NISTIR 6008

Report on the Open Forum on Establishment of the National Council for Laboratory Accreditation (NACLA) at the National Institute of Standards and Technology January 7, 1997

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March 1997

U.S. DEPARTMENT OF COMMERCE
William M. Daley, Secretary

TECHNOLOGY ADMINISTRATION
Mary L. Good, Under Secretary for Technology

NATIONAL INSTITUTE OF STANDARDS
AND TECHNOLOGY
Robert E. Hebner, Acting Director

FOREWORD

The following announcement for the open forum on establishment of the National Council for Laboratory Accreditation (NACLA), to be held at the National Institute of Standards and Technology, was distributed to thousands of potentially interested organizations and individuals. A program agenda was provided to encourage a broad cross-section of representatives to attend and participate in discussions. The issues to be addressed related to changing the U.S. multi-faceted approach to laboratory accreditation and seeking support for a proposal to establish a public-private partnership for implementing a national system for laboratory accreditation with the goals of facilitating domestic commerce and achieving international acceptance of test data generated by laboratories in the United States.

Announcement of the Open Forum
Tuesday, January 7, 1997

National Institute of Standards and Technology

Open Forum on:
Establishment of the National Council for Laboratory Accreditation (NACLA)

An open forum will be held at the National Institute of Standards and Technology on January 7, 1997, to discuss the establishment of the National Council for Laboratory Accreditation (NACLA). NACLA is proposed as a cooperative partnership between the public and private sectors that provides for realization and implementation of a comprehensive U.S. laboratory accreditation infrastructure for national and international recognition and acceptance of accredited laboratory competence. It is envisioned as an organization with active participation by all affected interests: laboratories, accreditors, and those who require accreditation, both from industry and government.

NACLA will specify uniform procedures based on national and international standards and guides for organizations that accredit calibration and testing laboratories. National and international acceptance of their competency will be achieved through NACLA recognition. All parties of interest will benefit from widespread acceptance of the results of tests (performed only once) on a given product. This will eliminate the current duplication, reduce costs, and lead to one-stop shopping.

The meeting will provide a forum for discussion of the NACLA planning documents. It is intended to develop a consensus to establish NACLA as the unifying organization to meet national needs for laboratory accreditation. Presentations will include accreditation issues, background, and future organizational plans. Attendees are invited to discuss all aspects of the plans.

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ABSTRACT

An Open Forum on Establishment of the National Council for Laboratory Accreditation (NACLA) was held at the National Institute of Standards and Technology (NIST), in Gaithersburg, Maryland on January 7, 1997. The forum was jointly sponsored by NIST, ACIL (formerly the American Council of Independent Laboratories), and the American National Standards Institute (ANSI). It was attended by more than 300 representatives from private industry and the government. The purpose of the Forum was to discuss a proposal to establish the National Council for Laboratory Accreditation (NACLA), which would be a cooperative partnership between the public and private sectors designed to provide a national infrastructure for laboratory accreditation in the United States. The agenda for the Forum included a keynote address by Dr. Mary Good, Under Secretary of Commerce for Technology, presentations on the history of the joint NIST/ANSI/ACIL effort to address the problems of laboratory accreditation in the United States and the development of the NACLA proposal, six stakeholder breakout sessions, an open discussion, a presentation of next steps to be taken toward the establishment of NACLA, and a presentation concerning the process for nominating an interim Board of Directors for NACLA.

The six stakeholder breakout sessions included two sessions each for industry and laboratory representatives, and one session each for accrediting bodies and government representatives. Each of the two-hour sessions addressed the following topics:

- How NACLA participation will benefit stakeholders;
- Potential disincentives or disadvantages to NACLA participation;
- Key strengths and weaknesses of the proposed NACLA organizational structure and operating functions;
- Key issues for NACLA to address; and
- The concept and composition of and Interim NACLA Board of Directors.

In the afternoon plenary session, a representative from each breakout session presented a report on the outcome of the group discussions.

The NACLA proposal included provisions for appointing an Interim Board of Directors for NACLA, consisting of four representatives from the laboratory community, four representatives from industry, four government representatives, three accrediting body representatives, and two general interest representatives. The proposal further suggested that the Interim Board be Chaired by a representative from NIST. Participants were encouraged to nominate prospective Board members, in writing, by February 7, 1997. Final selection of the Interim Board was to be made by the Laboratory Accreditation Work Group (LAWG) Steering Committee on February 19, 1997.

AGENDA
Open Forum on Establishment of the
National Council for Laboratory Accreditation

January 7, 1997

National Institute of Standards and Technology
Red Auditorium
Gaithersburg, Maryland

8:00 AM	Registration
8:45 AM	Welcome to NIST - Dr. Robert Hebner, NIST
8:55 AM	Chairman's Opening Remarks, Mr. Sergio Mazza, ANSI
9:00 AM	Keynote Address, Dr. Mary Good, Department of Commerce
9:30 AM	Recapitulation of LAWG History - Mr. Joseph O'Neil, ACIL
9:45 AM	NACLA Summary - Dr. Belinda Collins, NIST
10:15 AM	Procedures for Breakout Sessions - Ms. Jan Jablonski, consultant
10:30 AM	Break
10:45 AM	Breakout Sessions
12:45 PM	Lunch (NIST Cafeteria)
1:45 PM	Reports from Breakout Sessions
2:30 PM	Open Discussion - moderated by Mr. Sergio Mazza
3:15 PM	Next Steps - Mr. Walter Leight, NIST
3:45 PM	Nominating Committee Report - Mr. Joseph O'Neil
4:15 PM	Concluding Remarks - Mr. Sergio Mazza

PLENARY SESSION

OPEN FORUM ON ESTABLISHMENT OF THE NATIONAL COUNCIL FOR LABORATORY ACCREDITATION

January 7, 1997

Plenary Session

An Open Forum on Establishment of the National Council for Laboratory Accreditation (NACLA) was held from 9:00 AM to 4:30 PM in the Red Auditorium at the National Institute for Standards and Technology (NIST), in Gaithersburg, Maryland. The forum was jointly sponsored by NIST, ACIL (formerly the American Council of Independent Laboratories), and the American National Standards Institute (ANSI). It was attended by more than 300 representatives from private industry and the government. **Mr. Sergio Mazza, President of ANSI**, served as Chairman of the forum.

Dr. Robert Hebner, Acting Deputy Director of NIST, welcomed the group to NIST and provided a brief overview of NIST programs. He stated that NIST hoped to achieve three objectives at the forum, which were to understand:

- How the private sector views the current laboratory accreditation system in the United States; how it is working and how it should work in the future;
- What role NIST should play in the U.S. laboratory accreditation system; and
- Who the ultimate customers for laboratory accreditation are and what their needs are.

He noted that NIST believes the forum is a very important step toward improving the system of laboratory accreditation in the United States.

In his opening remarks, Mr. Mazza reminded participants that the effort that led to the proposal for NACLA began over two and one-half years ago when NIST, ACIL and ANSI first met to address the need to coordinate laboratory accreditation in the United States. Mr. Mazza noted that five principal points have predominated in the subsequent discussions:

- International acceptance of test data generated in the United States is an important competitive issue;
- Domestic acceptance of U.S. test data is complicated by a patchwork of multiple accreditation systems;

- There is a general lack of confidence in U.S. accreditation systems in both the public and private sectors;
- There is a lack of widespread use of international standards as common baseline criteria by U.S. laboratory accreditation programs; and
- There is a compelling need to address these problems in a comprehensive and meaningful way.

Mr. Mazza stated that the purpose of the forum would be to focus attention on the concept of a national council for laboratory accreditation as an effective means for addressing these key points. His objective for the day was to find common ground over which all stakeholders can move forward together.

Dr. Mary Good, Under Secretary of Commerce for Technology, provided the Keynote Address. She noted the progress that has been made by the Laboratory Accreditation Working Group (LAWG) under the joint leadership of ANSI, ACIL and NIST. LAWG has made considerable progress in defining the problems associated with the existing laboratory accreditation system in the United States, understanding the needs of the ultimate users of laboratory accreditation, and developing a proposal for taking action to correct existing problems and to make the system more responsive to users.

