

PATHOLOGIST

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THE ROLE OF PROFESSIONAL ORGANIZATIONS IN THE ESTABLISHMENT OF STANDARDS AND THE EVOLUTION OF THE NCCLS

With each scientific, technical, and legislative event, the need for workable standards in the field of laboratory medicine, definable in terms of patient care, becomes more and more evident and imminent. These standards obviously involve the profession, the industry, and the various governmental agencies. Hence, an organization representing all three of these could clearly be in a position of possible leadership to identify and solve the problems that this need for standards creates. It is, therefore, appropriate to review the current status of the National Committee for Clinical Laboratory Standards as well as its history.

Several professional organizations were involved in the establishment of standards for medical laboratories prior to the formation of NCCLS. Each organization, unfortunately, was going its own way, generally without much communication between groups. There were some notable exceptions, however; the College of American Pathologists, the American Association for Clinical Chemistry and the American Academy of Pediatrics each cooperated in the establishment of a crystalline bilirubin standard. The National Research Council of the National Academy of Sciences also was involved in consultations with a variety of organizations prior to the establishment of specifications for standards such as the Cyanmet Hemoglobin Standard. The CAP standards laboratory also has been quite active for several years in meeting the responsibilities of checking lots of certain standards in addition to the Cyanmet Hemoglobin Standard. Two other examples of CAP activities developed in cooperation with other groups include the establishment of the Clinical Standard Solutions program in 1951 followed by a national conference to establish specifications for a cholesterol standard in 1964 and the inauguration of the Inspection and Accreditation program.

The Founding of NCCLS

The nidus for the NCCLS began on October 21, 1967, when, with the total commitment and support of the CAP, a meeting was arranged including a large number of representatives of professional organizations interested in the setting of standards for clinical laboratories. This meeting

was conducted by Dr. Russell J. Eilers and the participants included among others, Drs. Howard Bodily, Ralph Thiers, E. M. Flipse, Andrew Fodor, James Griffiths, and Mr. J. J. Moran.

The meeting resulted in a provocative and stimulating discussion regarding a variety of approaches to the setting of standards, and the net result of the meeting was the establishment of a "provisional national committee for clinical laboratory standards." Dr. Russell J. Eilers was selected as chairman pro-tem and Dr. Ralph Thiers as secretary pro-tem. During the next several months, a tremendous amount of time and effort was extended by many individuals in order to develop a permanent organization. These efforts resulted in the permanent format of the National Committee for Clinical Laboratory Standards as we know it today.

The NCCLS as a result is a truly unique, sophisticated, and representative organization of virtually all groups and segments of the field of laboratory medicine. The success of the committee has been built on two pillars: The consensus approach to standards development and the balance of representation by the professional organizations, the industry, and governmental agencies.

Like any new organization, the NCCLS went through some initial difficult and frustrating periods of development. One can appreciate how particularly true this would be in a system trying to gain consensus and balance between professional, industrial and governmental interest. Credit should be given to the outstanding individuals in the profession, the industry, and government (state & federal) who made continual unselfish voluntary contributions of effort and time to insure the progress and development of the NCCLS. In addition, a small number of professional and industrial representatives repeatedly gave financial support so that the organization could meet its fiscal responsibilities. As the NCCLS progressed and developed, it became clear that it could not continue to grow and meet the needs, depending on this extraordinary voluntary effort alone. As a result, a decision was made to acquire a part-time executive director with a full-time administrative office to handle the administrative and fiscal matters of the NCCLS. The man selected was John McConnell, an individ-

ual with an established reputation as an executive and manager in the health industry field.

With increased accomplishments and membership, the NCCLS has passed from a period of struggle to one of outstanding potential and leadership in the entire area of standards for clinical laboratories, in the past two years. Before delineating these specific possibilities, we should look at the current existing anatomy of the NCCLS.

Structure of NCCLS

The elected officers and directors who compose the NCCLS Board must, according to the bylaws, represent a careful balance of the constituent members and professional disciplines. Members of the NCCLS may be private or public, educational, scientific, professional, governmental or industrial organizations. Each member organization is represented by one voting delegate and one alternate delegate who attend the semiannual general membership meeting and receive all NCCLS mailings. They are charged with responsibility of circulating all documents and materials to appropriate individuals within their organization for comments promoting and supporting standards, development activities, and participating in the balloting for action on standards and election of officers and directors. NCCLS membership at this date consists of 18 professional associations, 6 government agencies and 71 industrial organizations. The NCCLS has been fortunate to have been able to generate a cooperative effort from these organizations and agencies.

