Pure & Appl. Chem., Vol. 68, No. 10, pp. 1843–1846, 1996.
Printed in Great Britain.

Aims, objectives and work program of ISO/TC 212

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Abstract
The inaugural meeting of the newly constituted ISO Technical Committee 212 (ISO/TC 212) on Clinical laboratory testing and in vitro diagnostic test systems took place in Philadelphia, PA, USA on 31 May through 2 June 1995. The secretariat of the new technical committee was assigned by ISO to the American National Standards Institute (ANSI). NCCLS has been delegated responsibility for administering the secretariat. Committee membership includes 20 Participating Member Countries and 12 Observer members. The committee has recommended a structure composed of three working groups: Quality Management in the Clinical Laboratory, Reference Systems and In vitro diagnostic products. A tentative programme of work includes 11 work proposals for approval by the Participating Member Countries. The scope of committee activity and the specific items included in the work programme will be discussed.

Standardization has been an important activity for many centuries. History records many early steps to standardize language, units of measure, currency and other items necessary for communication, trade and the development of an orderly society. The development of laboratory medicine has depended upon the availability of standardized materials for the preparation of reagents, the publication of standard methods and procedures, the acceptance of standard characteristics to define bacteria and tissue cells, the acceptance of standard nomenclature to report laboratory findings and numerous other criteria and systems to help assure the usefulness of laboratory data.

Modern standardization can be considered to exist at three very broad levels:

- Technical (materials and methods)
- Professional (qualifications and evaluations)
- Regulatory (local, national and regional government requirements)

Technical standardization is necessary to obtain similar or comparable results when testing a given specimen. Such standardization goes beyond establishing methods and procedures to include the designation of reference materials and definitive methods for comparison purposes.

Professional standardization includes the designation of professional qualifications and peer group evaluation and accreditation programs.

Regulatory standards may apply to manufacturers of test systems and materials or to testing laboratories and personnel. They may address factors such as performance, safety, or evaluation methodology.

International standardization is intended to promote comparability and interchangeability of test methods, or to enhance the quality of testing, or to contribute to the safety of users of laboratory instruments and test systems or to reduce trade barriers.

The International Organization for Standardization (ISO) is a non-treaty organization that functions to develop standards that can be adopted in every country of the world. The standards are strictly voluntary; however, they can be used by industry, national standards bodies and governmental regulatory agencies if they possess appropriate technical merit and meet the needs of the countries involved. National membership in ISO consists of approximately 100 organizations representing voluntary standardization activities in their countries.

An International Standard begins as a work proposal submitted by almost any group within or outside ISO. If the proposed work is related to the scope of an existing technical committee, it is assigned to that committee by the ISO Technical Management Board. If a technical committee does not exist in the area proposed, the ISO Central Secretariat may survey member bodies for interest. If a 2/3 majority of the national bodies voting is in favor of the formation of a technical committee and if at least five (5) are willing to participate actively in the work, creation of the committee may be authorized. Every national body has the right to membership on a technical committee. It can choose P (Participating) or O (Observer) status and offer to hold the secretariat of the proposed committee.

A new technical committee, ISO/TC 212, was recently established by ISO in response to a proposal from NCCLS and ANSI (the American National Standards Institute), with the support of other international organizations. The proposed title "Clinical laboratory testing and in vitro diagnostic test systems" has been submitted to the ISO Technical Management Board for approval. The secretariat has been assigned to the United States (ANSI), and the responsibility for administration of ISO/TC 212 delegated to NCCLS by ANSI.

Following announcement by the ISO Central Secretariat, twenty (20) ISO-member countries selected "P" (Participating) status and twelve (12) selected "O" (Observer) status. The inaugural meeting of ISO/TC21 was held in the United States, in Philadelphia, PA, from 31 May through 2 June, 1995. A total of 74 attendees from Australia, Belgium, Canada, China, Denmark, France, Finland, Germany, Ireland, Italy, Japan, The Netherlands, New Zealand, Singapore, Sweden, Switzerland, the United Kingdom, and the United States participated in the work.

The outcome of the meeting was a series of resolutions, approved by the majority of those present on a one vote per country basis. The various recommendations require approval either by the ISO Technical Management Board or, in the case of the new work (project) proposals, by a majority of the "P" members of TC212.

The scope statement recommended to the ISO Technical Management Board is:

> " Standardization and guidance in the field of laboratory medicine and in vitro diagnostic test systems. This includes, for example, quality management, pre- and post-analytical procedures, analytical performance, laboratory safety, reference systems, external quality assurance, accreditation, and ethics."

The structure of the technical committee was discussed in depth, as was the list of new work items. The resulting recommendation includes three working groups with eleven (11) new work items distributed among them.

Working Group 1 - Quality Management in the Clinical Laboratory

- Pre- and post-analytical procedures for the clinical laboratory
- Clinical laboratory safety
- Quality assurance, including external quality assessment and internal quality control, and accreditation for clinical laboratory medicine
- Ethics in laboratory medicine

Working Group 2 - Reference Systems

- Contents and description of reference measurement procedures and reference procedures utilizing nominal and ordinal scales
- Contents and description of reference materials
- Requirements for laboratories performing reference procedures

Working Group 3 - In vitro diagnostic products

- Identification and determination of analytical and clinical performance goals for laboratory methodologies
- Determination of desirable performance criteria for blood glucose monitor systems for use in diabetes management
- Recommendations for validation of user quality control
- Symbols used in labeling of in vitro diagnostic products

A proposal for each work item has been circulated to the "P" members of ISO/TC 212 for their vote. Those obtaining the approval of the majority will have appropriate committees appointed in order to begin the project.

The vast amount of work already done and published in many of the new work areas was recognized. In order to take advantage of such information and to avoid duplication with ongoing activities, a number of liaison relationships were recommended. As is the case in many international activities, provision exists to adopt or endorse acceptable work performed by other agencies or expert groups.

Category A liaison is utilized for organizations which can make an effective contribution to, and participate actively in, the work of the technical committee. Such liaison includes exchange of documents and invitations to meetings. The following organizations were selected for Category A status:

WHO - World Health Organization
EDMA - European Diagnostic Manufacturers Association
ICSH - International Council for Standardization in Haematology
IFCC - International Federation of Clinical Chemistry
IUPAC- International Union of Pure and Applied Chemistry
WASP - World Association of Societies of Pathology
ECLM - European Confederation of Laboratory Medicine
ICTH - International Committee on Thrombosis and Haemostasis

Internal liaison has been requested between ISO/TC 212 and ISO/TC 48 (Laboratory glassware and related apparatus); ISO/TC 76 (Transfusion, infusion and injection equipment for medical use); ISO/TC 176 (Quality management and quality assurance); ISO/TC 210 (Quality management and corresponding general aspects for medical devices); and ISO/REMCO (ISO Council Committee on Reference Materials).

Representatives from the European Committee for Standardization (CEN) were present at the first meeting of ISO/TC 212. CEN/TC 140 (In vitro diagnostic systems) is engaged in a number of projects that could be included in the ISO/TC 212 work programme or submitted to parallel

approval under CEN lead, according to the provisions of subclause 5.2 of the Vienna Agreement on technical cooperation between ISO and CEN. In order to implement such cooperation, ISO/TC 212 will appoint experts to CEN/TC 140 and its working groups.

In response to an invitation from the German delegation, the next meeting of ISO/TC 212 will be held in Berlin from June 12 through June 14, 1996. At that meeting preliminary reports on the approved work items (projects) will be reviewed, and the process will begin to gain recognition of the technical committee as an effective agent in the worldwide effort to provide efficient and useful clinical laboratory services.