Dr. Good noted that laboratory accreditation began as an initiative of the laboratory industry. They viewed accreditation as a means for distinguishing among laboratories on the basis of competency, and sought independent third party accreditation to weed out poor performers. In the early 1970's, she noted, the laboratory industry asked NIST to establish a laboratory accreditation program. Since then, NIST has been an accreditor. NIST's role changed when President Clinton signed the Technology Transfer and Advancement Act in March of 1996, giving NIST responsibility for coordinating conformity assessment activities in both the public and private sectors. Dr. Good emphasized NIST's role and stated that, consistent with that role, NIST's purpose in participating in the forum was to facilitate the development of a credible U.S. domestic system for laboratory accreditation that addresses both domestic and international trade issues. She stated the need for a workable system that will be recognized as competent by all those who require accreditation - domestic and international agencies and industry. Dr. Good also noted that in order to work well, the U.S. laboratory accreditation system must allow manufacturers and other users to be confident that test data are generated by qualified laboratories using valid test methods and reliable operating procedures. The system must also allow governments at all levels within the United States to be confident that test data used to demonstrate regulatory compliance or conformance to purchasing specifications are valid and reliable.

In closing, Dr. Good reminded participants that in October 1995, at a previous open forum on laboratory accreditation, a consensus emerged on the following points:

- Use of international standards should be the basis for reciprocity among laboratory accreditation programs in the United States;
- There should be international acceptance of the U.S. system;
- High-quality accreditation and sound laboratory data must be preserved;
- Greater education of users is needed;
- Government programs involving laboratory accreditation need to be coordinated; and
- The common goals and interests of government and industry in this area should be explored.

She noted that the LAWG proposal for the NACLA infrastructure would address all of these objectives and that she expected sufficient ground work to be laid by the end of the forum to move toward establishment of NACLA.

Development of the NACLA Proposal

Mr. Joe O'Neil, President of ACIL, provided a brief historical summary of the activities of the Laboratory Accreditation Working Group (LAWG). He highlighted the following milestones, which led to the development of the proposed NACLA structure:

- May 17, 1994: the first meeting of ANSI, ACIL, and NIST was held to discuss the status of laboratory accreditation in the United States.
- August 22, 1994: the first open meeting of the NIST/ANSI/ACIL public-private partnership on laboratory accreditation was held, attended by approximately 50 representatives from industry, the laboratory community, accrediting bodies, standard-setting organizations, and government.
- Fall of 1994: LAWG Task Groups representing manufacturers, laboratories, accreditors, government organizations, and international concerns gathered interested individuals to discuss laboratory accreditation issues.
- December, 1994: the LAWG Task Group Co-Chairs met to report on the results of their task group discussions.
- January, 1995: the first meeting of the LAWG Steering Committee was held. The Steering Committee included representatives from the government, laboratories, industry, standard-setting organizations, and accrediting bodies.

- February 22, 1995: the National Research Council published its report entitled: *"Standards Conformity Assessment and Trade Into the Twenty-First Century,"* which affirms the need for improvements in the U.S. system for conformity assessment, including laboratory accreditation.

- Summer, 1995: the LAWG Steering Committee and Task Groups developed their vision for the U.S. laboratory accreditation system:

  "A U.S. laboratory accreditation system that includes a cooperative relationship among the public and private sectors and that achieves:

  For the testing laboratory, a single accreditation in a given field of testing with world wide recognition of the laboratory's competence.

  For the user, a test performed once with world wide acceptance."

- October 13, 1995: NIST, ANSI, and ACIL jointly sponsored an open forum on laboratory accreditation.

- March, 1996: the Technology Transfer and Advancement Act was enacted, giving NIST responsibility for coordinating conformity assessment in the United States.

- April, 1996: the LAWG Steering Committee generated its first draft concept paper on NACLA and its operating functions.

- November, 1996: the LAWG Steering Committee finalized its concept paper on the proposed structure and operating functions of NACLA for presentation at the 1997 open forum.

Dr. Belinda Collins, Director of the Office of Standards Services at NIST, presented an overview of the proposed NACLA concept. For purposes of background, Dr. Collins reminded participants of some of the problems with the current U.S. system of laboratory accreditation. For example, she noted that individual laboratories pay an estimated $10 thousand to $50 thousand annually for laboratory accreditations and that there are more than 150 accrediting bodies in the United States, the majority of which do not recognize each others' accreditations. At the Federal, state, and local levels of government, laboratory accreditations are sector-specific, with no formal or other means of extending reciprocity and little or no coordination among programs.

She noted that a national system for laboratory accreditation, such as the NACLA proposal, offers an opportunity to achieve a coordinated, cost-effective system that is built on a consensus approach. Dr. Collins also noted that the proposed structure for NACLA represents a public-private

partnership which will allow for all viewpoints to be heard. She reviewed the guiding principles that formed the basis for NACLA, which include:

- NACLA must be a formally chartered, identifiable private sector body with government participation;
- NACLA must be able to realize the vision of universal acceptability of test results by competent laboratories accredited by NACLA-recognized accreditors;
- NACLA must implement a comprehensive and rigorous domestic system for laboratory accreditation;
- NACLA must use widely recognized international standards and guides as the basis for its standards and procedures; and
- NACLA must implement a system for recognizing competent accreditors based on rigorous, uniformly applied standards.

Dr. Collins stated that agreement among all stakeholders will be the key to NACLA's success. To accomplish this goal, NACLA will have to allow for diversity in laboratory accreditation programs while implementing a system that reduces the overlap and duplication in the current system.

Dr. Collins stated that NACLA should include members from both the private and public sectors. Membership should be voluntary and open to anyone who subscribes to the NACLA vision, principles, and protocols. The LAWG proposal calls for establishment of a Board of Directors with governing and policy making responsibilities. NACLA's operating functions would focus initially on development of standards for assessing accrediting bodies. In the future, NACLA would serve as the U.S. focal point for laboratory accreditation and would develop and represent U.S. positions on laboratory accreditation within the international community.

Stakeholder Breakout Sessions

Six stakeholder breakout sessions were organized, each facilitated by a member of the LAWG Steering Committee, as follows:

- Group 1 - Industry Representatives, led by Mr. Lou Dixon of the Ford Motor Company;
- Group 2 - Accrediting Body Representatives, led by Mr. Peter Unger of the American Association for Laboratory Accreditation (A2LA);

- Group 3 - Government Representatives, led by Mr. Richard Baldwin of the U.S. Food and Drug Administration;
- Group 4 - Laboratory Representatives, led by Ms. Lynne Neumann of Entela, Inc.;
- Group 5 - Industry Representatives, led by Ms. Kim Phillipi, of Entela, Inc.; and
- Group 6 - Laboratory Representatives, led by Mr. David Krashes of the MMR Group, Inc.

Each of the two-hour breakout sessions addressed the following topics:

- How NACLA participation will benefit the stakeholders.
- Potential disincentives or disadvantages to NACLA participation.
- Key strengths and weaknesses of the proposed NACLA organizational structure and operating functions.
- Key issues for NACLA to address.
- The concept and composition of an Interim NACLA Board of Directors.

In the plenary session which followed the breakout sessions, a representative from each group presented a report on the outcomes of group discussions.

STAKEHOLDER BREAKOUT SESSION REPORTS

OPEN FORUM ON ESTABLISHMENT OF THE NATIONAL COUNCIL FOR LABORATORY ACCREDITATION

January 7, 1997

Stakeholder Breakout Session Reports

Group 1 - Industry Representatives

Report presented by: Mr. Lou Dixon, Ford Motor Company

1. Stakeholder Benefits

   - Reduce costs from laboratories to manufacturers and customers
   - Reduce number of audits
   - Lower administrative costs
   - Faster time to market
   - Facilitate Mutual Recognition Agreements (MRAs)
   - Level U.S. and international playing field
   - Mutual recognition of test results among participants

2. Disincentives/Disadvantages

   - Fewer accrediting bodies
   - "Downsize" state/local accrediting agencies
   - Additional fees (will industry get what they pay for?)
   - Voluntary vs. mandatory program

3. Strengths/Weaknesses

   Strengths:

   - Government authority if full participation
   - Uniform evaluating system for accreditors
   - Industry participation
   - Diversity of participants
   - Board of Directors to include international perspective

   Weaknesses:

   - Overlap between NACLA and NELAC
   - Larger groups make consensus more difficult
   - Unspecified size of committees

4. Key Issues

- Power of enforcement
- Lowest common denominator or impossible high standards for accreditation (need to develop workable standards)
- Regulatory authorities must participate
- Participate in the review and revision of OMB Circular A-119
- Transparent and open participation
- Anti-trust (accreditors)
- Mutual acceptability internationally
- Accelerate process to facilitate commerce
- Exclusion of non-U.S. entities
- Consider existing models