Each member of the Board of Directors of NCCLS is charged with the duty of being a liaison between the Board and the various area committees. Currently there are nine area committees dealing with the disciplines of clinical chemistry, hematology, immunohematology, diagnostic immunology, ligand assay, microbiology, labeling, instrumentation and evaluation protocol. The area committee chairpersons are carefully chosen on the basis of expertise in a given discipline as well as an ability to work with the liaison and committee members. It is the president-elect's responsibility to coordinate these area committee activities. Each area committee chairperson develops the membership of their area committee with Board and presidential approval and subcommittees in various areas are established in a similar fashion. Within the area of clinical chemistry, for example, there are established a total protein subcommittee, "urine sugar" subcommittee and enzyme subcommittee for the analysis of temperature standards, etc. The goals and objectives for each area committee have been and are now being established as well as a set of priorities for those standards to be developed.

As a standard is developed, it is edited, and following Board approval it is submitted to the membership as a proposed standard. After membership review and comments, the proposed standard is elevated to the level of tentative standard with Board approval and submitted to the membership and field at large for review, revision, etc. Then following membership vote, it is an approved standard of the NCCLS. Table I is the current status of NCCLS standards.

A Role of Leadership

The rapidly developing area of leadership for the NCCLS revolves around the awareness of professional organizations, industry and governmental agencies of the unique role that the NCCLS can play through its consensus mechanism, not only for primary use in the United States but with important benefits to international cooperation as well. Certain specific events clearly elucidate this emergence of the NCCLS as a leader. For example, the CAP Commission on Standards recommended and the College's Board of Governors has approved the policy that any standard development of the CAP will be submitted to the NCCLS for approval through the consensus mechanism.

Governmental agencies likewise are turning to the NCCLS for guidance, advice and aid in the development of standards, more and more of which are being required as legislation and regulations increase. Specifically, the NCCLS has received approval of a contractual arrangement with the FDA to examine the consensus of methodologic principles for a given number of analytes through an expert panel. These deliberations will hopefully be available to the FDA within 12 months. Industry is also enlisting the good offices of the NCCLS to help it establish priorities and courses of action regarding the development of an application of standards within the health industry.

In closing, it is worthwhile to examine consensus mechanism. The most commonly registered complaint is that of the time involved from the inauguration of a proposed standard through the consensus mechanism to an approved standard. Most people with extensive experience in the development of standards for laboratory medicine find this to be an asset rather than a defect. Because of the tremendous impact that these standards have on the industry and the clinical laboratory, as well as the legislative force given to these through the regulatory mechanism, it is appropriate that considerable thought and input with revision and editing go into these standards before they are propagated through the field.

Likewise, none of these standards are "cast in stone" and are constantly subjected to re-evaluation, re-appraisal and revision. Due to the role these standards play and will be asked to play, the survival of good patient care and medical usefulness can only be assured if standards in the clinical laboratory field are carefully selected, well-developed, thoroughly processed through the consensus mechanism, and released only when their medical usefulness has been defined in terms of improving patient care rather than meeting a regulatory or

legislative need. Only in this way can laboratory medicine lead and maintain responsiveness in the legislative mechanism rather than be dictated by it.

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Table 1. Current Status of NCCLS Standards as of December 1, 1976

<u>CLINICAL CHEMISTRY</u>		
ASC - 1	Standardized Protein Solution (Bovine Serum Albumin)	\$ 4.00
ASC - 2	Standards for Calibration, Reference and Control Materials in Clinical Chemistry	\$ 4.00
PSC - 3	Reagent Water Specification and Test Methods for Water Use in the Clinical Laboratory	\$ 4.00
PSC - 4	A Reference Method for the Determination of Total Calcium in Serum	\$ 4.00
<u>EVALUATION PROTOCOLS</u>		
PSEP - 1	Protocol for Establishing the Precision and Accuracy of Automated Analytic Systems	\$10.00
<u>HEMATOLOGY</u>		
TSH - 1	Standard for Evacuated Tubes for Blood Specimen Collection	\$ 4.00
TSH - 2	Standard Method for the Human Erythrocyte Sedimentation Rate (E.S.R.) Test	\$ 4.00
<u>IMMUNOHEMATOLOGY/BLOOD BANKING</u>		
TSI/BB - 1	Specifications for Standard Isotonic Sodium Chloride Solution for Immunohematologic Testing	\$ 4.00
<u>INSTRUMENTATION</u>		
ASI - 1	Preparation of Manuals for Installation, Operation, and Repair of Laboratory Instruments	\$ 4.00
TSI - 2	Standard for Temperature Calibration of Water Baths, Instruments, and Temperature Sensors	\$ 4.00
PSI - 3	Standard for Determining Spectrophotometric Performance Criteria	\$ 4.00
<u>LABELING</u>		
ASL - 1	Labeling of Laboratory Reagents	\$ 4.00
<u>LIGAND ASSAY</u>		
PSLA-1	Guidelines for Standards to Assess the Quality of Radioimmune Systems	\$ 4.00
<u>MICROBIOLOGY</u>		
ASM - 1	Standard Test for Labeling Efficiency of FITC	\$ 4.00
ASM - 2	Performance Standards for Antimicrobial Disc Susceptibility Tests	\$ 5.00
TSM - 4	Determination of Fluorescein/Protein Ratios in Fluorescein Isothiocyanate Labeled Protein	\$ 4.00
PSM - 5	Standard for Rubella Hemagglutination-Inhibition (HAI) Reagents and Test Procedure	\$ 4.00

