CONFERENCE ON A NATIONAL UNDERSTANDING FOR THE DEVELOPMENT OF REFERENCE MATERIALS AND METHODS FOR CLINICAL CHEMISTRY

NOVEMBER 16 – 17, 1977
HYATT REGENCY HOTEL
ATLANTA, GEORGIA

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Center for Disease Control

GENERAL FORMAT

The Conference is planned as a two-day meeting for approximately 150-200 participants representing the concerned Federal Agencies, clinical laboratory professions, and the appropriate health industries.

The Conference will address three major topics, each of which will be subdivided into more manageable working groups. Sponsors and co-sponsors will have a designated representative on each Working Group. The purpose of these Working Groups will be to review the scientific advice contained in position papers submitted prior to the Conference by the sponsors and co-sponsors. This advice will be reviewed, and, together with the deliberations of the Working Group, will be organized into the proceedings of the Conference which will be published at an early date.

OBJECTIVES

This Conference will attempt to further the understanding of the components necessary for the development, the acceptance, and the utilization of reference materials and methods in clinical chemistry.

Such a scheme on a national basis can be termed a National Reference System in Clinical Chemistry (NRSCC).

The objectives of this two-day Conference are (1) to define criteria for and essential characteristics of reference methods and materials used in establishing national standards for the accuracy of quantitative methods in clinical chemistry, and (2) to develop a total framework in which government agencies, professional organizations, and industry can cooperate on a national basis in the orderly development of a National Reference System in Clinical Chemistry.

PROGRAM

NOVEMBER 16 (WEDNESDAY)

8:00 – 8:30	Registration
8:30 – 8:40	Announcements (Dr. David D. Bayse)
8:40 – 8:55	Welcoming Address (Dr. William Foege)
8:55 – 9:25	Keynote Address (Dr. Morton K. Schwartz)
9:25 – 10:30	Convene with Topic Coordinators
10:30 – 10:50	Coffee
10:50 – 12:00	Convene Working Group Sessions
12:00 – 1:00	Working Lunch
1:00 – 3:00	Working Group Sessions
3:00 – 3:20	Coffee
3:20 – 5:30	Working Group Sessions
6:30 – 7:30	Mixer
7:30	Dinner

NOVEMBER 17 (THURSDAY)

8:30 – 10:00	Working Group Sessions
10:00 – 10:30	Coffee
10:30 – 12:00	Working Group Sessions
12:00 – 1:00	Working Lunch
1:00 – 2:30	Working Group Sessions
2:30 – 2:45	Coffee
2:45 – 4:30	Working Groups Report to Conference
4:30	Adjournment

CONFERENCE CHAIRMAN: DR. DAVID D. BAYSE, CDC

TOPIC 1. ORGANIZATIONAL DEVELOPMENT OF A NATIONAL REFERENCE SYSTEM FOR CLINICAL CHEMISTRY (NRSCC)

Coordinator: Dr. Eloise Eavenson, FDA

Group 1.1 Analytical Goals and Quality Requirements Working Group

Chairman: Dr. Franklin Elevitch, CAP

CDC	Dr. Alan Mather
FDA	Henry T. Lee, Jr.

NBS	Dr. Philip D. LaFleur
NCCLS	Dr. Robert W. Pritchard
AACC	Dr. George N. Bowers, Jr.
ASCP	Dr. Desmond Burke
CAP	Dr. Roy N. Barnett
INDUSTRY	Dr. Stanley Bauer

The Analytical Goals and Quality Requirements Working Group will attempt to identify those laboratory applications requiring specific performance levels. In addition it will evolve a framework for decision making that can serve as a basis for defining such goals in terms of medical usefulness in the development of reference methods and materials. Such a framework could provide a bridge between routine clinical laboratory practice and a national reference system.

Group 1.2 Organizational Component of National Reference System for Clinical Chemistry

Chairman:	Dr. Joseph H. Boutwell, Jr., CDC
CDC	Dr. Gerald R. Cooper
FDA	Dr. Dale Fisher
NBS	J. Paul Cali
NCCLS	Jaxon A. White, Jr.
AACC	Dr. Nathan Gochman
ASCP	Dr. Rex B. Conn, Jr.
CAP	Dr. Roger K. Gilbert
INDUSTRY	William T. Ryan

Organizational Component of National Reference System for Clinical Chemistry Working Group will design an organizational plan that will effectively and efficiently use the available national resources of both government and private sectors. One aspect will be improvement of communications between the professions and promotion of group scientific investigation.