Group 2 - Accrediting Body Representatives

Report presented by: Mr. Peter Unger, A2LA
Mr. Fred Grunder, American Industrial Hygiene Association (AIHA)
Mr. C. E. Ramani, ICBO Evaluation Services

Benefits:

- International recognition
- Standardization
- Improved quality of accreditation systems
- Proficiency testing improvements
- Credibility
- One umbrella
- Reciprocity
- Consistency
- Self-regulation
- Technical competence of laboratories
- Greater value to laboratory customers
- Minimize proliferation
- Simplified mechanism

Disadvantages:

- Surrender of autonomy
- Some may go out of business
- Costs (laboratories/accreditors)
- Additional requirements to meet
- Dilution of quality

- Liability
- Time
- Forced change

Strengths:

- Flexibility
- Uniformity
- Broad-based support
- Voluntary
- Increased credibility
- Public participation
- Breadth and generality
- NIST umbrella
- Increased authority

Weaknesses:

- Flexibility
- Bureaucracy
- Implementation
- Lack of authority (Federal mandate)
- Cost
- Lack of participation by Federal agencies
- Response time
- Lack of permanent staff
- Small organization participation
- Lack of stakeholder checks and balances

Key Issues:

- Implementation/obstacles
- Acceptability of program
- Recognition
- Process vs. diversity
- Horizontal vs. vertical
- Anti-trust
- Authority/legislation
- Standardization issues
- Training and education
- Cost
- Liability

Composition of Board:

Three groups with equal representation:

- Accreditors
- Laboratories
- Users

Government and non-government representatives for all three groups

Operations Committee:

- Composition
- Process (most important)
- Several models exist (e.g., EAL/APLAC, CLIA, NVCASE)

Group 3 - Government Representatives

Report presented by: Mr. Richard Baldwin, U.S. Food and Drug Administration

1. Statement of support for NACLA.

   - Lukewarm, mixed (because it is a lofty goal, much detail yet to be developed)
   - Support in principle -- but need more specific detail on process
   - Have not yet outlined a mechanism to assure acceptance of each others' processes and accreditations
   - Need many more meetings (confidence building, exchange of documents, and commitment that this is worth doing)
   - Weaknesses need to be addressed in detail
   - The international arena is going to force U.S. action on the issue (an EAL/NACLA agreement would have tremendous force)
   - Congress at this point is asking us nicely to do this (it could become more forceful if there is not internal U.S. cooperation to act)
   - Need a strategy to get "head of agency" support (e.g., Mary Good to convene such a group, then get top-level agency support and buy-in)
   - "Conditional love" at this point -- agencies must get more details and then determine their intent for participation

2. What are the advantages / disadvantages to NACLA participation?

   Advantages:

   - Consumer baseline for accreditation procedures

- Standardization, reciprocity
- Fewer regulatory interactions
- Less financial resource utilization
- Promotes commerce and decreases cost of commerce
- Increase quality of testing and calibration data
- Less governmental intrusion (privatization)
- Get rid of poor labs through increased competition/quality
- Increase public safety
- Simplify requirements, decrease duplication, leading to better compliance
- Better compatibility between products
- Decrease non-tariff trade barriers, foster commerce
- Give a stronger voice internationally in standards development (i.e., better coordination of U.S. input)
- Bringing together diverse interests in a powerful way (i.e., greater voice)
- Increase U.S. government input into international standards
- Decrease duplicity
- Facilitates the introduction of new technology (i.e., increase ease of new technology approval) - also technology transfer
- Give U.S. trade negotiators a bargaining chip
- Generally facilitates internal interactions on all fronts - trade, negotiations (both dialog and interactions)

Disadvantages:

- Conflict with statutory and regulatory requirements of regulatory agencies (statutory requirements and regulations may be in conflict with NACLA standards, leading to potential diminished authority of regulatory agencies and delegation of authority to non-regulatory entities -- e.g., delegated test methods)
- Single accreditation may be too simplistic (there are multiple test methods for different attributes, also multiple audits are conducted for a broad range of sectors within single lab facilities)
- NACLA will need to hold accreditors to the same technical standards for very different types of laboratories
- International standards as bases may lead to variability of interpretations
- Potential NACLA liability for faulty test data
- NACLA will potentially be in the middle of conflicts over jurisdiction
- Need for specific accreditation and test standards (NACLA needs to specify tests and methods, also accreditation for specific test methods)
- Could be another level of bureaucracy
- Voluntary or mandatory -- potential problems either way
- May force U.S. regulators to accept reciprocity before we are ready (i.e., before everyone plays fairly or before there is a level playing field)

3. Proposed NACLA organizational structure and operational functions:

Strengths

- Allows participation at all levels (including internationally)
- Promotes uniformity of standards
- Makes an attempt to achieve cooperation among stakeholders

Weaknesses

- Accountability/coordination role outlined in law is ambiguous
- Limited to accreditation against international standards vs. national standards
- U.S. standards are law, have implications for manufacturer liability
- What are the international standards and who recognizes them?
- Need procedure for arriving at consensus
- Political change may move more rapidly than the bureaucracy of NACLA (ability to provide continuity to keep pace with rapid political change)
- Proposed structure does not provide a mechanism for achieving consensus among diverse perspectives (stakeholders) on issues of common interest

4. Recommendations:

- Get the interest groups together to communicate ideas and concerns to each other
- Need to build trust among the stakeholders
- Recognize that internationally, we are behind the power curve (the international arena is forcing U.S. action on this issue)
- Need to better understand the international support for NACLA

5. The concept and composition of the NACLA Interim Board:

- Look at the existing 150 accrediting bodies ⇒ see what sectors are represented
- Needs to be a combination of stakeholders and sectors
- Maintain a link between standards developers and accreditors
- Size ⇒ 15 to 18 members (3-5 being federal/state government representatives)
- Chair should be NIST (high-level management)
- Self-nomination process open to all stakeholders
- Members should be familiar with ISO Guides 58 and 25, and should thoroughly understand (360° / top to bottom) the accreditation process
- LAWG selects the Interim Board, but NACLA membership should select permanent board members
- Look for consensus and ownership on the board
- Membership on the board is a WORKING commitment (lots to do quickly)

6. Key issues that need to be addressed by NACLA:

- NACLA needs to established good liaison with existing groups
- Need to flush out issues of jurisdiction and authority
- How to determine frequency and length of accreditation.
- Accreditation scheme needs to accommodate diversity. (i.e., the process needs to accommodate the variety of activities that take place within a single laboratory)
- NACLA needs to be cognizant of the existing diversity among and within laboratories, and coordination needs to be situational to individual issues
- Practical application of international guidelines and standards (the outcome must lead to credible results and high quality products)
- Money speaks (perceived loss of fees from accreditation/licensing activities)
- How to actually achieve U.S. government reciprocity
- What to do if international standards are lower than U.S. standards
- Need confidence-building within the U.S. regarding laboratory accreditation (i.e., what do we mean by accreditation, and what do we expect? -- the requirements in ISO Guide 25 are very basic)
- Legal aspects of voluntary versus mandatory participation (can the government hold contractors to this process if it is a voluntary system?)
- Issue of a national mark (like a CE mark) -- will NACLA have one?
- How will NACLA be funded (i.e., the nature of funding)? -- membership fee, etc.? (NIST is willing to provide a secretariat on an interim basis, but ultimately NACLA needs to be self-sustaining, and costs/fees need to remain low)
- NACLA needs to develop "recognition criteria" (similar to ISO Guide 58) to recognize accreditors
- What are the incentives and mechanisms to realize NACLA's objectives (need more detail on process)?
- How is NACLA going to bring stakeholders together, regardless of who they are?
- How does NACLA assure the technical expertise of their technical auditors?
- Need to develop similarity of requirements for sector groups
- NACLA needs to explain the details, and facilitate further discussion among those with common interests
- How to handle privileged information of independent and industry laboratories (confidentiality issues)
- How will NACLA handle dishonesty, fraud, etc. (enforcement issues)?
- What is an accrediting body?

Group 4 - Laboratory Representatives

Report presented by: Ms. Lynne Neumann, Entela, Inc.

1. Benefits to Laboratories

- Eliminate multiple accreditation
- International and national recognition
- Meaningful accreditation status
- Reduce artificial trade barriers
- Increase productivity

2. Potential Disadvantages

- Additional levels of cost and bureaucracy
- Coordinating groups
- Timeliness of goals (how quickly can this be achieved?)
- Forced to accept standards which do not meet our minimum quality level
- Funding
- "Flavor of the Month" managements

3. Key Strengths and Weaknesses

- Volunteer participation
- Conflicts of interest
- Key contact for recognition of U.S. system
- What are the incentives for accreditation bodies to become participants?
- How are QC, product certification, and data validation to be addressed?