The status of the Standards is indicated by the first letter of the Code. "A", indicates an Approved Standard, "T", is a Tentative Standard, "P", is a Proposed Standard.

The above Standards are available post paid at the prices shown. For orders outside the United States, please add \$.50 per Standard. To keep the cost of Standards as low as possible we request a check with order.

MEMBERSHIP
As of December 1, 1976

Professional Members

American Academy of Allergy
American Academy of Microbiology
American Academy of Pediatrics
American Association of Bioanalysts
American Association of Blood Banks
American Association for Clinical Chemistry
American Chemical Society
American Medical Technologists
American Osteopathic College of Pathologists
American Public Health Association
American Society of Clinical Pathologists
American Society of Hematology
American Society for Medical Technology
American Society for Quality Control
Association for Advancement of Medical Instrumentation
Clinical Laboratory Management Association
College of American Pathologists
International Society of Clinical Laboratory Technologists
Society of Nuclear Medicine

Government Members

Center for Disease Control
Commonwealth of Pennsylvania Bureau of Laboratories
DHEW/PHS/Food & Drug Administration
National Bureau of Standards
National Institutes of Health
Veterans Administration Central Office

Industrial Members

Abbott Laboratories
American Monitor Corporation
Ames Company (Div. Miles Laboratories)
J. T. Baker Chemical Company
B-D Spear Medical Systems
Bausch & Lomb
Beckman Instruments, Inc.
Becton, Dickinson & Company
Behring Diagnostics
Bio-Dynamics/BMC (Div. Boehringer Mannheim)
BioQuest (Div. Becton, Dickinson & Co.)
Bio-Science Enterprises
Bolin Laboratories, Inc.
Burroughs-Wellcome Company
Calbiochem
Clay Adams (Div. Becton, Dickinson & Co.)
Cooke Laboratory Products (Div. Dynatech Laboratories, Inc.)
Corning Glass Works
Coulter Electronics, Inc.
Culligan USA, (Div. Culligan International Co.)
Curtis Nuclear Corporation
Dade (Div. American Hospital Supply Corp.)
Difco Laboratories

Dow Chemical Company
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Electro-Nucleonics Company
Eli Lilly and Company
Environmental Chemical Specialties, Inc.
Every Ready Thermometer Company
Fisher Scientific Company
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Geometric Data Corporation
Gibco Diagnostics (Div. The Mogul Corp.)
Gilford Instrument Laboratories, Inc.
Harleco (Div. American Hospital Supply Corp.)
Hycel, Inc.
Hyland (Div. Travenol Laboratories, Inc.)
Hynson, Westcott & Dunning, Inc.
Instrumentation Laboratory, Inc.
Lab-Line Instruments, Inc.
Laboratory Computing, Inc.
Lederle Diagnostics (American Cyanamid Co.)
Mallinckrodt, Inc.
Micromedic Systems (Div. Rohm & Haas Co.)
New England Nuclear Corporation
Nobel Scientific Industries, Inc.
Nuclear Medical Laboratories, Inc.
Ortho Diagnostics
Owens-Illinois
Oxford Laboratories
P-L Biochemicals, Inc.
Perkin-Elmer Corporation
Pfizer Diagnostics (Div. Pfizer, Inc.)
Pharmacia Diagnostics (Div. Pharmacia, Inc.)
Photovolt Corporation
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