industry may get standards which it doesn't need and doesn't like. In such cases the cost of complying with such standards may be much higher than the costs for sending industry participants into the standards working groups.

EDMA Standardisation Working Party



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