4. General Concerns

- Develop trust and confidence between accreditors
- Marketability of accreditation
- Value to laboratories
- Expand the number of accreditation bodies (increased competition)
- Structure to gain authority
- NACLA assessor validation
- International and domestic acceptance
- NACLA should not be an accreditor of laboratories
- Address reciprocity

Group 5 - Industry Representatives

Report presented by: Mr. Gerald Ritterbusch, Caterpillar, Inc.

1. Benefits to Industry

- High quality data that are comparable
- Common standards, guidelines, and procedures for audits

- NACLA will be a forum for discussion
- Want test data to be accepted by other bodies (domestic and international)
- Improve government confidence in laboratories and laboratory data
- NACLA will provide guidance for and demand consistency in audits

2. Disincentives/Disadvantages

- Laboratories may experience changes in market share - they must recognize that their market can be increased by wider acceptance of test data
- Additional level of accreditation without it being mandated. Is there an incentive to participate?
- Agreement on the definition of "good"
- NACLA lacks enough detail for understanding all of the issues. Could it create a wider disparity between laboratories?

3. Strengths/Weaknesses

Strengths

- Compactness - Board and 2 committees
- Stakeholders have opportunity to participate in shaping the outcome
- Single operations committee to produce common interpretations

Weaknesses

- No link to international accreditations
- No defined link to NVCASE
- Not all encompassing in conformity assessment (product certification)
- Need milestones for further steps in the total conformity assessment world (standards and listing agencies)
- Need to know what it will look like when mature

4. Key Issues to Be Addressed

- Stakeholders must fully participate
- Need to market those who will realize benefits
- Government agency participation
- How does NACLA make sure that their program produces reciprocity with accreditors and laboratories?
- Expedite operation to ensure no new intervention by Congress or government agencies
- Must ensure that data from laboratories are comparable
- Adequate funding for viability

5. NACLA Board of Directors Issues

- International liaison
- Use existing models/systems for harmonization
- Government agency participation: (EPA, FDA, FA, OSHA, FCC, HUD, DOE, CDC)

Group 6 - Laboratory Representatives

Report presented by: Mr. David Krashes, MMR Group, Inc.

1. Benefits to Laboratories

- Avoid multiple audits
- Accreditation will be respected worldwide
- Accreditation based on one standard
- Save money

2. Potential Disincentives or Disadvantages

- Don't want a bureaucracy
- Solving international problems before domestic problems

3. Strengths and Weaknesses

Strengths

- Will be good for laboratories (almost unanimous)
- Everybody pulls together

Weaknesses

- Environmental laboratories are split off
- NIST has NVLAP
- If government agency (Federal or state) doesn't have to comply, it won't
- No time line established for NACLA to start approvals
- No "hammer" to force compliance with NACLA

4. Key Issues for NACLA to Address

- Lack of a government directive or law to mandate implementation
- Industry acceptance of NACLA
- Getting accrediting bodies to agree on one standard
- Obtaining effective and meaningful input from the laboratory community

- Establishing reasonable costs
- Timely implementation
- 2/3 believe the problem is domestic; 1/3 believe the problem is international
- Will laboratories have access to NACLA's ratings of accreditors?
- NACLA must do the job well enough to ensure that all accreditors are credible

5. Other Recommendations

- Moderate annual dues are acceptable
- There must be a way to achieve reciprocity (both by accreditors and laboratory users)

OPEN DISCUSSION AND NEXT STEPS

OPEN FORUM ON ESTABLISHMENT OF THE NATIONAL COUNCIL FOR LABORATORY ACCREDITATION

January 7, 1997
Open Discussion and Next Steps

Open Discussion

Following the presentation of reports from the stakeholder breakout sessions, Mr. Mazza invited participants to ask questions or make comments on the issues presented. Questions were addressed by a panel consisting of Mr. Mazza, Dr. Collins and the group leaders. A summary of the questions, comments and responses follows.

Comment: Mr. Howard Forman, an attorney who specializes in alternative dispute resolution, encouraged the NACLA Interim Board to consider using alternative dispute resolution techniques to resolve conflicts as they arise in the process of establishing NACLA.

Question: Mr. Leonard Frier, of Met Laboratories, Inc., asked whether NACLA would be an accreditor of accrediting bodies or a coordinator of accrediting bodies.

Mr. Mazza responded that NACLA is not intended to be "super accreditor." Instead, NACLA would employ a peer review process which will allow accrediting bodies in the United States to recognize each others' work.

Comment: Mr. Ross Hansen, Quality Assurance Manager for Retlif Laboratories, stated that laboratory representatives have contended strongly that the laboratory community does not welcome an additional layer of accreditation bureaucracy. He further suggested that NACLA implementation go forward with a sunset clause that would call for the activity to stop if some or all of its goals are not accomplished in 18 to 24 months. Mr. Hansen also stated that he believes NACLA should focus on addressing domestic issues related to laboratory accreditation as its first priority.

In response, Mr. Mazza noted that government representatives agreed in their breakout session that issues of international recognition are likely to be an important factor motivating participation in NACLA by regulatory agencies.

Comment: Ms. Joanne Wilson of Lucent Technologies, stated that the proposed operating function for NACLA will make it an accreditor of accrediting bodies.

Mr. Unger stated in response that NACLA, like numerous similar European organizations, will have both a coordinating (horizontal) and an oversight (vertical) function to fulfill. Mr. Mazza noted that this has been an important issue for the LAWG Steering Committee for some time. He further stated that, in order to achieve international recognition, NACLA will have to recognize accreditor competency.

Question: Mr. Joseph Cotruvo, of NSF International, asked the panel what incentives they see for accrediting bodies to reach consensus on an accreditation standard and process.

In response, Mr. Unger stated that accrediting bodies maintain an interest in NACLA in order to respond to the concerns of their clients: laboratories interested in reducing redundance and overlap in accreditation. Mr. Mazza agreed that much of the motivation for LAWG came out of a recognition by accreditors that they needed to respond to the demands of their market place. Mr. Dixon noted that industry representatives also have expressed a strong desire for a reliable accreditation system on which manufacturers can rely, instead of qualifying laboratories themselves.

Comment: Mr. John Locke, former President of A2LA, described the process by which the EAL grants accreditations, using a group of peer reviewers to assess accreditors and make a recommendation to the governing body of EAL.

Comment: Ms. Deborah Rade of Underwriters Laboratories, stated that she does not believe that a significant case has been made for establishing NACLA, and that further work should be done to demonstrate its potential benefit to the American public and to public safety, before proceeding with implementation.

Mr. Krashes noted that, within his breakout group, there was virtually unanimous agreement that NACLA would be beneficial.

Ms. Rade further stated that it has not been demonstrated that NACLA is the appropriate organization to address the problems that have been identified. She suggested that a better approach would be to allow Congress to provide a statutory mandate for NACLA, or a similar organization, through Federal legislation. In response, Mr. Mazza noted that Congress has already provided a gentle prod in the form of the Technology Transfer and Advancement Act of 1996, which requires NIST to coordinate conformity assessment in the United States. He further stated that, consistent with that statutory mandate, NACLA is intended to be a forum that brings together all stakeholders for purposes of agreeing on reasonable solutions to the problems we have identified.

Comment: Mr. George Marinenko of Waste Policy Institute noted, in response to Ms. Rade, that unanimous agreement is not necessary to establish the consensus opinion that NACLA should proceed. Rather, he stated, a majority is sufficient to indicate consensus.

Mr. Krashes stated that he was willing to stand and be counted as being in favor of NACLA and stated that others in the room were welcome to stand with him (whereupon a large majority of meeting participants stood and applauded to show their agreement that NACLA should proceed).

Question: Mr. Thomas Wiand of Hart Scientific, noted that calibration laboratories have a unique set of concerns related to laboratory accreditation, which differ from those of the testing laboratory

community. He asked the panel whether they would agree to establish a separate delegation or group to represent calibration laboratories.

In response, both Dr. Collins and Ms. Neumann agreed that the perspectives of the calibration laboratory community are both unique and important to NACLA and that input from a calibration laboratory delegation would be welcome.

Comment: Mr. Troy Stallard, President of Standards Laboratories, Inc. and Chairman of ACIL, stated that ACIL believes that the only real alternative that we have today is for a single accreditation system such as NACLA. He further stated that ACIL endorses NACLA and would like to see it go forward.