TOPIC 2. GUIDELINES FOR THE TECHNICAL DEVELOPMENT OF THE MATERIALS COMPONENT OF THE NRSCC

Coordinator: Dr. Thorne J. Butler, ASCP

Group 2.1 Standard Materials Working Group

Chairman:	Dr. George Uriano, NBS
CDC	Dr. Richard J. Carter
FDA	Dr. Nabeeh Mourad
NCCLS	Dr. Theodore Peters, Jr.
AACC	Dr. Royden N. Rand
ASCP	Dr. John A. Lott
CAP	Dr. Daniel J. Hanson
INDUSTRY	Dr. Thomas Adams

Standard Materials Working Group will outline and partially specify the criteria for selection, validation, characterizing, and labeling of such materials and will additionally consider priority needs for developing specific standards.

Group 2.2 Biological Reference Materials Working Group

Chairman:	Dr. Raymond E. Vanderlinde, AACC
CDC	Dr. Jane W. Neese
FDA	Dr. Amiran Daniel
NBS	Dr. Dennis Reeder
NCCLS	Dr. Huey V. Auger
AACC	Dr. Robert Rej
ASCP	Dr. Hermann Peter Lehmann
CAP	Dr. John G. Batsakis
INDUSTRY	Dr. Joseph L. Giegel

Biological Reference Materials Working Group will outline and partially specify the criteria for selection, validation, characterizing, and labeling sample-simulating biological matrix materials.

TOPIC 3. GUIDELINES FOR THE TECHNICAL DEVELOPMENT OF THE METHODOLOGICAL COMPONENT OF A NRSCC

Coordinator: Gerald E. Gallwas, INDUSTRY

Group 3.1 Definitive Methods Working Group

Chairman:	Dr. Robert Schaffer, NBS

CDC	Dr. John A. Liddle
FDA	Dr. Charles Furfine
NCCLS	Dr. Matthew M. Patton
AACC	Dr. Ralph E. Thiers
ASCP	Dr. Robert C. Rock
CAP	Dr. John B. Fuller
INDUSTRY	Walter Slavin

Definitive Methods Working Group will outline and partially specify the criteria for selection, validation, and adoption of definitive methods as well as how they will be applied.

Group 3.2 Reference Methods Working Group

Chairman: Dr. Basil Doumas, AACC

CDC	Dr. Carl A. Burtis
FDA	Dr. Barbara Tejeda
NBS	Dr. Rance Velapoldi
NCCLS	Col. Edward C. Knoblock
AACC	Dr. Graham Widdowson
ASCP	Dr. Bradley E. Copeland
CAP	Dr. Noel Lawson
INDUSTRY	Dr. Charles C. Allain

Reference Methods Working Group will outline and partially specify the criteria for selection, validation, and adoption of reference methods. This discussion will include reference methods with and without a *definitive* accuracy base.

Group 3.3 Provisional Reference Principles Working Group

Chairman: Dr. Ronald H. Laessig, NCCLS

CDC	Dr. Dayton T. Miller
FDA	Alfred Bracey
NCCLS	Dr. David M. Jeffers
AACC	Dr. Thomas O. Tiffany
ASCP	Dr. Thorne J. Butler
CAP	Dr. Charles G. Massion
INDUSTRY	Dr. Andris Indriksons

Provisional Reference Principles Working Group will outline and partially specify the criteria for selection of analytical principles or materials for interim use as common bases of reference.

GENERAL INFORMATION

Attendance will be limited to invitees only. For information concerning attendance, please contact the appropriate representative of the following organizations:

AACC	Dr. Theodore Peters
ASCP	Dr. Thorne J. Butler
CAP	Dr. Roger K. Gilbert
CDC	Dr. David D. Bayse
FDA	Dr. Eloise Eavenson
INDUSTRY	Gerald E. Gallwas
NBS	Dr. Philip D. LaFleur
NCCLS	Dr. Pierre Keitges

Admission to each Working Group session will be restricted to those wearing specific badges for that Group. In addition to participants, a limited number of observers, including international visitors, have been invited.

Advance registration is requested using the form attached to this notice. Please be sure to indicate first, second, and third choice for Working Group attendance.

A registration fee of $55.00 will be required.

Registration should be made on or before October 1, 1977. Registration fee cannot be refunded after this date. Checks should be made payable to the NATIONAL REFERENCE CONFERENCE.

HOTEL INFORMATION

All Conference activities, as well as lunches and lodging, will be at the Hyatt Regency Hotel located in downtown Atlanta. A block of rooms has been reserved by the Conference, but each participant must check in personally at the hotel desk, and is responsible for all hotel charges. Participants and observers should complete the enclosed card in order to obtain the special Conference rate and return it directly to the hotel. Requests for hotel reservations should be made before October 1. Transportation by limousine or taxi is available between the airport and the hotel.

PREPARATION OF CONFERENCE PROCEEDINGS:

On Friday, November 18, a post-Conference discussion will be held at the Center for Disease Control consisting of Topic Coordinators, Working Group Chairmen, and other designated parties to assist in the preparation of the Conference proceedings.