

CLSI Organizational Policy on Harmonization

Over the past 25 years, more countries have experienced economic expansion due to open markets, open political systems, and access to communication technologies. This also has had an impact on healthcare and laboratory medicine. The consequence is that in many countries there are comparable standards in safety and quality. These standards have been enhanced by technology transfer, as well as international cooperation and exchange of information.

CLSI, as a global leader in standardization and harmonization, is firmly committed to achieving global harmonization wherever possible. CLSI recognizes that medical conventions in the global metrological community have evolved differently in the United States, Europe, and elsewhere; that these differences are reflected in CLSI, ISO, and CEN documents; and that legally required use of terms, regional usage, and different consensus timelines are all obstacles to harmonization. In light of this, CLSI recognizes that harmonization facilitates the global application of standards. Implementation of this policy must be an evolutionary and educational process that begins with new projects and revisions of existing documents.

Harmonization and globalization help medical practice to reach a comparable level in all developed countries. This is also true for laboratory medicine, where CLSI standards frequently describe best practices. This is in the best interest of patients by promoting quality and availability of patient testing.

Harmonization is a continual collaborative process with the ultimate goal of having CLSI documents applicable globally. The process includes: (1) awareness of the differences; (2) alignment of terms and definitions; and (3) alignment of processes and/or outcomes.

CLSI should harmonize its documents in order to achieve global acceptance of CLSI standards and support the globalization of CLSI membership, volunteers, and processes. CLSI's harmonization efforts support the interests of manufacturers and complements regulatory bodies and manufacturers work to harmonize the regulatory environment (GHTF). Standards play a major role in this context for registration purposes and admission of products to market.

Terms and definitions are fundamental parts of documents therefore it is necessary to standardize their use. CLSI will start with harmonization of terms and definitions, and secondarily (and perhaps more difficult) is the harmonization of approaches and ideas (e.g., measurement traceability vs. horizontal comparability), which also must be addressed.

CLSI will:

- 1) identify harmonization issues as early as possible in the consensus process;
- 2) implement the protocol for use of terms and definitions that recognizes ISO terms as the preferred term and identifies terms from other sources and applies them as appropriate;
- 3) fully implement this protocol beginning with new projects and newly initiated revisions of existing documents;

- 4) maintain an up-to-date database of nomenclature and definitions used in CLSI, ISO, and CEN standards, and ensure access to the database by committee participants;
- 5) be proactive in educating CLSI volunteers, committees, and constituents on the importance of harmonization; and
- 6) develop a process for harmonizing approaches and ideas.

All staff and CLSI volunteers are responsible for implementation of CLSI's harmonization policy.

CLSI Operational Plan on Harmonization

This procedure is for new standards projects in 2002 and revisions of published documents [i.e., those moving from A1 (Approved-level first edition) to A2] started in 2003. The rationale for selecting this starting point is that CLSI has had or will have an orientation for these new subcommittees where we can present CLSI's harmonization policy.

All other documents currently at the proposed-level (P-level) will incorporate the policy, where feasible, and will carry language describing CLSI's efforts in harmonization. Chairholders Council should prioritize those existing and new documents that are most valuable if harmonized.

Overcoming Harmonization Issues from the Outset

- Seek to understand what is going on in other standards venues, e.g., ISO, CEN, ICSH, IFCC, WHO, etc.
- Identify harmonization goals for the document, e.g., how does the CLSI document relate to what already exists
- Ensure adequate non-U.S. participation/membership on the committee
- Research existing documents on the topic
- Appoint a subcommittee member to monitor harmonization issues

Guidance to Subcommittees on Harmonizing Terms and Definitions

- Harmonization of Terms and Definitions
 - ISO definitions give a framework for universal acceptance
 - Orientation on ISO Terminology, because CLSI is a member of ISO/TCs and holds the secretariat of ISO/TC 212
- Where are the problems?
 - Semantic differences, (also British and American English)
 - Differences caused by legal definitions, e.g., labeling
 - ISO definitions are frequently rather abstract and concise. They are not easy to understand
 - A change in meaning is difficult to communicate and needs a long time to take hold
- Orientation on ISO definitions
 - CLSI is creating a relational database of NRSCL8, ISO, and CEN definitions

- Area Committees are not free to choose alternative definitions unless they have a valid justification of their choice for not using an existing definition
- Subcommittees should think at an early stage of document development, especially with revisions of documents, about definitions and decide on their use - this part is frequently done last, which may cause partial rewriting of the document, in case the term does not fit the meaning
- Area Committees should also be aware of other standards (ISO/CEN) that cover a similar area as the CLSI project. Difference in approaches and definitions should be noted and taken into account.

This does not necessarily mean that all terms need to be changed, or that the same approach needs to be followed, but at least differences should be pointed out in notes or explanatory text.

- Guidance on choosing a definition
 - Check on existing definitions
- Guidance on writing a definition
 - When creating a new definition follow the ISO rules, see the *ISO/IEC Directives*
- Concise, preferably without article or "any"
- Use NOTES for further explanation
- When in doubt, consult with CLSI staff

Harmonization Team

- proposed Harmonization Team tentatively consists of Emil Voelkert, John Zlockie, Treecee Polgar, Donna Wilhelm, Neil Greenberg, and Kay Setzer
- a specific charge to the Harmonization Team is being developed

Comprehensive Communication Plan

- a comprehensive communication plan is being developed that will promote understanding of the policy within and outside of CLSI
- Chairholders and other volunteers, journal editors, members and non-members
- Letter that goes out with the document

Guidance to Subcommittees on Harmonizing Procedures

- There are in fact only few areas where there are fundamental issues, mostly in the metrological field, e.g., accuracy, trueness; precision, repeatability, reproducibility; error