Comment: Mr. Ed Nemeroff, Vice President of the National Conference of Standards Laboratories, stated that he and NCSL President, Mr. Kevin Ruhl, would request that the NCSL Board of Directors appoint a delegation from its membership to be an active part of NACLA.

Next Steps

Mr. Walter Leight, Deputy Director of the Office of Standards Services at NIST, provided a brief summary of the next steps to be taken by the LAWG Steering Committee, as follows:

- A report on the proceedings of the open forum will be prepared and distributed.
- Nominations for the NACLA Interim Board of Directors will be accepted until February 7, 1997.
- The nominating committee (established by the LAWG Steering Committee) will review the nominations and present a slate of nominees to the LAWG Steering Committee at its next meeting on February 19, 1997.
- At that meeting, the LAWG Steering Committee will elect the NACLA Interim Board and appoint a Chair for the Board.
- At the close of its meeting on February 19, the LAWG Steering Committee will cease its functions.
- The Chair of the NACLA Interim Board of Directors will convene the first meeting of the Board with staff support offered by NIST.
- The Interim Board will meet to appoint committees, devise procedures and prepare for permanent establishment of NACLA.

- At the conclusion of its work, the Interim Board will present its recommendations to the potential membership of NACLA at another open forum.

Mr. Leight stated that nominations for the Interim Board should be forwarded to Mr. Joe O'Neil of ACIL.

Nominating Committee Report

Mr. O'Neil gave a brief overview of the process for establishing the NACLA Interim Board of Directors. He stated that the slate of nominees will be developed and presented by the Nominating Committee established by the LAWG Steering Committee in the Fall of 1996. Members of the Committee include Mr. O'Neil, Mr. Leight, and Mr. John Locke. Mr. O'Neil noted that their assignment was to nominate a group of people qualified to address all of the issues discussed at this and the previous forum. He further stated that, at the conclusion of its work, the Interim Board will present its proposed by-laws, procedures, practices, and committee structure for NACLA.

Mr. O'Neil stated that, at its meeting in December of 1996, the LAWG Steering Committee agreed to appoint an Interim Board of 18 members with:

- Four laboratory representatives;
- Four industry representatives;
- Four government representatives;
- Three representatives from accrediting bodies; and
- Two general interest representatives.

The Steering Committee also agreed that the Chair of the Interim Board should be Dr. Belinda Collins, Director of NIST's Office of Standards Services. He noted that Dr. Collins' appointment as Chair signifies the Steering Committee's belief that it is important to have the visible leadership of NIST continue in this effort.

Mr. O'Neil reiterated that nominations for the Interim Board will close on February 7, 1997 and that all nominations should be mailed or faxed to him at ACIL. He asked that people who are nominated be qualified to address the issues before the Board and that they be willing to commit to participating in three to four meetings during the coming year and to do some work on NACLA issues between meetings. He noted that NIST provided forms for nominations which show his address and fax number and encouraged participants to make nominations as soon as possible.

At the completion of Mr. O'Neil's presentation, Mr. Mazza thanked the participants for their efforts and declared the open forum adjourned.

APPENDIX A

Proposed Structure for the National Council for Laboratory Accreditation

"PROPOSED STRUCTURE FOR THE NATIONAL COUNCIL FOR LABORATORY ACCREDITATION" (NACLA)

The National Council for Laboratory Accreditation (NACLA) is made up of those in the United States who actively support development of a system for recognizing the competence of testing and calibration laboratories, and worldwide acceptance of their test and calibration reports.

Background

Since 1994, ACIL (formerly the American Council of Independent Laboratories), the American National Standards Institute (ANSI), and the National Institute of Standards and Technology (NIST) have sponsored an informal Laboratory Accreditation Working Group (LAWG) to examine issues related to laboratory accreditation and recognition in the United States, and to suggest solutions aimed at developing a system for the United States. Concerned with multiple, duplicate assessments and the lack of domestic or international recognition of accreditations, the group explored solutions which could lead the United States toward the goal of one assessment per laboratory in a given field of testing (testing includes calibration for the purposes of this notice), using internationally accepted procedures that can be accepted by all who require (or need) laboratory accreditation. Development of a credible domestic system for laboratory accreditation must be compatible with international systems so that international recognition of the U.S. efforts is achievable. LAWG solicited input and participation from all players in the process: laboratories, accreditors, industry, and government (Federal, state and local), as well as input from those concerned with international trade issues. The working group agreed on a vision and principles for a system, and identified the needs and desires of the key players, as follows:

- Manufacturers and other users must be confident that the test data from suppliers are generated by qualified laboratories that perform the testing according to valid test methods and which follow appropriate operating procedures.

- Governments at all levels within the United States must be confident that laboratory test data used to demonstrate compliance with regulations or procurement actions are generated by qualified test laboratories using valid methods and procedures.

- Laboratories need a single, consistently-applied mechanism for demonstrating their competence in generating test data and for evaluating their quality assurance procedures, with no duplication of valid assessments.

- Governments, industry and other users of laboratory test data in the United States need a mechanism for ensuring their confidence in the laboratory test data supplied to demonstrate compliance with their procurement actions, regulations, or standards.

- Foreign governments also need a means for obtaining recognition of the competence of U.S. laboratory data. The global market requires that laboratory accreditation procedures used on all sides of a trading relationship be similar, transparent, readily available, and based on international performance guides for their performance. Additional procedures may be needed to ensure recognition of the competence of an accreditation done by a particular body.

- Government, industry and other users require a mechanism for recognizing the competence of different laboratory accreditation bodies, while competent accreditation bodies require a level playing field where their accreditations are reciprocally accepted across political boundaries.

On October 13, 1995, an open Forum (see, Proceedings of the Open Forum on Laboratory Accreditation, October 13, 1995, NIST Special Publication 902, 1996) was held to discuss these issues and provide suggestions for solving the problems. During the Forum, consensus emerged on a vision to reduce the problems with the current "system." There was agreement that: international standards should serve as a basis for accreditation and recognition; reciprocity of competent accreditations in the United States is needed; there should be international acceptance of an effective U.S. system; high-quality accreditation and sound laboratory data must be preserved; greater education of users is needed; regulators at all levels (Federal, state, and local) must coordinate among themselves; and that common interest and goals between government and industry must be explored.

Making the Vision a Reality

During the Forum, there was consensus that a single public/private entity to coordinate laboratory accreditation activities within the United States is a reasonable solution. It would allow the needs of the various interest groups to be met, while allowing for competition among accreditors, governmental recognition, and international acceptance. This entity would develop common agreement on procedures for both accreditation and reciprocity of accreditation by all parties. The consensus approach used by standards developers in the country would provide for participation of interested and affected parties in the development of these procedures, and is a central element for the proposed system.

The proposed public/private entity, provisionally entitled the National Council for Laboratory Accreditation (NACLA), is envisioned as a formal arrangement among affected parties who agree on operational procedures. To be effective, NACLA must:

1. Agree on and adopt procedures for "recognizing" or "accepting" the competence of these accreditations, again using international guides.
    a. Agree on and adopt procedures for accreditation of testing and calibration laboratories, using the international guides as a starting point.
    b. Ensure procedures for withdrawing an accreditation or recognition.
2. Provide means for meeting specific Federal regulatory needs, while providing for regulatory recognition of those who meet these needs in their accreditation process.
3. Agree on and adopt procedures for internal operations.
4. Develop formally constituted basis for NACLA establishment and conduct for assuring that NACLA recognition follows appropriate procedures.
5. Work toward an infrastructure in which accreditors recognized as competent by NACLA can be considered for acceptance for both domestic and international requirements. NACLA will:
    a. Address domestic issues and work to build a system which meets domestic needs and which is compatible with international systems.
    b. Coordinate the U.S. positions for regional and international activities such as the

International Laboratory Accreditation Cooperation (ILAC), the Asia Pacific Laboratory Accreditation Cooperation (APLAC), and the European Cooperation for Accreditation of Laboratories (EAL), etc.,

c. Serve as the primary U.S. signatory on behalf of NACLA members for new international laboratory accreditation agreements with foreign national, regional and coordination bodies.

d. Work toward a truly North-American system for laboratory accreditation.

