FOR IMMEDIATE RELEASE

ACIL Adopts Blueprint for Accreditation Success in the 21st Century

Washington, DC, July 14, 2005 – The American Council of Independent Laboratories formally announces the release of its "Blueprint for Success in the 21st Century: An International System for Laboratory Accreditation". In the early 1990's, ACIL published its first "Blueprint for Success: A National System for the Accreditation of Laboratories." In "Blueprint," ACIL outlined the essential "elements" of a national accreditation system as well as the types of laboratory accreditation programs that should function in that system. These bear repeating as ACIL believes that they apply in today's evolving international conformity assessment activities as well as they did a decade ago.

The Blueprint states that it is imperative that the United States establish its own system of Accreditation Body (AB) recognition and ensure the system is adequately funded. The following elements should be incorporated:

- Mutual acceptance of accreditation by ABs
- Participation in Cooperations
- Recognition of the laboratories as the customers of the ABs
- Joint assessments as the norm, not the exception
- Uniform national deviations

The Blueprint document is available at no charge on the ACIL Web site, www.acil.org, under Publications, then Government Relations.

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# Blueprint for Success in the 21st Century: An International System for Laboratory Accreditation

In the early 1990's, ACIL published its first "Blueprint for Success: A National System for the Accreditation of Laboratories." In "Blueprint," ACIL outlined the essential "elements" of a national accreditation system as well as the "types" of laboratory accreditation programs that should function in that system. These bear repeating as ACIL believes that they apply in today's evolving international conformity assessment activities as well as they did a decade ago.

## Elements of an International System for Laboratory Accreditation

- Principally private sector – to take advantage of existing experience and expertise and to avoid the creation of duplicative government bureaucracies.

- Subject to government oversight – to serve the public good in areas such as safety, health and the environment, and to assure international acceptance.

- Open and transparent – so that no public, private, tariff or non-tariff barriers exist to prevent equal and simultaneous access to the system.

- Subject to administrative procedures required by law – government involvement should follow procedures required by the Administrative Procedures Act.

- Non-preemptive of existing federal programs unless requested by the affected agency – the new system should not disrupt existing programs that are operating effectively. However, it should allow such programs to operate within its scope, if desired by the federal agency.

- Contain sufficient checks and balances – to assure fairness in the system's development and implementation.

Types of Programs under an International Laboratory Accreditation System

The affected industry sector, composed of all materially-affected parties, should select the "type" of program it wants under the following parameters:

- When the industry sector finds no legitimate government role, the accrediting function should be left to the private sector.

- When the industry sector desires private sector accreditation, but where a legitimate government role is necessary because of safety, health, consumer or environmental concerns, the government should support a program to recognize accrediting bodies.

- When the industry sector desires direct government accreditation of laboratories, the government should establish such a program.

ACIL takes great pride in the fact that virtually every accreditation program that has developed in the United States since the publication of the first "Blueprint" contains its "elements" and one of the three "types" identified therein.

**Elements for the 21st Century**

Since the early 90's, the globalization of conformity assessment has taken place. Accreditation systems are supporting this effort. There has been an international effort to establish consensus policies and procedures for the recognition of accreditation bodies, both on a regional and an international cooperation level. Regional Cooperations have been established to make the recognition process as efficient as possible.

Simply stated, recognition is a process through which both Governments and private Regional Cooperations evaluate the competency of the accreditation bodies (ABs) to assess the competency of laboratories in order to promote data acceptance among trading partners and facilitate trade.

It is imperative that the United States establish its own system of AB recognition (e.g., NACLA or other) regardless of international considerations and ensure the system is adequately funded. Such a system should incorporate the following elements:

**Mutual Acceptance of Accreditation by AB's**

One of the objectives in establishing a unified system is to reduce or even eliminate duplicative, redundant accreditations. This unified system also provides a fair forum for accreditation and prevents monopoly by one AB. For a unified and fair system to be accomplished, it is imperative that a recognized system be set whereby AB's accept each others' accreditation (i.e. mutual acceptance of accreditation).

This system needs to provide a structured process, a reasonable timeline and to encourage AB's to work cooperatively. In accordance with the requirements of NACLA (or other regional AB cooperative), the review process shall include an assessment to the applicable requirements of ISO/IEC 17011, including resolution of non-conformities prior to acceptance of the unrecognized AB. Once the unrecognized AB has completed this review process, the non-conformities have been closed, and the AB has been recommended for recognition by NACLA (or other regional AB cooperative), the system should provide for swift final approval within 30 days. It should be the goal of the AB cooperative to recognize an experienced, applying AB in no more than one year.

Once the applying AB has been recommended for approval, the recognized AB's should mutually accept the applicant AB or be required to evaluate the applicant AB's competence and provide specific feedback on the reasons for rejection of acceptance. By fostering this development and review process, new AB's will arise out of the process stronger, more competent and sooner,

thus providing healthy competition and adequate options to testing and calibration laboratories seeking accreditation.

If the recognized AB refuses to cooperate or provide an assessment process for the recommended applicant AB and provide specific feedback on lack of competence, then the applying AB should report their complaint or concerns to the applicable AB cooperative. It is the responsibility of the AB cooperative to investigate each claim independently and according to the rules of the mutual recognition agreement and provide sanctioning where necessary.

It is important to note that the AB cooperative needs to be independent and willing to enforce the rules of its cooperation to promote development of the accreditation scheme and to eliminate duplication and redundancy. If the AB cooperative and the recognized AB's refuse to assist in this effort, it is a road block to the fundamental purpose of the system.

**Participation in Cooperations**

The United States should not participate in any Cooperations when the terms and conditions of the Cooperation are not fair and equitable to US ABs and laboratories. The U.S. must work to redefine the rules under which regional Cooperations operate. Otherwise, the US will continue to be at a disadvantage.

**The Labs Are the Customers**

The laboratories are the customers of the ABs. They need to be recognized as such and be a party to defining the rules that govern their businesses. The US system must make provisions to accommodate this principle.

**Joint Assessments Should be the Norm, Not the Exception**

The easiest way to eliminate duplication and redundancy in the international system of accreditation is joint assessments. The laboratory and its accreditation bodies should work together to ensure that joint assessments can take place whenever possible. The laboratory is in a position to manage their accreditations through joint assessments if they alert their ABs to their schedule of assessments so that the ABs can work together to perform them jointly. The US-implemented international system should accommodate such an approach.

**National Deviations Must Be Communicated and Understandable**

If the laboratories must submit to more than one assessment to the same standard (i.e., ISO/IEC 17025) by different ABs, these assessments should be similarly conducted by equally qualified technical assessors, with a uniform interpretation of the standard. The US implemented recognition system should strive to foster full uniformity among ABs.

**The Future**

These new "elements", combined with those of a decade ago, will lay the groundwork for an effective and efficient national and international accreditation system for the 21st century.

Adopted by the ACIL Board of Directors February 4, 2005