



# National Cooperation for Laboratory Accreditation

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The Honorable Cass R. Sunstein  
Administrator  
Office of Information and Regulatory Affairs  
Office of Management and Budget  
Washington, DC 20503

**Comment Letter Submitted Regarding  
FR Doc No: 2012-7602**

**Federal Participation in the Development and Use of Voluntary Consensus  
Standards and in Conformity Assessment Activities**

*Delivered Electronically*

Dear Mr. Sunstein,

The National Cooperation for Laboratory Accreditation (NACLA) was founded in 1998 as a not-for-profit organization, Internal Revenue Service (IRS) Code 501 (c) (6) organization. NACLA focuses on domestic recognition of accreditation bodies (ABs).

NACLA was founded by representatives of public and private-sector organizations to provide coordination and focus for laboratory accreditation programs in the U.S. NACLA's primary mission is to evaluate U.S. ABs and to grant recognition to those ABs found to be in compliance with NACLA procedures and the relevant international standards for competent ABs including ISO / IEC 17011:2004, "Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies." NACLA also provides educational and training opportunities to persons interested in the recognition of ABs and the relevant standards for laboratory accreditation.

NACLA is a stakeholder organization. Accordingly, its leadership body, the Board of Directors/Operations Council is composed of balanced representation from the four key stakeholder groups: Industry, Government, Laboratories and Accreditation Bodies. Past and present members of the Board/Council include representatives of Caterpillar, National Institute of Standards and Technology (NIST), General Motors, Ford, General Electric,

Lucent Technologies, US Department of Defense, US Department of Energy, US Food and Drug Administration, US Department of Transportation / Federal Highway Administration, US Department of Agriculture, major laboratory associations and major accreditation bodies.

At its April 11, 2012 Conformity Assessment Workshop, NIST Director Dr. Patrick Gallagher spoke to the complexity of the conformity assessment system in the United States. The complexity Dr. Gallagher spoke of is the reason NACLA was created. It was the consensus of the stakeholders (including NIST) in late 1990's that created NACLA to allow each stakeholder to have a vote on how the recognition process and resulting accreditation process should proceed for the benefit of US stakeholders.

It appears that the current NIST policy on the participation in the development and use of conformity assessment related to recognition of competent ABs has shifted. Instead of utilizing NACLA as the cooperative basis for discussion and development of conformity assessment in US, NIST only recommends an international AB member organization, the International Laboratory Accreditation Cooperation (ILAC). While NACLA believes ILAC is a good choice, particularly for those stakeholders and agencies concerned with the importation of products, the development and use of that system can and should be vetted within a stakeholder cooperation in the US, NACLA. NIST policy has turned each specifier, governmental and private, back to direct negotiations with the ABs leaving out the input of laboratories and creative layers of redundant recognition in the US.

NIST's exclusive recommendation of the method of conformity assessment comes at the exclusion of all other accepted recognition bodies such as NACLA. This creates an anti-competitive advantage for ILAC and its recognized accreditation bodies. What makes this position even more problematic for NIST is the participation of its accreditation body, NVLAP as one of those recognized accreditation bodies within the ILAC membership. This biased approach goes directly against the concept of the free enterprise concepts that are the bedrock of doing business in the United States. ILAC is an international organization composed only of ABs. NACLA structure includes stakeholder organizations (those that specify and regulate standards, governmental and private), ABs (those that inspect and accredit laboratories) and the laboratories themselves. The NACLA structure includes all stakeholders in the process and allows for one agreed approach to the recognition of ABs and the utilization of national and international standards for the accreditation of laboratories.

As an example, NACLA has developed a Recognition procedure describing accreditation requirements for laboratories operating in the Construction Materials Testing (CMT) field. It was prepared by the Construction Materials Testing Subcommittee of the NACLA under the Technical Requirements Committee, and reflects requirements established by the Federal Highway Administration, Federal Aviation Administration, United States Army Corps of

Engineers, and the Bureau of Reclamation to meet their needs for competent construction materials services. This type of cooperation is not available in any other cooperation in the United States or abroad and represents exactly what is needed for the development and use of conformity assessment standards related to the accreditation of laboratories and recognition of ABs. Other NACLA recognition program developed to assist the US Navy and NASA include the Accreditation Body Evaluation Procedure for ANSI / NCSL Z540.3-2006 subclause 5.3. Other NACLA programs are in development to support stakeholder requirements.

As the sole third-party, US-based recognition organization that is accepted by a wide variety of industry and government organizations, NACLA should not be put at a competitive disadvantage by NIST. The following partial list of organizations that accept NACLA recognitions indicates the organizations status:

- Chrysler Motors
- Federal Communications Commission
- Fokker Aerostructures B.V.
- General Motors
- General Services Administration
- Goodrich
- Harlow Aerostructures, LLC
- Nadcap
- National Association of State Fire Marshals
- Smart Grid Interoperability Panel - IPRM Ver. 2, **January 2012**
- State of California
  - Department of Transportation
- US Coast Guard
- US Department of Transportation
  - Federal Highway Administration
- US Environmental Protection Agency
- US Navy

In an effort to reduce the costs associated with the recognition of ABs, the laboratories and ultimately the US consumer, NACLA provides the framework for the coordination of the recognition of ABs for the US. NACLA is willing to work with any and all stakeholders in the process of conformity assessment. NACLA recognizes the work of ILAC both in its policy and procedures and the process of recognition. NACLA provides the framework for the US working within ILAC, and more importantly those stakeholders who need to work both inside and outside the US conformity assessment system. .

It is the position of NACLA that when directing conformity assessment for the United States government, NIST should direct agencies to choose both accepted laboratory accreditation cooperations in the United States – the National Cooperation for Laboratory Accreditation (NACLA) and the International Laboratory Accreditation Cooperation (ILAC).

Respectfully submitted,

*RF Uttenweiler* (signed electronically)

Robert F. Uttenweiler  
Executive Officer  
NACLA

cc: Dr. Patrick Gallagher, Director, National Institute of Standards and Technology (NIST)  
Raymond P. Towle, Executive Director, Political Affairs & Federation Relations,  
U.S. Chamber of Commerce  
Paul R. Verkuil, Chairman, Administrative Conference of the United States  
Carl Malamud, President and Founder, Public.Resource.Org.  
Robert C. Fine, JD, CAE, Executive Director, American Nuclear Society  
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