6. Provide means for financial support.

NACLA should be a legally chartered public/private entity that will: agree on criteria and procedures used for accreditation and recognition of accreditation (following international guidelines) in the United States, review uniform implementation of procedures and provide a mechanism for appeal of decisions, provide for governmental (or appropriate industry) recognition of accreditation, and provide U.S. representation to international fora; and provide recognition of U.S. accreditations for foreign governments. Accreditation is performed by accrediting bodies (private and public sector); "official" recognition is provided by governmental bodies. When a number of accrediting bodies are recognized as competent, a user will be able to select among them. Reciprocity among accreditors will be based on a common recognition by NACLA authorities, which can include peer assessment of accreditors if acceptable by the authority requiring accreditation (private sector or regulatory agency). Peer evaluation may take the form of mixed private sector/public sector teams.

NACLA Structure

Vision

The NACLA vision is one of a U.S. laboratory accreditation system that includes a cooperative relationship among the public and private sectors and achieves the following:

For the testing laboratory, a single accreditation in a given field of testing, with worldwide recognition of the laboratory's competence.

For the user, a test performed once, with worldwide acceptance.

Accreditation based on uniform criteria is intended to ensure that a laboratory is qualified to provide data of consistent quality.

Guiding Principles (these principles were developed for presentation at the Forum, but have been modified slightly to serve as principles for the NACLA structure).

- Realize the Vision: universal acceptability of the results of any valid test or calibration performed by a competent laboratory accredited by a NACLA recognized accreditor.

- Eliminate duplication and inefficiency in the current laboratory accreditation process and enhance U.S. competitiveness in domestic and global markets.

- Develop a comprehensive and rigorous domestic system, using appropriate domestic and international guides and standards, for recognizing competent laboratories, both governmental and private sector, to promote acceptance of their results by domestic and foreign regulators and product purchasers.

- Exercise appropriate government oversight at Federal, state, and local levels to ensure satisfaction of regulatory requirements (does NOT imply setting of regulatory requirements).

- Achieve recognition by the U.S. government when such recognition is necessary for a laboratory's accreditation to be accepted by foreign governments.

- Allow for participation by all parties to laboratory accreditation, including consumers, laboratory customers, testing laboratories, accrediting bodies, and organizations (both public and private sector) that require accreditation in the United States.

- Apply appropriate domestic and international guides and standards for accreditation and recognition, and adapt them to meet the special requirements of Federal and state regulatory bodies or particular user's needs (some agencies may need to specify sector requirements for specific regulatory requirements and purposes).

- Ensure that all laboratories (i.e., manufacturer's, third-party independent, and government) are equally eligible to apply for accreditation, and that equivalently rigorous procedures are used to accredit each laboratory in a given field (some regulatory agencies may limit acceptance of accreditation for mandated programs to third-party or independent laboratories).

- Ensure formulation of and adherence to appropriate ethical principles and standards of conduct in all NACLA operations.

Mission

To develop and administer common accreditation procedures that can be accepted by all NACLA parties to provide coordination and focus for laboratory accreditation programs in the U.S. and to serve national and international needs in laboratory accreditation.

Objective

To bring together the various parties who require accreditation, who perform accreditation, and who are accredited, to develop and administer common accreditation procedures that can be reciprocally accepted (regardless of accreditor) by different authorities requiring accreditation. The active participation by government agencies will allow them to ensure that regulatory needs are met without multiple or duplicate accreditations of laboratories, while the active participation by both accreditors and laboratories will allow their input into the development and implementation of technically sound, realistic procedures for accreditation.

Composition

NACLA is a partnership of public and private organizations with an interest in laboratory accreditation: they include government agencies (Federal, state and local), industrial firms and associations, standards organizations, accreditors, laboratories and laboratory associations, and other interested parties.

Authority and Responsibility

NACLA is empowered on behalf of its participating organizations to act in their behalf, and is to be, both nationally and internationally, the U.S. entity to coordinate laboratory accreditation activities, and develop and represent U.S. positions for regional and international organizations dealing with laboratory accreditation with authority in the area of laboratory accreditation. It is hoped that government agencies will participate in and rely on NACLA recommendations in carrying out their regulatory and other governmental responsibilities.

Organizational Structure

Membership - Membership is open to all interested parties who subscribe to the NACLA vision, principles and protocols through a formal application process. Upon application, an organization will state its stakeholder interest.

Board of Directors - The Board is the policy making and governing body of NACLA. It includes a balanced representation from laboratories, assessors, users and other Stakeholder Committees. Representatives may be either public or private sector. ANSI serves, ex officio, as a member of the Board. Board members are elected by their respective group and serve for staggered 3-year terms. The Board maintains liaison with other national and international accreditation and recognition bodies. The Board also serves as the NACLA appeals body.

Operations Committee - The Operations Committee, the technical arm of NACLA, is responsible for granting recognition to accreditors, dealing with standards and assessment issues, operational procedures and other technical matters. It too has broad representation from a balance of affected interests. It is appointed for a fixed term by the Board based on nominations of the Stakeholder Committees.

Stakeholder Committees - Each substantial interest, or stakeholder, will have its own Committee, where its perspectives and specific issues can be discussed and resolved. The Committees will nominate Board representatives and representatives to the Operations Committee. Each new committee must be approved by the Board. Committees envisioned include ("Government" includes all Federal, state and local levels):

> Government Regulators, Non-regulatory Officials, Accreditors, Manufacturers and Industries, Trade Associations, Independent and Allied Laboratories, Code Authorities, Professional and Standards Bodies, Council of Consumers and Other Interested Parties.

Any entity that performs more than one function may be represented in more than one committee. Committees are responsible for surfacing issues related to their own constituencies and proposing solutions for decision by the Board.

Secretariat - The Secretariat is responsible for implementing Board Decisions and coordinating Operations Committee activities. The Board will decide at an appropriate time as to who will provide the Secretariat.

NACLA Operational Functions

Accreditation Standards - Relevant national and international standards, such as ISO/IEC Guide 58 for Accreditors, ISO/IEC Guide 43 for Proficiency Testing, and ISO/IEC Guide 25 for Laboratories, should form the basis for procedures used by NACLA participants. In consultation with the Stakeholder Committees, additional procedures must be approved by the Board of Directors.

Assessment of Accreditors - The Operations Committee will coordinate the audits and reviews of accrediting bodies (accreditors). It will develop detailed operating procedures in consultation with the Committee of Accreditors for approval by the Board. (NOTE: One possible assessment model that might be considered is a peer review process, such as that used in EAL and in APLAC. If used in NACLA, the review team for assessment of a private-sector accrediting body might have a majority of private sector accreditors; a review team for a government accreditor would have a majority of accreditors from the government sector. Another possible model is for recognition using appropriate ISO/IEC guides by the authority having jurisdiction, again using appropriate NACLA procedures).

Recognition of Accreditors - Decisions of the Operations Committee will be final, but may be appealed to the Board for final decision.

Listing of Recognized Accreditors and Laboratories - The NACLA Secretariat will maintain a listing of recognized accreditors and access to their lists of accredited laboratories.

Appeals Process - A full-scale appeals procedure will be developed by the Operations Committee and submitted for approval by the Board. If an accreditor applies for recognition by NACLA, but is denied that recognition, it has the right of appeal to the Board of Directors.

NACLA Interface with Regulators and Other Government Bodies - NACLA will actively work to achieve the goal of Federal agency acceptance of NACLA procedures and functions. As applicable, participating Federal agencies are encouraged to work toward harmonization of their accrediting and recognition requirements and practices with those of other public and private sector entities to the extent that the uniqueness of their underlying regulatory and public health laws allow. While special procedures may be needed and developed for a particular sector, these should be applied consistently throughout that sector. NIST will work with the Office of Management and Budget on guidance for Federal agency participation in NACLA to meet its responsibilities under the National Technology Transfer and Advancement Act of 1995 (PL 104-113) to minimize duplication and overlap in conformity assessment activities in the United States.

NACLA Membership Obligations - All NACLA Members shall sign an agreement of mutual commitment to abide by NACLA procedures.

NACLA Interface with the International Community - NACLA will coordinate and advocate U.S. positions that are advanced in international accreditation organizations such as ILAC and APLAC.

LAWG Background on NACLA

The sponsors, along with other representatives and users of laboratory accreditation, undertook preliminary planning of NACLA based upon evaluation of key issues concerning laboratory accreditation. The LAWG Steering Group drafted the "Proposed Structure for the National Council for Laboratory Accreditation," which provides for establishing and implementing NACLA. It provides for uniform procedures for adoption and recognition of laboratory competency in testing and calibration. The planned national laboratory infrastructure includes concepts for organizational structure and operational functions that will provide for national and international recognition. The plan addresses the widely recognized need that unnecessary burdens of laboratory accreditation must be eliminated by a streamlined system that removes current duplication and unnecessary costs in laboratory accreditation.

A public forum was held in October 1995 and reported in NIST Special Publication 902, "Proceedings of the Open Forum on Laboratory Accreditation at the National Institute of Standards and Technology, October 13, 1995." Recognition of the need for a unified national system was found to be essential to satisfy domestic economic requirements and to facilitate trade. It was agreed that any infrastructure, to be successful, must be acceptable to all affected parties with recognition for the results accepted nationally, and even globally.

The establishment of NACLA requires that organizational descriptions are complete and appropriate to the intended purposes and functions, operational procedures and processes. Expansion of details are necessary as well as further refinement of composition of the Board of Directors, Stakeholder(s) Committees and their scope, Secretariat, membership, and other issues leading to "one-stop-shopping" in testing and laboratory accreditation.

The essential concept was put forth in the challenges raised by the National Research Council study of *Standards, Conformity, Assessment and Trade*, ".....domestic policies and procedures for assessing conformity of products and processes to standards require urgent improvement." In the National Technology Transfer and Advancement Act of 1995 (P.L. 104-113), NIST was charged with coordinating Federal, state and local conformity assessment activities with those of the private sector to eliminate unnecessary duplication and complexity. The planned NACLA activities are in response to this challenge.

The discussion of issues at the forum is intended to achieve consensus on the planning document so that an organization which reflects national priorities and needs can be established. Efficient accreditation procedures with provision for reciprocity in mutual recognition of laboratory competence reflect a national priority for "one-stop-shopping" laboratory accreditation.

APPENDIX B

Presentations

JANUARY 7, 1997

A LOOK BACK AT LAWG

ACIL

LAWG Retrospective

5/17/94

MEETING OF ACIL, ANSI AND NIST AT NIST HEADQUARTERS

ACIL LAWG Retrospective

8/22/94

FIRST OPEN MEETING AT NIST

LAWG Retrospective

Fall, 94

FIRST TASK GROUP MEETINGS

ACIL

LAWG Retrospective

12/12/94

2ND OPEN MEETING AT U.S. CHAMBER

LAWG Retrospective

Jan. 95

FIRST MEETING OF LAWG STEERING COMMITTEE

ACIL LAWG Retrospective

STEERING COMMITTEE MEMBERS:

- NIST, EPA, FDA, MSHA
- ACIL, ANSI
- A2LA, AIHA, ICBO
- FORD, H-P

ACIL LAWG Retrospective

2/22/95

NRC STUDY RELEASED: PROBLEM HIGHLIGHTED

LAWG Retrospective

Summer, 95

VISION AND PRINCIPLES IDENTIFIED

LAWG Retrospective

10/13/95

OPEN FORUM ON LAB ACCREDITATION AT NIST

ACIL

LAWG Retrospective

March, 96

TECH TRANSFER BILL SIGNED INTO LAW: NEW ROLE FOR NIST

LAWG Retrospective

April, 96

NACLA PROPOSED TO LAWG STEERING COMMITTEE

ACIL

LAWG Retrospective

Sept., 96

NACLA CONCEPT SUPPORTED AT ILAC IN AMSTERDAM

Oct., 96

JAN. 7 FORUM ON NACLA ANNOUNCED

ACIL

LAWG Retrospective

Nov., 96

DRAFT PLAN FOR NACLA IMPLEMENTATION APPROVED

NATIONAL COUNCIL FOR LABORATORY ACCREDITATION

Belinda L. Collins, Ph.D.

National Institute of Standards and Technology

BACKGROUND

- Cost of accreditation to a single U.S. laboratory often exceeds $10,000 - $50,000 per year
- More than 150 U.S. accrediting bodies
- Accreditation required by both government and private sector
- Accreditation often not accepted by other parties
- Accreditation practices not uniform and do not conform to internationally accepted guides

GOVERNMENT ACTIVITIES

- Sector specific and fragmented
  - Lack of coordination among agencies, private sector
  - Much duplication of effort
- Technology Transfer Act (PL104-113) places NIST in coordinating role

HISTORY OF LAWG

- ANSI, NIST and ACIL have worked with:
  - Users ,both government and industry
  - Testing laboratories
  - Accrediting bodies and other interested parties
- Through informal Laboratory Accreditation Working Group since 1994

LAWG ISSUES

U.S. industry at growing competitive disadvantage with other countries

- US testing laboratories burdened by multiple, overlapping and duplicate accreditations

- Differing requirements for accreditation imposed by users -- federal, state, and local governments,

LAWG ISSUES continued

- Little acceptance of common procedures
- Costs of multiple programs affect:
  - testing laboratories
  - users of the testing and accreditation services
  - product buyers
- Test results often not accepted in domestic or foreign markets

LAWG Activities 1994-1996

- Obtain views of interested parties
- Identify problems for those who accredit, and those who are accredited
- Address issues such as "one-stop shopping"
- Oct 13, 1995 Forum identified problems

LAWG FORUM - 1995

- Consensus among attendees:
  - U.S. needs mechanism for recognizing competent laboratory accreditation
  - International standards must be basis for accreditation and recognition
  - High-quality accreditation and sound laboratory data must be preserved

LAWG FORUM - 1995
Opportunities

- Achieve a coordinated, cost effective system

- Eliminate domestic barriers to competent accreditation

- Ensure international acceptance of an effective U.S. system and U.S. test results

LAWG PROPOSAL

- NAtional Council for Laboratory Accreditation (NACLA) as private/public partnership to provide:
  - For the lab, a single accreditation in a field of testing, with worldwide recognition of its competence
  - For the user, a test performed once, with world wide acceptance

Guiding Principles

- NACLA to be formally chartered
  - Realize the Vision: universal acceptability of the results of any valid test by a competent laboratory accredited by a NACLA recognized accreditor
  - Implement a comprehensive and rigorous domestic system
    - use appropriate international guides
    - recognize competent accreditors

Guiding Principles

- Accreditation based on uniform criteria attests to laboratory's competence to provide data of consistent quality
- Equivalently rigorous procedures to accredit each laboratory in a given field
- Appropriate ethical principles and standards of conduct

Proposed NACLA Activities

- Accreditation done by accrediting bodies (private and public sector)

– User can select among accrediting bodies recognized as competent

– Reciprocity among accreditors based on common NACLA procedures

– Official recognition by government when

COMPOSITION

- Partnership of public and private organizations
  - government agencies (federal, state and local)
  - industrial firms and associations
  - accreditors
  - standards organizations
  - laboratories and laboratory associations
  - other interested parties

Authority and Responsibility

- NACLA:
  - Will coordinate laboratory accreditation activities in the United States for interested parties
  - Will develop and represent U.S. positions for regional and international accreditation

Organizational Structure

- Membership - open to all who subscribe to the NACLA vision, principles and protocols
- Board of Directors - policy making and governing body
- Operations Committee
- Stakeholders Committees

NACLA Operational Functions

- Accreditation Standards
  - International standards are the basis for NACLA procedures
  - Additional procedures as recommended by stakeholders Council and approved by Board

- Assessment of Accreditors
  - Operations Committee coordinates audits and reviews of accrediting bodies

Functions

- NACLA Interface with Regulators and Other Government Bodies
  - Government agencies to agree on harmonizing common accrediting requirements and practices
  - May require special procedures but should apply them consistently
- Under PL 104-113 NIST will work to minimize duplication and overlap in laboratory accreditation

Next Steps for NACLA

- Formal notice of intent and agreement to establish NACLA

- Appoint secretariat and elect NACLA Board in 1997

- Agree on common principles for accreditation in 1997

- Recognize competent programs in 1997-98

SINCE THE FORUM, THE FOLLOWING ACTIONS HAVE OCCURRED.

Interim Board Appointed

- LAWG met for the final time on Feb 19, 1997
- Voted on Interim Board
  - Federal Participants include FDA, DOD, DOE, FCC, FHWA
  - Industry participants include Ford, Caterpillar, Schering-Plough, Lucent Tech.
  - Laboratories include Guideline, MMR, Entela, and NSF International
  - Accrediting Bodies include AIHA, A2LA,

Interim Board - Continued

- At-large participants include ANSI and SCC/CSA
- Mexican observer status will be sought
- NIST will chair interim board and serve as provisional secretariat
- First meeting - April 1997
- Stakeholder Committee Chairs will be selected

NEXT STEPS

- ☆ Transition from LAWG ➜ Interim Board ➜ NACLA
- ☆ Nominations Process
- ☆ Stakeholder Committees
- ☆ Summary Report of Forum

NOMINATIONS PROCESS

- ✯ **Nominations and profiles sent by 7 February 1997 to Joe O'Neil, 1629 K St. NW Suite 400, Washington, D.C. 20006**
- ✯ **Committee screens nominations, checks availability for active service**
- ✯ **Recommended slate, with alternates, to LAWG Steering Group by 14 February 1997**

SUMMARY REPORT

- ☆ NIST will prepare and distribute
- ☆ Prepared presentations
- ☆ All submitted viewgraphs
- ☆ Digest of (taped) floor discussions

TRANSITION PROCESS

- ✯ LAWG Steering Group elects Interim Board on 19 February 1997
- ✯ LAWG Steering Group appoints temporary Chair of Interim Board
- ✯ Temporary Chair convenes initial meeting of Interim Board
- ✯ Interim Board appoints committees to devise procedures, prepare for formal establishment of permanent NACLA
- ✯ Establishment of and recruitment for Stakeholder Committees
  - ☞ Express your interests now or in future

ACIL LAWG Nominating Committee

CHARGE:

TO NOMINATE AN INTERIM BOARD OF DIRECTORS FOR NACLA

ACIL LAWG Nominating Committee

Composition:

- J. O'Neil, ACIL
- W. Leight, NIST
- J. Locke, A2LA

ACIL Interim NACLA Board

ROLE:

TO GET
NACLA
UP AND RUNNING

ACIL Interim NACLA Board

TERM:

ONE YEAR

ACIL Interim NACLA Board

SIZE - 18:

- 4 FROM LABS
- 4 FROM INDUSTRY
- 4 FROM GOVERNMENT
- 3 FROM ACCREDITORS
- 2 FROM GENERAL INTEREST
- CHAIR, NIST OSS DIR.

ACIL Interim NACLA Board

Schedule:

- 1/7- Nominations opened
- 2/7- Nominations closed
- 2/19- Board slate approved

ACIL Interim NACLA Board

Criteria for nominees:

- Interest
- Knowledge
- Commitment to Meetings
- Willingness to Work

ACIL Interim NACLA Board

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APPENDIX D

NACLA Interim Board of Directors
(Selected February 19, 1997)

Interim Board of Directors for the National Council for Laboratory Accreditation (NACLA)

On February 19, 1997, the Laboratory Accreditation Working Group (LAWG) Steering Committee met to elect the NACLA Interim Board of Directors. In accordance with recommendations made by the Nominating Committee, the Steering Committee agreed that:

- The number of Government representatives should be increased from four to five.
- The number of Accrediting Bodies representatives should be increased from three to four.
- The name of the General Interest category should be changed to "Members at Large."
- NIST should continue to serve as the Interim Secretariat for the NACLA Interim Board of Directors.

The Committee further agreed to the following membership for the NACLA Interim Board of Directors:

Chair

Belinda L. Collins, Director
Office of Standards Services
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Dr. Collins, a co-chair of the Laboratory Accreditation Working Group (LAWG), chairs the Interagency Committee on Standards Policy (ICSP) and serves on the boards and councils of several major standards developing organizations. Her office is responsible for implementing the Technology Transfer and Advancement Act with respect to coordinating standards and conformity assessment activities within government and with the private sector.

Government Representatives

Linda Horton, JD, Director
International Policy
Office of Policy
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Ms Horton serves as the Standards Executive for the Food and Drug Administration (FDA) of the Department of Health and Human Services and sits on the ICSP. She has responsibility for all FDA matters pertaining to domestic and international standards issues and policies.

Julius Knapp
Federal Communications Commission
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Mr. Knapp, Chief of the FCC Equipment Authorization Division, authorizes telecommunications and electronic equipment to ensure compatibility with FCC technical standards for controlling radio frequency interference. These procedures entail use of accredited test laboratories, a field in which Mr. Knapp has been active, both domestically and with respect to international conformity assessment matters, including MRA negotiations with the European Union.

Michael J. Luwe
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Mr. Luwe is Associate Director of the Directorate and has linkages to Joint Service/DOD metrology programs and DOD contractors and laboratories, including the application of laboratory accreditation.

Richard B. Pettit
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Dr. Pettit is manager of the Primary Electrical Standards Laboratory at Sandia, responsible for the electrical standards and calibration program for the Department of Energy (DOE). He serves on the DOE steering committees responsible for initiatives in metrology and accreditation and is also Chairman of the National Conference of Standards Laboratories (NCSL) committee on Intrinsic/Derived Standards.

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As Leader of the Materials Group, Mr. Rafalowski is responsible for agency policies and guidance in materials sampling and testing. He developed the regulations used for accrediting laboratories that perform particular functions.

Industry Representatives

Louis T. Dixon, Ph.D.
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Dr. Dixon, Manager of Body and Chassis Standards in Ford's Automotive Safety and Engineering Standards Office, is responsible for internal processes, test methods, standards and specifications for vehicles, components, and materials, as well as the company's interface for ISO and European (CEN) standards and conformity assessment issues. He was co-chair of the LAWG industry group.

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Mr. Heirman is the manager of Lucent's global product compliance laboratory, with emphasis on telecommunications and information technology products. An internationally recognized expert and leader in EMC measurements, he is an elected member of the IEEE Standards Board, ANSI Accredited Standards Committee C63 (for EMC), and several other domestic and international committees.

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As Director of Safety and Industrial Hygiene for Schering-Plough Corporate, Mr. Peck has world-wide responsibility for industrial hygiene monitoring and a strong interest in the laboratory accreditation programs that support this work. He has participated in the development of industrial hygiene, asbestos abatement, and environmental lead accreditation programs as a committee member, committee chair, and member of the American Industrial Hygiene Association (AIHA) Board of Directors.

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Mr. Ritterbusch's corporate responsibilities include conformity assessment for all company products, working with laboratories around the world. He served on the National Research Council committee that developed the recommendations in it report on standards and conformity assessment, especially the need for synergy in laboratory accreditation.

Laboratory Representatives

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Mr. Anderson was the 1996 President of the National Conference of Standards Laboratories (NCSL) and is the President and CEO of Guildline Instruments, a manufacturer of standards and calibration instruments and a provider of calibration services. He has had extensive experience in calibration, testing, and measurements and in the subject of technical barriers to trade.

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Mr. Kendzel is Senior Director Corporate QA of the NSF International, responsible for maintaining all NSF accreditations, including state certifications for drinking water analysis, building code body accreditations, and accreditations by ANSI and the Dutch Council of Accreditations (RvA). He serves on the ANSI accreditation Committee and on the ICBO ES Advisory Council on Accreditation.

Dave Krashes
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Mr. Krashes founded and since 1962 has built a group of multi-accredited independent laboratories. He has been a member of ASTM E-36, Committee on Accreditation, and an active member of LAWG.

Lynne Neumann
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Ms. Neumann has 20 years of experience in QA and ten in laboratory quality assurance, all in accredited laboratories. She is a member of the working group for the revision of ISO Guide 25, an active participant in ILAC, a member of the A2LA Board, chair of the ACIL Accreditation Committee, and an active participant in LAWG.

Accrediting Bodies

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Mr. Grunder is Manager of AIHA's Laboratory Accreditation Programs and a member of the ANSI task force that instigated the formation of LAWG, in which he has been an active participant. He is also active in NELAC. In the past, he has directed accredited laboratories and has served on many committees, including two laboratory accreditation committees. He is a member of ASTM, ACS, AAIH, CESSE, and an AIHA Fellow.

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Mr. Ramani is Administrator of the ICBO ES laboratory accreditation program and Chairman, ICBO ES Advisory Council on accreditation. He is a member of the APLAC MRA committee and the ASTM E5 and # 36 committees and has previously managed a consumer product testing laboratory, as well as having audited testing agencies in the United States and abroad.

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Mr. Unger is President of a diversified private sector accrediting body with prior experience in government, including NVLAP. He has been active in ILAC and in developing Mutual Recognition Agreements with national and regional accrediting bodies and an active participant in LAWG.

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Mr. Wagner is Managing Director of PRI, with responsibility for the National Aerospace Defense Contractor Accreditation Program (NADCAP).

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Mr. Donaldson is a Vice President of ANSI, responsible for conformity assessment. He was formerly the Chief of the NIST NVLAP Program, Head of the U.S. delegation to ILAC and a member of the ILAC Executive Committee, member of the ISO Guide 58 Working Group, and one of the co-chairs of LAWG.

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